

# Assessing quality of life in patients with autoimmune bullous diseases using the Persian version of Treatment of Autoimmune Bullous Disease Quality of Life questionnaire finds similar effects in women as men

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## ABSTRACT

**Background:** In autoimmune bullous diseases (AIBDs), autoantibodies loosen molecular adhesions in the skin and/or mucosa and lead to blisters and erosions. Immunosuppressive drugs reduce mortality of the AIBD; therefore, patients will have to live longer with comorbidities.

**Objective:** This study aims to determine the quality of life of AIBD patients undergoing systemic treatment while investigating the survey's relationship with various factors.

**Methods:** In this 2-step cross-sectional study, we initially included 53 consecutive pemphigus patients to investigate reliability and validity of the Persian version of Treatment of Autoimmune Bullous Disease Quality of Life (TABQOL) questionnaire. Then, we conducted the study on 119 AIBD patients, currently under treatment at an AIBD clinic in Iran.

**Results:** The mean TABQOL score for our patients was  $13.87 \pm 7.51$ . The highest TABQOL was for epidermolysis bullosa acquisita ( $24 \pm 8.485$ ) followed by pemphigus foliaceus ( $20.5 \pm 14.181$ ) and the lowest for pemphigus vulgaris ( $13.24 \pm 6.54$ ). There was no significant difference between patients' TABQOL scores and their gender, history of rituximab injection, and disease severity scores. We only found a positive correlation between TABQOL and prednisolone dose.

**Conclusion:** Treatments of AIBD considerably impact the quality of life of patients and an impairment in quality of life is correlated to higher doses of prednisolone.

**Keywords:** autoimmune bullous disease, prednisolone, quality of life, TABQOL

## Introduction

Autoimmune bullous diseases (AIBDs) refer to a group of diseases in which autoantibodies loosen molecular adhesions in the skin and/or mucosa and lead to erosions and blisters. Pemphigus vulgaris (PV), pemphigus foliaceus (PF), bullous pemphigoid (BP), and epidermolysis bullosa acquisita (EBA) are all different types of AIBDs.<sup>1</sup>

Before the 1950s and advent of corticosteroids, the life expectancy of the majority of AIBD patients was less than a year. The introduction of corticosteroids into the therapy regimen changed this trend, and 1-year mortality decreased from 75% to 30%.<sup>2</sup> With decreased mortality, patients have to live longer with comorbidities of AIBD caused by both the disease itself and the use of immunosuppressive drugs that have a negative effect on the patient's quality of life (QOL).<sup>3</sup>

Burning and itching sensations caused by skin lesions, painful oral lesions and skin infections are some of the manifestations of AIBD.<sup>4</sup> Long-term use of corticosteroids can cause complications such as immunosuppression, infection, weakness, fatigue, decreased bone density, avascular necrosis, hypertension, and diabetes. Other noncorticosteroid drugs have reduced dependency on corticosteroids, but they have complications of their own such as headache, lethargy, fever, myalgia, gastrointestinal symptoms, hepatotoxicity, bone marrow suppression, and immunosuppression.<sup>5</sup>

AIBDs are also associated with psychological morbidities, such as anxiety disorders and depression, especially in patients with lesions on visible parts of their body.<sup>6</sup> Most of the AIBD patients complain about financial issues associated with their disease and treatment costs.<sup>7</sup>

Until 2013, assessment of QOL in AIBD patients was done using the Short Form (36) Health Survey and Dermatology Life Quality Index questionnaires, and neither of them was specific for these diseases. In 2013, the Autoimmune Bullous Disease Quality of Life and later, Treatment of Autoimmune Bullous Disease Quality of Life (TABQOL) were developed in Australia for assessing the QOL of AIBD patients.<sup>8,9</sup>

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**What is known about this subject in regard to women and their families?**

- Treatment of Autoimmune Bullous Disease Quality of Life (TABQOL) questionnaire evaluates the effect of treatment on quality of life of autoimmune bullous disease patients; higher values represent worse quality of life.
- There is usually no significant difference between the scores of men and women.
- Older patients have lower TABQOL scores.

**What is new from this article as messages for women and their families?**

- TABQOL scores were higher in women than men but this difference was not statistically significant.
- Women were more worried about worsening autoimmune bullous disease upon tapering medications compared with men.
- The Persian version of the TABQOL is valid and reliable.

As previous studies have stated, the side effects of AIBD treatment especially due to long-term use of corticosteroids, may complicate patients' lives more than the disease itself. In this regard, assessing AIBD patients' quality of life related to treatment using TABQOL is of great importance.<sup>4,5</sup> In this study, we have measured AIBD patients' quality of life using the Farsi TABQOL questionnaire.

**Methods**

This cross-sectional study was conducted in 2 steps. The first step was done on 53 pemphigus patients from the AIBD outpatient clinic of Razi Hospital in Tehran, Iran, to analyze the reproducibility, validity, and responsiveness of the translated TABQOL questionnaire (Persian version, <http://links.lww.com/IJWD/A4>). In step 2, 119 patients were included from the AIBD outpatient clinic of Razi Hospital in Tehran, Iran, from May 2020 to September 2020 (the previous 53 patients were not included in this step). The study protocol was approved by the ethics committee of Tehran University of Medical Sciences (IR.TUMS.MEDICINE.REC.1399.172). The inclusion criteria consisted of patients older than 16, who have histopathology and direct immunofluorescence reports of any types of AIBD, currently under treatment for their diseases and consented to be enrolled in this study.

A 2-part questionnaire consisting of demographic characteristics, clinical/laboratory data and a Persian version of the TABQOL questionnaire was used in this study (<http://links.lww.com/IJWD/A4>).

Demographic characteristics include age, sex, education, marital status, and the clinical severity of pemphigus patients according to Pemphigus Disease Area Index (PDAI) or severity of BP patients according to Bullous Pemphigoid Disease Area Index (BPDAI), which were calculated based on clinical examinations. The laboratory data included values of desmoglein (Dsg) 1 and Dsg 3 autoantibodies in PV and PF patients and anti-BP 180 and anti-BP 230 in BP patients.

TABQOL is a scale range from 0 (the minimum effect of treatment on quality of life) to 51 (the maximum effect of treatment on quality of life) based on 17 questions. For the translation and cross-cultural adaptation of the TABQOL questionnaire, we used World Health Organization recommendations<sup>10</sup> (Forward-backward translation method).

In the first step, the TABQOL questionnaire was translated by 2 fluent English speakers independently and 2 versions were matched and confirmed, then the Persian version was translated

to English by another bilingual native person who had not read the original form of the questionnaire (back-to-back translation). Subsequently, the final form of the English-translated version questionnaire was matched with the original English version. The differences were found and reviewed by the translators, and some words in the Persian version were replaced by new words to accurately depict the original TABQOL questionnaire. Finally, 2 dermatologists confirmed the final version of the questionnaire.

After finalizing the questionnaire, 53 consecutive pemphigus patients (<http://links.lww.com/IJWD/A5>) (42 female and 11 male, 49 PV and 4 PF) were included from the AIBD outpatient clinic of Razi Hospital in Tehran, Iran. Patients completed the questionnaire in the first session and 2–3 weeks later. In these 2 times, the main investigator of the study answered comments and questions of the patients. After 53 patients answered the questionnaire, essential revisions were made based on the opinion of the research team on findings.

All statistical analyses were conducted using IBM SPSS Statistics for Windows, Version 25.0. Mean, standard deviation, and median were used for reporting quantitative variables, and frequency was used to report qualitative variables. In order to evaluate internal consistency (reliability), the Cronbach alpha is calculated and a value greater than .7 was considered as a high level of reliability. In order to evaluate the ability of questionnaire to reproduce same result over time, test-retest reliability was conducted, and correlation coefficient was calculated. We used factor analysis for assessing the construct validity.

The Mann-Whitney *U* test was used to find significant correlations between the distributions of 2 rank variables. Spearman correlation coefficient was used to compare the 2 rank variables. Analysis of variance was used to compare means of several normally distributed groups.  $P < .05$  were considered statistically significant.

**Results**

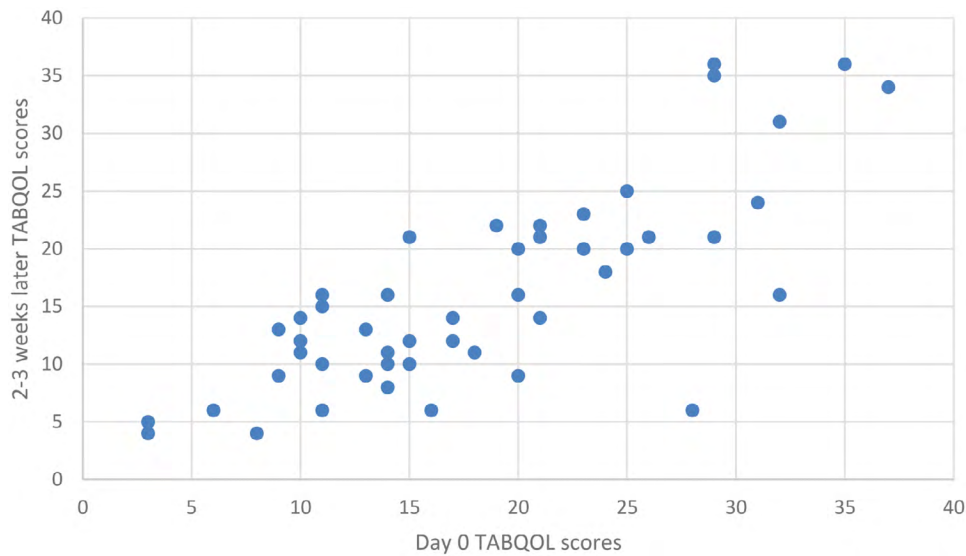
To investigate the reproducibility, validity, and responsiveness of the Persian TABQOL questionnaire, 53 patients (consisting of 42 [79.2%] female and 11 [20.8%] male, 49 [92.5%] PV and 4 [7.5%] PF patients, with the mean age of  $45.85 \pm 13.48$  years) completed the translated TABQOL questionnaire on day 0 and 2–3 weeks later.

For 17 items, the Cronbach alpha was .804, which shows a high level of internal reliability for our questionnaire. The test-retest reliability (R) was .794,  $P < .001$ , 95% confidence interval = 0.666–0.876, which shows good reliability over time (Fig. 1).

With considering 3 factors for questionnaire dimension (as in the original article) with using varimax rotation method, 46.27% of variance between items are explained. Bartlett's test of sphericity ( $P < .0001$ ) suggested that factor analysis of the data was appropriate and sample size was adequate (Kaiser-Meyer-Olkin = 0.648) (Table 1).

In the second step, 119 AIBD patients completed the final Persian version of TABQOL questionnaire (<http://links.lww.com/IJWD/A6>) (after proving its validity and reliability in the first step) and consisted of 51 (42.9%) male and 68 (57.1%) female. The clinical diagnoses of the study population were the following: 99 PV, 12 BP, 6 PF, and 2 EBA. The mean age was  $46.50 \pm 10.96$  and ranged from 23 to 88 years old. The median duration of treatment was 24 months (interquartile range, 65 months) with a range of 1 month to 25 years (Table 2).

The TABQOL score for all patients ranged from 1 to 44 with a mean score of  $13.87 \pm 7.51$ . The highest TABQOL score, hence the greater impact of treatment on the QOL, was among EBA patients ( $24 \pm 8.485$ ) followed by PF ( $20.5 \pm 14.181$ ) and the lowest was  $13.24 \pm 6.539$  for PV patients. The mean TABQOL score for BP patients was  $14 \pm 8.914$  (Table 2).



**Fig. 1.** Test-retest reliability of the TABQOL questionnaire. TABQOL, Treatment of Autoimmune Bullous Disease Quality of Life.

Easy bruising or bleeding and nightmare or bad memory were the least reported complications (20.2%, 23.5%), whereas having worries about the treatment being dangerous and finding it time consuming were the most undesirable items among patients (79.8%, 74.8%). Only 41.2% of patients did not have financial issues as a result of AIBD treatment costs (Fig. 2).

There was a significant relationship between the dose of prednisolone and TABQOL scores, higher TABQOL scores were related to higher doses of prednisolone used by the patients ( $P = .011$ , correlation coefficient = .239). There was no significant difference between the participant's TABQOL scores with respect to their gender, age, marital status, education level, disease severity as PDAI in pemphigus patients or BPDAI score in BP patients, history of rituximab injection, having comorbidities (diabetes and hypertension), times admitted to hospital, autoantibody levels, disease duration, and treatment duration (Table 2).

**Table 1.** Factor analysis for the final Persian version of TABQOL questionnaire<sup>a</sup>

Question number	Factor 1	Factor 2	Factor 3
1	-0.081	0.604	0.389
2	0.018	0.059	0.573
3	0.690	0.389	0.088
4	-0.064	0.758	0.083
5	-0.066	0.600	0.057
6	0.300	0.611	-0.206
7	0.300	0.627	0.198
8 <sup>b</sup>	0.647	0.522	-0.105
9	0.581	-0.081	-0.047
10	0.399	-0.081	0.580
11	0.023	0.053	0.712
12	0.457	0.204	0.208
13	0.224	0.258	0.618
14	0.447	0.295	0.297
15	0.471	-0.002	0.160
16	0.356	0.369	0.245
17	0.725	-0.158	0.090

TABQOL, Treatment of Autoimmune Bullous Disease Quality of Life.

<sup>a</sup> Loadings more than 0.4 or less than -0.4 are considered significant.

<sup>b</sup> Item complexity occurred.

Questions 3, 8, 9, 12, 14, 15, and 17 loaded on factor 1. Questions 1, 4, 5, 6, and 7 loaded on factor 2. Questions 10, 11, and 13 loaded on factor 3. Question 16 did not load on any factor.

We found that with reduction in the medication dosage, women were more worried than men about the worsening of their blistering disease ( $P = .033$ ). Moreover, older patients worried less about the treatment being dangerous ( $P = .012$ , correlation coefficient = -.230). Highly educated patients had more nightmares or bad memories as a result of treatment ( $P = .043$ , correlation coefficient = .186), but fewer financial difficulties ( $P = .007$ , correlation coefficient = -.248). Not being able to think as quickly or clearly as before treatment had a positive correlation with the duration of treatment ( $P = .037$ , correlation coefficient = .191).

Patients with higher PDAI scores, higher anti-Dsg 1 levels, and higher dose of prescribed prednisolone, complained more about taking many medications for their blistering disease ( $P = .001, .036, <.001$ ; correlation coefficient = .310, .255, .489, respectively).

Higher levels of anti-Dsg 1 and higher prednisolone doses were also related to stopping enjoyable activities to avoid getting sick as a result of AIBD treatment ( $P = .011, .010$ ; correlation coefficient = .307, .242, respectively).

Patients with higher PDAI scores and taking higher doses of prednisolone complained more about treatment affecting their holidays ( $P = .047, .014$ ; correlation coefficient = .195, .231, respectively). Also, higher doses of prednisolone were correlated with finding treatment time consuming ( $P = .026$ , correlation coefficient = .210).

Patients with diabetes reported more difficulty in walking due to AIBD treatments and less worry about getting sick as a result of immunosuppression given by AIBD treatments ( $P = .023, .002$ ). Moreover, patients with hypertension worried less about treatment being dangerous ( $P = .024$ ).

**Discussion**

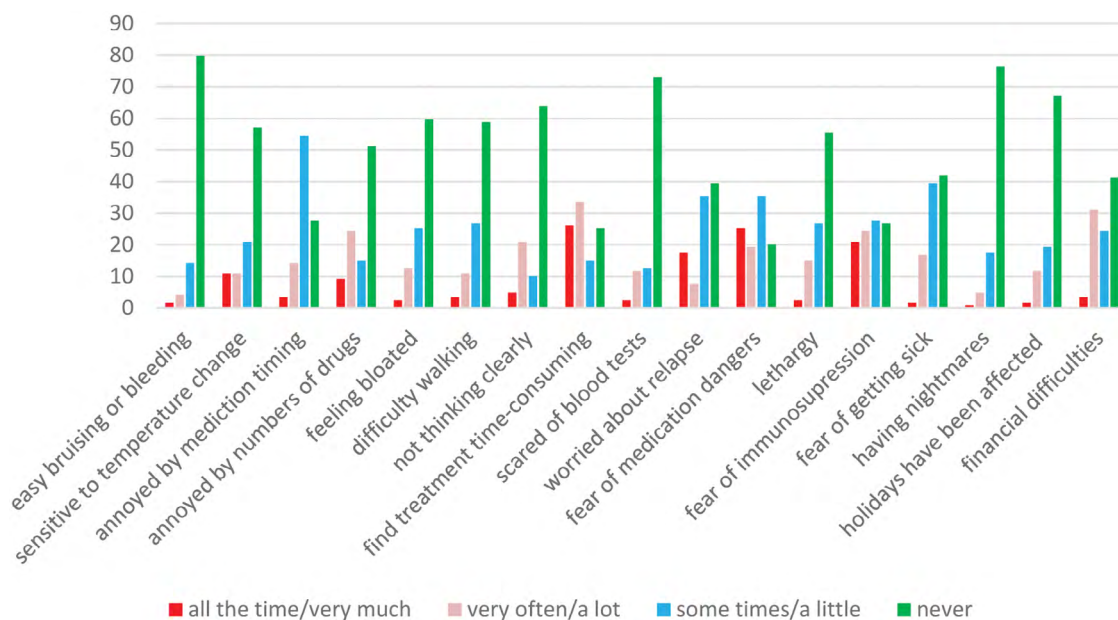
Studies showed that AIBD treatment can impact the quality of life as much as disease itself.<sup>4,5,7</sup> In this study, TABQOL scores of PV, BP, and all patients were lower than TABQOL scores reported in Australia,<sup>9</sup> China,<sup>11</sup> Poland,<sup>7</sup> Turkey,<sup>12</sup> and Egypt<sup>13</sup>; while PF patients in our study had higher TABQOL scores than previously reported studies, probably due to cultural differences or treatment approach. Compared with our population, Australian and Turkish<sup>9,12</sup> studies demonstrated the highest TABQOL among EBA patients; also, in the Egyptian study,<sup>13</sup> EBA was reported to have the second-highest TABQOL score.

**Table 2.**  
**Characteristics of AIBD patients and TABQOL scores**

AIBD patients = 119	Characteristics	TABQOL (0–51), mean ± SD	P
Gender, n			
Female	68	14.93 ± 7.646	.052
Male	51	12.45 ± 7.148	
Age (mean ± SD, y)	46.50 ± 10.960	—	.083
Marital status, n			.693
Married	98	14.06 ± 7.896	
Single	21	12.95 ± 5.390	
Types of AIBD, n			
BP	12	14 ± 8.914	
EBA	2	24 ± 8.485	
PF	6	20.5 ± 14.181	
PV	99	13.24 ± 6.539	
PDAI	8.49 ± 14.150, N = 105	13.66 ± 7.268	.206
BPDAl	14.75 ± 13.572, N = 12	14 ± 8.914	.345
Treatment duration (mo) (minimum–maximum, median, interquartile range)	(1–300, 24, 65)	—	.604
Diagnosis duration (mo) (minimum–maximum, median, interquartile range)	(1–300, 24, 64)	—	.591
Prednisolone dose (median, mean ± SD)	10, 18.133 ± 18.786	—	.011
Number of hospitalization in the last year (median, range)	0, 0–4	—	.373
History of rituximab injection, n			
Yes	75	13.51 ± 7.375	.555
No	44	14.48 ± 7.774	
Education			.171
Illiterate	12	11.08 ± 7.704	
High school	34	13.79 ± 6.914	
Diploma	38	14.37 ± 8.973	
Associate degree	8	10.13 ± 5.592	
Bachelor	23	15.65 ± 6.206	
Master	4	15.25 ± 5.123	
Comorbidities, n			
Diabetes	15	13.73 ± 6.974	.933
Hypertension	16	11.94 ± 7.280	.177
None	98	14.22 ± 7.664	
Anti-desmoglein 1 (IU/mL) (N = 68)	59.56 ± 77.69	—	.225
Anti-desmoglein 3 (IU/mL) (N = 68)	94.58 ± 87.48	—	.273
Anti-BP 180 (IU/mL) (N = 3)	200 ± 00.000	—	.729 <sup>a</sup>
Anti-BP 230 (IU/mL) (N = 3)	1.6 ± 1.032	—	.611 <sup>a</sup>

AIBD, autoimmune bullous disease; BP, bullous pemphigoid; BPDAl, Bullous Pemphigoid Disease Area Index; EBA, epidermolysis bullosa acquisita; IU/mL, international units per milliliter; mo, months; PDAI, Pemphigus Disease Area Index; PF, pemphigus foliaceus; PV, pemphigus vulgaris; SD, standard deviation; TABQOL, Treatment of Autoimmune Bullous Disease Quality of Life; y, years.

<sup>a</sup> There were limited number of patients with information about anti-BP levels (N = 3). Thus, these analyses are not very valid.



**Fig. 2.** AIBD patient's responses to each question of TABQOL questionnaire (percentage). AIBD, autoimmune bullous disease; TABQOL, Treatment of Autoimmune Bullous Disease Quality of Life.

The majority of AIBD patients included in this study had been diagnosed with PV, which confirms a higher prevalence of PV than other AIBD types in Iran.<sup>14</sup> BP patients generally have a good response rate to treatment meaning lower doses of prednisolone prescription. However, in our study, BP patients had higher TABQOL scores than PV patients, which is in agreement with Turkish,<sup>12</sup> Chinese,<sup>11</sup> and Egyptian<sup>13</sup> studies and in contrast with Polish<sup>7</sup> and Australian<sup>9</sup> studies. This discrepancy is probably due to the difference in the number of BP patients included in each study. In our study and the 3 former mentioned studies, a small proportion of participants were BP patients (our study: 10.1%, Chinese: 21.1%, Turkish: 11.7%, and Egyptian: 1.3%), whereas in Polish and Australian studies, the proportion of BP patients in their sample sizes was much higher (Australian: 36% and Polish: 62%).

Furthermore, with the increase in the prescribed prednisolone dose, patients are more prone to corticosteroid complications, which is the main cause of the positive correlation found in our study between TABQOL score and dose of prednisolone. This represents the importance of attempting to treat the disease with the lowest prednisolone dose possible.

We did not find any correlation between PDAI and TABQOL score; this finding is similar to Egyptian,<sup>13</sup> Chinese,<sup>11</sup> and Polish<sup>7</sup> studies, while it is in contrast with Turkish<sup>12</sup> study that found a positive correlation between PDAI and TABQOL. We also did not find any correlation between TABQOL and BPDAI scores similar to as Polish<sup>7</sup> and Turkish<sup>12</sup> studies. Although our findings show that QOL is not necessarily related to visible manifestations of the disease, we should consider that the TABQOL questionnaire evaluates the impact of treatment on the QOL rather than the disease itself.

Studies showed that rituximab is a promising treatment for AIBD patients<sup>15-17</sup>; it decreases steroid consumption and is associated with higher rate of remission in patients with PV.<sup>16,17</sup> However, in our study, like PDAI and BPDAI, we did not find any relationship between TABQOL score and history of rituximab injection. This finding is in agreement with the study of Heelan et al.<sup>18</sup> in which there was no relationship between Dermatology Life Quality Index and receiving rituximab or disease severity. This result could be due to the cross-sectional study design.

Moreover, in all previously mentioned studies,<sup>7,9,11,13</sup> there was no significant difference between female and male TABQOL scores. Except for the Turkish study<sup>12</sup> in which women had higher TABQOL scores meaning a worse QOL. However, in our study, the TABQOL scores of women were higher than men; however, the difference was not statistically significant ( $P = .052$ ) despite being close to significance. A previous study, which has already been done in the same center as this study, showed that women had a lower QOL using the ABQOL questionnaire.<sup>19</sup>

Among TABQOL studies, the Egyptian study<sup>13</sup> found an inverse correlation between TABQOL scores and age and education level that was not significant in our study. Our findings showed that women worried more about worsening of AIBD after decreasing their AIBD medication dose; this could be caused by higher psychological adverse effects of AIBD in women.<sup>6,20</sup> We also found that older patients worried less about their treatment being dangerous, probably due to their life experience and the general idea that they have fewer years left of their lives in comparison to younger adults.

Similar to the Polish study,<sup>7</sup> finding treatment time consumed translated to higher TABQOL scores. This result indicates that patients value the time they lose in the process of treatment, and it has a negative effect on their quality of life; therefore, the matter of time should be acknowledged more than before in prescribing treatment to the patients with AIBD. In the Chinese study,<sup>11</sup> question 9 regarding worries of needles had the lowest score that was also among the lowest scores in

our study. This represents that blood tests do not affect QOL of patients as much as other aspects of AIBD treatment like medications.

This study showed that 58.8% of AIBD patients suffer from financial difficulties due to their AIBD treatment, and this effect was reported in 46% of the population in the Egyptian study<sup>13</sup> and 65% of the population in the Polish study.<sup>7</sup> This illustrates that adopting new policies to decrease treatment costs for AIBD patients can help to increase their quality of life.

Patients with longer treatment duration showed more difficulty in thinking clearly and quickly as before treatment. This could be as a result of increased treatment complications with increased treatment duration.

The aforementioned results in this study show that treatment can impair the quality of life of AIBD patients, and some aspects of treatment play more important roles. Therefore, further research on this matter could be helpful to consider newer and better treatment processes that have a lesser impact on the QOL of AIBD patients.

One limitation of this study is the small size of BP, PF, and EBA patients. This represents the low incidence of these types of AIBD in our community. The other limitation is the fact that patients were recruited from a single outpatient dermatology clinic. The small number of patients with more severe disease is another limitation of our study. Further studies could include more centers, a larger sample size, and more patients with severe forms of AIBD.

## Conclusion

TABQOL questionnaire is a disease-specific quality of life measurement tool that assesses the impact of AIBD treatments on the QOL of patients. This study showed that the Persian TABQOL is valid and reliable, and AIBD treatments considerably impact the quality of life of patients. This impairment correlates with higher doses of administered prednisolone.

## Author contributions

M.N., D.F.M., and M.D. were responsible for the study's conception and design. A.B. and S.Y. collected the data. A.B. and N.K. did the statistical analyses. A.B. and M.N. interpreted the data. A.B. drafted the manuscript. G.G., M.N., H.K., D.F.M., and M.D. provided a critical revision of the manuscript. All authors have given their final approval to the manuscript.

## Conflicts of interest

The authors made the following disclosures: D.F.M. and her team: Invented TABQOL, but the license belongs to the Australasian Blistering Diseases Foundation. A.B., G.G., M.N., S.Y., H.K., N.K., and M.D.: None.

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## Funding

None.



## Study approval

The author(s) confirm that any aspect of the work covered in this manuscript that has involved human patients has been conducted with the ethical approval of all relevant bodies.

## Supplementary materials

Supplementary material associated with this article can be found at <http://links.lww.com/IJWD/A4>, <http://links.lww.com/IJWD/A5>, and <http://links.lww.com/IJWD/A6>.

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