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Title page

Title: A detailed analysis of 'not relevant' responses on the DLQI in psoriasis: potential biases in treatment decisions

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Abstract

Background: Dermatology Life Quality Index (DLQI) is the most common health-related quality of life measure in dermatology that is widely used in treatment guidelines for psoriasis. Eight out of the 10 questions of the DLQI offer a 'not relevant' response (NRR) option that is scored as the item had no impact on patients' life at all.

Objective: To explore the occurrence of NRRs on the DLQI in psoriasis patients, and to examine the effect of several socio-demographic and clinical factors on giving NRRs.

Methods: Data were obtained from two cross-sectional surveys among psoriasis patients at two academic dermatology clinics in Hungary. Health-related quality of life was measured by employing DLQI and EQ-5D-3L, while disease severity was graded by Psoriasis Area and Severity Index (PASI). Multivariate logistic regression was applied to determine the predictors of providing NRRs.

Results: Mean age of the 428 patients was 49 years, and 65% were males. Mean PASI, DLQI and EQ-5D-3L index scores were 8.4±9.5, 6.8±7.4 and 0.74±0.28, respectively. Overall, 38.8% of the patients had at least one NRR: 19.6% (one), 11.5% (two), 5.1% (three) and 2.6% (more than three). Most NRRs occurred in sport, sexual difficulties and working/studying items of the DLQI (28.4%, 16.4% and 14.0%, respectively). Female gender (OR 1.65; 95% CI 1.04-2.61), older age (OR 1.05; 95% CI 1.03-1.07) and higher PASI score (OR 1.03; 95% CI 1.01-1.06) were associated with providing more NRRs, whereas highly educated patients (OR 0.34; 95% CI 0.16-0.72) and those with a full-time job (OR 0.47; 95% CI 0.29-0.77) less frequently tended to tick NRRs.

Conclusion: The high rate of psoriasis patients with NRRs, especially among women, less educated and elderly patients, indicates a content validity problem of the measure. A reconsideration of the use of the DLQI for medical and financial decision-making in psoriasis patients is suggested.

Keywords: psoriasis, health-related quality of life, DLQI, medical decision-making, clinical guidelines

Introduction

Dermatology Life Quality Index (DLQI) was the first, and to date, is the most commonly used health-related quality of life (HRQoL) measure in dermatological settings.[1-3] Over the past two decades, it has pervaded the management of psoriasis patients in multiple ways. It serves as an easy-to-use instrument and a useful benchmark to evaluate treatment efficacy both in routine clinical work and in a variety of researches.[4] It is by far the most commonly applied HRQoL tool in randomised controlled trials for interventions in psoriasis.[5] According to the European consensus, DLQI is among the diagnostic criteria of moderate-to-severe psoriasis to determine which patients need to be offered systemic treatments.[6-8] Furthermore, in many European countries, including the UK, Sweden, Denmark, Hungary, Poland, Romania and Croatia, DLQI is among reimbursement criteria for biological therapy alongside the Psoriasis Area and Severity Index (PASI).[9-11]

The DLQI is a simple self-administered questionnaire that assesses the impact of a skin disease on HRQoL of the patient over the last week.[1] The 10-item instrument includes the following six dimensions of HRQoL: symptoms and feelings, daily activities, leisure, work and school, personal relationships and treatment. Each question is scored on a four-point Likert-scale ('not at all'=0, 'a little'=1, 'a lot'=2 and 'very much'=3). Moreover, eight questions have 'not relevant' response (NRR) options that are given the same zero scores as 'not at all' responses. Scores of individual items are added to yield a total score ranging from 0 to 30, where a higher score represents a greater impairment of HRQoL.

A NRR option in up to 80% of the questions of a HRQoL measure is rather unusual, especially in case of such a short questionnaire. Nevertheless, the literature regarding the occurrence of NRRs on the DLQI is scarce and inconsistent. The overwhelming majority of DLQI studies, including validation studies neglect to report the number of NRRs on the DLQI items or the proportion of patients with NRRs.[1,12-30] On the other hand, studies from a variety of countries noted very high, others, on the contrary reported almost no NRRs in most questions of the DLQI.[31-38]

Given that all NRRs are scored as 0 (equal to 'not at all' responses), they may artificially improve the DLQI score of patients who give at least one NRR in any item. The large number of NRRs may implicate a problem with the content validity of the DLQI. Despite the obvious anomaly in this answer option and its scoring, no study has provided a detailed analysis on

NRRs on the DLQI, so far. The objective of this study is thus to explore the occurrence of NRRs on the DLQI in a large sample of psoriasis patients, and to examine the effect of several socio-demographic and clinical factors on giving NRRs.

Methods

Study design

Data from two cross-sectional questionnaire surveys among psoriasis patients aged 18 or above were combined. Detailed methodology of the studies has been published elsewhere.[39-43] Both surveys have been performed in a paper-based fashion at academic dermatology clinics in Hungary. The first study was carried out between September 2012 and May 2013 at two clinics: Semmelweis University, Department of Dermatology, Venereology and Dermatooncology (hereinafter referred as clinic #1) and at the University of Debrecen, Department of Dermatology (hereinafter referred as clinic #2). The survey involved 200 consecutive outpatients with moderate-to-severe psoriasis. The second study, undertaken from September 2015 to June 2016 at clinic #1, enrolled 238 psoriasis patients regardless of disease severity. Consecutive outpatients, as well as patients hospitalized due to psoriasis were recruited to complete the questionnaire.

Patient population

A total of 438 psoriasis patients filled in the two questionnaire surveys. As clinic #1 participated in both studies (99 patients in the first survey and 238 patients in the second survey), we tested whether an overlap would exist between the two patient populations. We identified four patients who completed both surveys; therefore, their data were included once (the later). Out of the 434 patients left after exclusion, further six patients were excluded, for whom a total DLQI score could not be calculated due to missing responses. Thus, the valid patient population for analysis consisted of 428 psoriasis patients.

Outcome measures

DLQI was applied to measure dermatology-specific HRQoL. A description of the DLQI and its scoring is provided in the Introduction. General health status and HRQoL was measured by the Hungarian version of the EQ-5D-3L (hereinafter referred as EQ-5D) questionnaire, which showed a good validity and responsiveness in psoriasis.[43-46] It consists of two

measures, the EQ-5D descriptive system and the EQ visual analogue scale (EQ VAS). The descriptive system is based on the following five dimensions of HRQoL: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Patients may report no problems, some or moderate problems or extreme problems in each dimension, which results in a total of $3^5=243$ possible health states. In the lack of Hungarian national value set, EQ-5D index scores were calculated according to the UK one developed by Dolan,[47] so values ranged between -0.594 and 1. The EQ VAS records the respondent's self-rated health on a 20 cm vertical line, ranging from 0 (worst imaginable health state) to 100 (best imaginable health state).

Disease severity was evaluated by PASI that grades the severity of psoriasis by the presence of erythema, induration and scaling and the extension of the lesions with respect to four body regions: head, trunk, upper and lower extremities.[48] The PASI total score ranges from 0 to 72, where a higher score corresponds to a higher disease severity.

Data analysis

Descriptive statistics were computed for all socio-demographic and clinical variables as well as for HRQoL outcomes. Frequencies of responses in each DLQI item and mean DLQI scores were calculated. Patients were stratified into subgroups according to the banding DLQI system proposed by Hongbo et al. (DLQI scores 0-1 = no effect; DLQI scores 2-5 = small effect; DLQI scores 6-10 = moderate effect; DLQI scores 11-20 = very large effect; DLQI scores 21-30 = extremely large effect).[49] Two different approaches were used to analyse the occurrence of NRRs on the DLQI. First, the proportion of NRRs was calculated for each item of the DLQI with the exception of the first and second, which offer no NRR options. Secondly, the total number of NRRs per patient was determined. This value was measured on a Likert-scale from 0 to 8.

Due to skewed distribution of data, we applied Kruskal-Wallis test and Dunn-Bonferroni post-hoc test to compare DLQI, PASI, EQ-5D and EQ VAS scores between groups of patients classified according to their number of NRRs. Multivariate logistic regression was applied to determine predictors of providing NRRs. An odds ratio (OR) and its 95% confidence interval (CI) were calculated for each variable. The associations between gender and the number of NRRs along the DLQI items were analysed by Chi-square test. All the statistical tests were two-sided, and a $p<0.05$ was considered statistically significant. Data

were analysed by using IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp. (2013).

Results

Characteristics of the patient population

Mean age of the 428 psoriasis patients was 49.2±14.3 years (min. 18, max. 86 years), and 65% were males (Table 1). Almost one-third of the patients had a college or university degree, and less than half of them worked in a full-time job. Similarly to the general population in Hungary higher rate of male patients worked (either full time or part time) in our sample, compared to females (62.6% vs. 44.7%, p<0.001). There was no significant difference among women and men concerning education (p=0.628). Mean disease duration was 19.9±12.3 years, and there were merely six patients who had been diagnosed less than a year before participating in the study. More than 80% of the patients presented with moderate-to-severe psoriasis. Mean PASI, DLQI, EQ-5D and EQ VAS scores of the total sample were 8.4±9.5, 6.8±7.4, 0.74±0.28 and 69.1±14.0, respectively. Distribution of patients according to DLQI bands is presented in Table 1. The majority of the patients were treated by biologics (43.7%), while 25% received systemic non-biological and 24.1% topical therapy only. There were 31 patients (7.2%) who received no medical treatment at the time of the survey. Most of them had a PASI score of over 10 and were right before the initiation of systemic therapy.

Descriptive results of 'not relevant' responses

Concerning items 6 (sport), 9 (sexual difficulties) and 7 (working or studying) 28.4%, 16.4% and 14% ticked a NRR, respectively (Table 2). In contrast, less than 3% of answers were NRRs in items 4 (clothes), 10 (treatment difficulties) and 5 (social activities).

Out of the 428 patients, 166 (38.8%) gave at least one NRR on the DLQI. Of these, there were 84 patients (19.6%) with 1 NRR, 49 (11.5%) with 2 NRRs, 22 (5.1%) with 3 NRRs, seven (1.6%) with 4 NRRs, one (0.2%) with 5 NRRs, two (0.5%) with 6 NRRs, none with 7 NRRs and one (0.2%) with 8 NRRs. Item 6 was ticked by the majority of patients with only one NRR (61.9%), followed by items 9 (20.2%) and 7 (15.5%). By increasing the number of

NRRs, the percentage of item 6 gradually decreases, while those of items 7, 8 and 9 clearly rise (Fig. 1).

The proportion of NRRs per DLQI score bands is depicted in Fig. 2. Overall, 28% of patients with DLQI scores of 0 or 1 had at least one NRR. Corresponding percentages for patients with DLQI total scores of 2-5, 6-10 and 11-20 were 38%, 52% and 53%, respectively. The proportion of NRRs in patients with a DLQI ≥ 21 was 13%, on average.

Determinants of 'not relevant' responses

Mean DLQI scores of patients with 0, 1 and 2≤ NRRs were 6.5±8.0, 7.2±6.6 and 7.3±6.0, respectively (p=0.049). This trend, that patients with higher DLQI scores had more NRRs can be seen in Fig. 2 as well, with the exception of the group who had a result of more than 20 points on the DLQI. Patients with 0, 1 and 2≤ NRRs showed mean PASI scores of 6.5±8.0, 9.3±9.7 and 11.3±10.5, respectively (p<0.001). Worse general HRQoL (lower EQ-5D and EQ VAS scores) was also associated with a higher number of NRRs (p<0.001). Pairwise comparisons between groups confirmed these differences for PASI, EQ-5D and EQ VAS (Table 3).

In a multivariate logistic regression, several socio-demographic and clinical characteristics were found to have a significant impact on NRRs (Table 4). Female gender was associated with a higher odds of providing NRRs (OR 1.646; 95% CI 1.039-2.608). Having a secondary school or a college/university degree decreased the odds of NRRs (OR 0.405; 95% CI 0.209-0.784 and OR 0.343; 95% CI 0.164-0.717). Patients with full-time jobs less frequently had NRRs (OR 0.474; 95% CI 0.290-0.774). Besides these variables, older age (OR 1.049; 95% CI 1.031-1.068) and higher PASI score (OR 1.030; 95% CI 1.006-1.055) were related to an increased odds of the occurrence of NRRs.

To identify which DLQI items are responsible for the difference between women and men, we compared responses of these two groups according to DLQI items (Table 5). The gender difference in providing NRRs was present in items 5 (social activities), 9 (sexual difficulties) and 10 (treatment difficulties) (p=0.008, p<0.001 and p=0.044, respectively). Items 6 (sport) and 8 (interpersonal problems) also demonstrated a trend towards significance (p=0.056 and p=0.058).

Discussion

In the present study, we analysed the occurrence of NRRs on the DLQI in a large sample of psoriasis patients and revealed that DLQI total score, PASI and several socio-demographic factors affected the number of NRRs given by a patient. We believe that our study provides three major findings.

First, 38.8% of psoriasis patients provided at least one NRR. Furthermore, more patients with DLQI scores of 6 to 20 had at least one NRR than those who did not. This suggests that certain items of the DLQI are not important for a significant number of psoriasis patients. Secondly, as NRRs are scored as being 0, higher number of NRRs is expected to yield a lower DLQI total score. Yet evidence from our study testifies the contrary; the higher the DLQI score, the more NRRs are ticked (Fig.2). The high rate of psoriasis patients with NRRs and the unexpected inverse association between DLQI score and the number of NRRs indicates a content validity problem of the measure. This is supported by the fact that patients with more NRRs had more severe psoriasis (i.e. higher PASI scores). By eliminating DLQI items that were answered NRRs in the calculation of the total score and then converting these raw scores to scores on a 0 to 30 scale, the mean total DLQI score of the 166 patients with NRRs in our sample would increase from 7.23 to 8.94 (p<0.001). The rise in DLQI score is more prominent in the age group of >65 years (n=46), whose mean DLQI total score would rise from 7.41 to 10.15 points (p<0.001). Thirdly, we observed that some socio-demographic groups tended to provide more NRRs. In our study, these groups were elderly, females, those not working full-time and less educated patients. The gender difference is particularly important considering the fact that in large European registries, a higher proportion of men with psoriasis are treated with systemic therapy.[11,50] Nevertheless, more studies with larger sample sizes are required to confirm the generalisability of these findings.

In consistent with the literature, NRRs were the most common in the items of sport, sexual difficulties and working or studying.[31-34,36-38] It appears that these items are more often not relevant to elderly psoriasis patients compared with their younger peers. Nevertheless, psoriasis is a life-long condition and a HRQoL instrument should be relevant for every patient regardless of age. This is becoming more important with the increasingly aging population in the developed countries.

A further, very important problem about items 6 (sports) and 9 (sexual difficulties) is that the DLQI assesses the impact of a skin disease on HRQoL of the patient over the last week. On the one hand, there are many arguments in favour of applying a one-week time frame; for example, the shorter recall period can be more sensitive to recent changes in health status or less recall bias may occur.[51] On the other hand, many people, also among members of the general population, are not involved in these activities on a weekly basis. Thus, if the DLQI covered a longer time span, items 6 and 9 would be more likely relevant for a higher proportion of patients, and they might report a problem in these items, too.

Limitations of the current study include the following. First, despite the large sample size, less than 10 NRRs were reported in some items of the DLQI and only a few patients reported more than two NRRs. However, a heterogeneous psoriasis patient population was recruited both in terms of socio-demographic and clinical characteristics, which was excellent for the purposes of the study. Secondly, some authors have addressed that patients may misunderstand the term 'not relevant' and cannot judge between 'not at all'.[31,32] We have no data regarding how many patients were not able to make a clear difference between the NRR and the 'not at all' answer options on the DLQI. For example, none of the 31 patients who were not treated at the time of the survey provided a NRR on item 10 (treatment), or out of the 19 unemployed patients in our study, six marked any NRR in the questionnaire, only one of which occurred in the working/studying item. Based on these, the actual rate of NRRs could be overestimated or even underestimated in the current study. The term 'not relevant' is translated differently in other language versions of the DLQI, which may, in part, explain the variances in the rates of NRRs across countries [e.g. German: 'betrifft mich nicht' (=it does not concern me), Hungarian: 'nem vonatkozik Önre' (=it is not relevant for you), Italian: 'Non riguarda il mio caso' (=It does not affect my case), Swedish – 'Ej tillämpligt' (=Not applicable)].[52] This draws the attention to the presence of systematic measurement bias in multi-country studies in which the DLQI is filled in by patients with different languages.

At the time the DLQI was developed in the early 1990s, the aim of HRQoL assessment was to quantify the quality of life loss experienced by patients. Being the first dermatology-specific HRQoL measure, it brought a paradigm shift in dermatological care, and its merits should not be overlooked.[53] In the context of the present paper, NRRs may be useful, for example, to identify patients who are unemployed or do not go in for sport. Yet very few studies reported on the number of NRRs and exploited this additional information provided by the DLQI.[31-38] Over the past two decades, owing to advances in therapy such as biological

drugs, the DLQI has become a reference point for not only medical but financial decision-making. Currently, the DLQI is widely used in diagnostic criteria for moderate-to-severe psoriasis − (body surface area >10 or PASI>10) and DLQI>10 − and for reimbursement decision-making regarding biologics.[7-10,54]

There is, however, a growing body of literature questioning the feasibility and pointing out the inherent limitations of the DLQI as a HRQoL measure. In previous studies, Rasch analysis and factor analysis could not confirm its unidimensionality (i.e. that all items in the scale underlie the same construct) and detected that certain DLQI items are affected by external factors, such as age, gender and cultural background of patients.[16,20,34,55-59] Another study found discrepancies between DLQI scores and time trade-off utility values, suggesting that HRQoL in two patients with identical DLQI scores might be significantly different, while patients whose DLQI scores differ larger than the minimal clinically important difference may be equal.[60,61] Considering the number of jurisdictions, in which the DLQI is used in national guidelines, including the European S3-Guidelines on the systemic treatment of psoriasis vulgaris,[7-11,62-66] the amount of patients affected worldwide may be very large. Our results, taken together with other findings in the literature, suggest that the applicability of the DLQI in the management of psoriasis patients may be called into question.

References

1   Finlay AY, Khan GK. Dermatology Life Quality Index (DLQI)--a simple practical measure for routine clinical use. *Clin Exp Dermatol* 1994; **19**: 210-216.
2   Basra MK, Fenech R, Gatt RM, Salek MS, Finlay AY. The Dermatology Life Quality Index 1994-2007: a comprehensive review of validation data and clinical results. *Br J Dermatol* 2008; **159**: 997-1035.
3   Lewis V, Finlay AY. 10 years experience of the Dermatology Life Quality Index (DLQI). *J Investig Dermatol Symp Proc* 2004; **9**: 169-180.
4   Obradors M, Blanch C, Comellas M, Figueras M, Lizan L. Health-related quality of life in patients with psoriasis: a systematic review of the European literature. *Qual Life Res* 2016; **25**: 2739-2754.
5   Ali FM, Cueva AC, Vyas J, Atwan AA, Salek MS, Finlay AY et al. A systematic review of the use of quality of life instruments in randomised controlled trials of psoriasis. *Br J Dermatol* 2016.
6   Finlay AY. Current severe psoriasis and the rule of tens. *Br J Dermatol* 2005; **152**: 861-867.
7   Mrowietz U, Kragballe K, Reich K, Spuls P, Griffiths CE, Nast A et al. Definition of treatment goals for moderate to severe psoriasis: a European consensus. *Arch Dermatol Res* 2011; **303**: 1-10.

8   Pathirana D, Ormerod AD, Saiag P, Smith C, Spuls PI, Nast A et al. European S3-guidelines on the systemic treatment of psoriasis vulgaris. *J Eur Acad Dermatol Venereol* 2009; **23 Suppl 2**: 1-70.

9   Wakkee M, Thio HB, Spuls PI, de Jong EM, Nijsten T. Evaluation of the reimbursement criteria for biological therapies for psoriasis in the Netherlands. *Br J Dermatol* 2008; **158**: 1159-1161.

10   Rencz F, Kemény L, Gajdácsi JZ, Owczarek W, Arenberger P, Tiplica GS et al. Use of biologics for psoriasis in Central and Eastern European countries. *J Eur Acad Dermatol Venereol* 2015; **29**: 2222-2230.

11   Hagg D, Sundstrom A, Eriksson M, Schmitt-Egenolf M. Decision for biological treatment in real life is more strongly associated with the Psoriasis Area and Severity Index (PASI) than with the Dermatology Life Quality Index (DLQI). *J Eur Acad Dermatol Venereol* 2015; **29**: 452-456.

12   He Z, Lu C, Basra MK, Ou A, Yan Y, Li L. Psychometric properties of the Chinese version of Dermatology Life Quality Index (DLQI) in 851 Chinese patients with psoriasis. *J Eur Acad Dermatol Venereol* 2013; **27**: 109-115.

13   Zachariae R, Zachariae C, Ibsen H, Mortensen JT, Wulf HC. Dermatology life quality index: data from Danish inpatients and outpatients. *Acta Derm Venereol* 2000; **80**: 272-276.

14   Shikiar R, Bresnahan BW, Stone SP, Thompson C, Koo J, Revicki DA. Validity and reliability of patient reported outcomes used in psoriasis: results from two randomized clinical trials. *Health Qual Life Outcomes* 2003; **1**: 53.

15   Shikiar R, Willian MK, Okun MM, Thompson CS, Revicki DA. The validity and responsiveness of three quality of life measures in the assessment of psoriasis patients: results of a phase II study. *Health Qual Life Outcomes* 2006; **4**: 71.

16   Ofenloch RF, Diepgen TL, Weisshaar E, Elsner P, Apfelbacher CJ. Assessing health-related quality of life in hand eczema patients: how to overcome psychometric faults when using the dermatology life quality index. *Acta Derm Venereol* 2014; **94**: 658-662.

17   Lennox RD, Leahy MJ. Validation of the Dermatology Life Quality Index as an outcome measure for urticaria-related quality of life. *Ann Allergy Asthma Immunol* 2004; **93**: 142-146.

18   Aghaei S, Sodaifi M, Jafari P, Mazharinia N, Finlay AY. DLQI scores in vitiligo: reliability and validity of the Persian version. *BMC Dermatol* 2004; **4**: 8.

19   Kent G, al-Abadie M. Factors affecting responses on Dermatology Life Quality Index items among vitiligo sufferers. *Clin Exp Dermatol* 1996; **21**: 330-333.

20   Liu Y, Li T, An J, Zeng W, Xiao S. Rasch analysis holds no brief for the use of the Dermatology Life Quality Index (DLQI) in Chinese neurodermatitis patients. *Health Qual Life Outcomes* 2016; **14**: 17.

21   Liu Z, Xie Z, Zhang L, Jin Y, Guo H, Jiang Z et al. Reliability and validity of dermatology life quality index: assessment of quality of life in human immunodeficiency virus/acquired immunodeficiency syndrome patients with pruritic papular eruption. *J Tradit Chin Med* 2013; **33**: 580-583.

22   Ozturkcan S, Ermertcan AT, Eser E, Sahin MT. Cross validation of the Turkish version of dermatology life quality index. *Int J Dermatol* 2006; **45**: 1300-1307.

23   Qi S, Xu F, Sheng Y, Yang Q. Assessing quality of life in Alopecia areata patients in China. *Psychol Health Med* 2015; **20**: 97-102.

24   Takahashi N, Suzukamo Y, Nakamura M, Miyachi Y, Green J, Ohya Y et al. Japanese version of the Dermatology Life Quality Index: validity and reliability in patients with acne. *Health Qual Life Outcomes* 2006; **4**: 46.

25   Mazharinia N, Aghaei S, Shayan Z. Dermatology Life Quality Index (DLQI) scores in burn victims after revival. *J Burn Care Res* 2007; **28**: 312-317.

26   Henok L, Davey G. Validation of the Dermatology Life Quality Index among patients with podoconiosis in southern Ethiopia. *Br J Dermatol* 2008; **159**: 903-906.

27   Thomas C, Narahari SR, Bose KS, Vivekananda K, Nwe S, West DP et al. Comparison of three quality of life instruments in lymphatic filariasis: DLQI, WHODAS 2.0, and LFSQQ. *PLoS Negl Trop Dis* 2014; **8**: e2716.

28   Wallenhammar LM, Nyfjall M, Lindberg M, Meding B. Health-related quality of life and hand eczema--a comparison of two instruments, including factor analysis. *J Invest Dermatol* 2004; **122**: 1381-1389.

29   Jobanputra R, Bachmann M. The effect of skin diseases on quality of life in patients from different social and ethnic groups in Cape Town, South Africa. *Int J Dermatol* 2000; **39**: 826-831.

30   Chuh AA, Chan HH. Effect on quality of life in patients with pityriasis rosea: is it associated with rash severity? *Int J Dermatol* 2005; **44**: 372-377.

31   Hahn HB, Melfi CA, Chuang TY, Lewis CW, Gonin R, Hanna MP et al. Use of the Dermatology Life Quality Index (DLQI) in a midwestern US urban clinic. *J Am Acad Dermatol* 2001; **45**: 44-48.

32   Mork C, Wahl A, Moum T. The Norwegian version of the dermatology life quality index: a study of validity and reliability in psoriatics. *Acta Derm Venereol* 2002; **82**: 347-351.

33   Mazzotti E, Barbaranelli C, Picardi A, Abeni D, Pasquini P. Psychometric properties of the Dermatology Life Quality Index (DLQI) in 900 Italian patients with psoriasis. *Acta Derm Venereol* 2005; **85**: 409-413.

34   Twiss J, Meads DM, Preston EP, Crawford SR, McKenna SP. Can we rely on the Dermatology Life Quality Index as a measure of the impact of psoriasis or atopic dermatitis? *J Invest Dermatol* 2012; **132**: 76-84.

35   Badia X, Mascaro JM, Lozano R. Measuring health-related quality of life in patients with mild to moderate eczema and psoriasis: clinical validity, reliability and sensitivity to change of the DLQI. The Cavide Research Group. *Br J Dermatol* 1999; **141**: 698-702.

36   Khoudri I, Lamchahab FZ, Ismaili N, Senouci K, Hassam B, Abouqal R. Measuring quality of life in patients with psoriasis using the Arabic version for Morocco of the Dermatology Life Quality Index. *Int J Dermatol* 2013; **52**: 795-802.

37   Ferraz LB, Almeida FA, Vasconcellos MR, Faccina AS, Ciconelli RM, Ferraz MB. The impact of lupus erythematosus cutaneous on the Quality of life: the Brazilian-Portuguese version of DLQI. *Qual Life Res* 2006; **15**: 565-570.

38   Mayrshofer F, Hertl M, Sinkgraven R, Sticherling M, Pfeiffer C, Zillikens D et al. Significant decrease in quality of life in patients with pemphigus vulgaris. Results from the German Bullous Skin Disease (BSD) Study Group. *J Dtsch Dermatol Ges* 2005; **3**: 431-435.

39   Heredi E, Rencz F, Balogh O, Gulacsi L, Herszenyi K, Hollo P et al. Exploring the relationship between EQ-5D, DLQI and PASI, and mapping EQ-5D utilities: a cross-sectional study in psoriasis from Hungary. *Eur J Health Econ* 2014; **15 Suppl 1**: S111-119.

40   Balogh O, Brodszky V, Péntek M, Szegedi A, Herédi E, Herszényi K et al. Cost-of-illness in patients with severe psoriasis; a cross-sectional survey in Hungarian dermatological centres. *Eur J Health Econ* 2014; **15**: S101-109.

41   Rencz F, Brodszky V, Péntek M, Balogh O, Remenyik É, Szegedi A et al. Disease burden of psoriasis associated with psoriatic arthritis in Hungary. *Orv Hetil* 2014; **155**: 1913–1921.

42   Rencz F, Hollo P, Karpati S, Pentek M, Remenyik E, Szegedi A et al. Moderate to severe psoriasis patients' subjective future expectations regarding health-related quality of life and longevity. *J Eur Acad Dermatol Venereol* 2015; **29**: 1398-1405.

43   Poor AK, Rencz F, Brodszky V, Gulacsi L, Beretzky Z, Hidvegi B et al. Measurement properties of the EQ-5D-5L compared to the EQ-5D-3L in psoriasis patients. *Qual Life Res* 2017.

44   EuroQol G. EuroQol--a new facility for the measurement of health-related quality of life. *Health Policy* 1990; **16**: 199-208.

45   Brooks R. EuroQol: the current state of play. *Health Policy* 1996; **37**: 53-72.

46   Yang Y, Brazier J, Longworth L. EQ-5D in skin conditions: an assessment of validity and responsiveness. *Eur J Health Econ* 2015; **16**: 927-939.

47   Dolan P. Modeling valuations for EuroQol health states. *Med Care* 1997; **35**: 1095-1108.

48   Fredriksson T, Pettersson U. Severe psoriasis--oral therapy with a new retinoid. *Dermatologica* 1978; **157**: 238-244.

49   Hongbo Y, Thomas CL, Harrison MA, Salek MS, Finlay AY. Translating the science of quality of life into practice: What do dermatology life quality index scores mean? *J Invest Dermatol* 2005; **125**: 659-664.

50   Kojanova M, Fialova J, Cetkovska P, Gkalpakiotis S, Jircikova J, Dolezal T et al. Characteristics and risk profile of psoriasis patients included in the Czech national registry BIOREP and a comparison with other registries. *Int J Dermatol* 2017; **56**: 428-434.

51   Keller SD, Bayliss MS, Ware JE, Jr., Hsu MA, Damiano AM, Goss TF. Comparison of responses to SF-36 Health Survey questions with one-week and four-week recall periods. *Health Serv Res* 1997; **32**: 367-384.

52   DLQI Different Language Versions. 2017; http://sites.cardiff.ac.uk/dermatology/quality-of-life/dermatology-quality-of-life-index-dlqi/dlqi-different-language-versions/ Accessed: 04/07/2017

53   Finlay AY. Quality of life in dermatology: after 125 years, time for more rigorous reporting. *Br J Dermatol* 2014; **170**: 4-6.

54   Boncz I, Sebestyen A. Financial deficits in the health services of the UK and Hungary. *Lancet* 2006; **368**: 917-918.

55   McKenna S, Meads D, Doward L. Scaling properties of the Dermatology Life Quality Index (DLQI).(PES16). *Value in Health* 2004; **7**: 750-751.

56   Nijsten T. Dermatology life quality index: time to move forward. *J Invest Dermatol* 2012; **132**: 11-13.

57   Nijsten T, Meads DM, de Korte J, Sampogna F, Gelfand JM, Ongenae K et al. Cross-cultural inequivalence of dermatology-specific health-related quality of life instruments in psoriasis patients. *J Invest Dermatol* 2007; **127**: 2315-2322.

58   Nijsten T, Meads DM, McKenna SP. Dimensionality of the dermatology life quality index (DLQI): a commentary. *Acta Derm Venereol* 2006; **86**: 284-285; author reply 285-286.

59   Nijsten TE, Sampogna F, Chren MM, Abeni DD. Testing and reducing skindex-29 using Rasch analysis: Skindex-17. *J Invest Dermatol* 2006; **126**: 1244-1250.

60   Rencz F, Baji P, Gulacsi L, Karpati S, Pentek M, Poor AK et al. Discrepancies between the Dermatology Life Quality Index and utility scores. *Qual Life Res* 2016; **25**: 1687-1696.

61   Rencz F, Poor AK, Pentek M, Gulácsi L, Beretzky Z, Hollo P et al. Is it appropriate to use the Dermatology Life Quality Index for medical-decision making in psoriasis patients? *Journal of Investigative Dermatology* 2016; **136**: S163.

62   Smith CH, Anstey AV, Barker JN, Burden AD, Chalmers RJ, Chandler DA et al. British Association of Dermatologists' guidelines for biologic interventions for psoriasis 2009. *Br J Dermatol* 2009; **161**: 987-1019.

63   Marchesoni A, Altomare G, Matucci-Cerinic M, Balato N, Olivieri I, Salvarani C et al. An Italian shared dermatological and rheumatological proposal for the use of biological agents in psoriatic disease. *J Eur Acad Dermatol Venereol* 2010; **24**: 578-586.

64   Kragballe K, Gniadecki R, Mork NJ, Rantanen T, Stahle M. Implementing best practice in psoriasis: a Nordic expert group consensus. *Acta Derm Venereol* 2014; **94**: 547-552.

65   Puig L, Carrascosa JM, Carretero G, de la Cueva P, Lafuente-Urrez RF, Belinchon I et al. Spanish evidence-based guidelines on the treatment of psoriasis with biologic agents, 2013. Part 1: on efficacy and choice of treatment. Spanish Psoriasis Group of the Spanish Academy of Dermatology and Venereology. *Actas Dermosifiliogr* 2013; **104**: 694-709.

66   Baker C, Mack A, Cooper A, Fischer G, Shumack S, Sidhu S et al. Treatment goals for moderate to severe psoriasis: an Australian consensus. *Australas J Dermatol* 2013; **54**: 148-154.

Figure legends

Figure 1 Distribution of DLQI items according to the number of 'not relevant' responses per patient*

*There is no 'not relevant' option in the first and second item of the DLQI.

Figure 2 Number of 'not relevant' responses by DLQI score bands

Tables
Table 1 Characteristics of the psoriasis patient population (N=428)

Variables	Mean (SD) or N (%)
Gender	
Female	150 (35.0%)
Male	278 (65.0%)
Age (years)	49.2 (14.3)
Disease duration (years)	19.9 (12.3)
Education	
Primary school	58 (13.6%)
Secondary school	243 (56.8%)
College/university	127 (29.7%)
Employment**	
Student	10 (2.3%)
Full-time	207 (48.4%)
Part-time	35 (8.2%)
Unemployed	19 (4.4%)
Retired	84 (19.6%)
Disability pensioner	60 (14.0%)
Other	26 (6.1%)
EQ-5D-3L (-0.594-1) (missing=5)	0.74 (0.28)
EQ VAS (0-100)	69.1 (14.0)
DLQI (0-30)	6.8 (7.4)
0-1	148 (34.6%)
2-5	95 (22.2%)
6-10	71 (16.6%)
11-20	90 (21.0%)
21-30	24 (5.6%)
Disease severity	
PASI (0-72)	8.4 (9.5)
Mild psoriasis	80 (18.7%)
Moderate-to-severe psoriasis*	348 (81.3%)
Clinical subtype**	
Chronic plaque psoriasis	314 (73.4%)
Guttate	27 (6.3%)
Erythrodermic	7 (1.6%)
Facial and/or inverse	78 (18.2%)
Scalp	205 (47.9%)
Palmoplantar	26 (6.8%)
Nail	194 (45.3%)
Psoriatic arthritis	154 (36.0%)
Pustular	2 (0.5%)
Treatments	
None	31 (7.2%)
Topical only	103 (24.1%)
Systemic non-biologic	107 (25.0%)
Biologic	187 (43.7%)

* Patients were considered moderate-to-severe if met the criteria of body surface area > 10 or PASI > 10 and DLQI > 10 [6,7] or if they were treated by systemic therapy either non-biological or biological at the time of the survey.

**Combinations may occur.

DLQI= Dermatology Life Quality Index; PASI = Psoriasis Area and Severity Index; VAS = visual analogue scale

Table 2 Distribution of responses on the 10 items of the DLQI

DLQI items	N	Not relevant	Not at all	A little	A lot	Very much
Item 1 (sore, itchy, painful)	428	N/A	157 (36.7%)	124 (29.0%)	87 (20.3%)	60 (14.0%)
Item 2 (embarrassment)	428	N/A	202 (47.2%)	102 (23.8%)	69 (16.1%)	55 (12.9%)
Item 3 (shopping/home)	427	7 (1.6%)	282 (66.0%)	75 (17.5%)	49 (11.5%)	14 (3.3%)
Item 4 (clothes)	428	3 (0.7%)	232 (54.2%)	75 (17.5%)	62 (14.5%)	56 (13.1%)
Item 5 (social activities)	428	11 (2.6%)	238 (55.6%)	80 (18.7%)	55 (12.9%)	44 (10.3%)
Item 6 (sport)	426	121 (28.4%)	200 (46.9%)	45 (10.6%)	31 (7.3%)	29 (6.8%)
Item 7 (working/studying)	428	60 (14.0%)	256 (59.8%)	61 (14.3%)	26 (6.1%)	25 (5.8%)
Item 8 (interpersonal problems)	428	20 (4.7%)	260 (60.7%)	83 (19.4%)	48 (11.2%)	17 (4.0%)
Item 9 (sexual difficulties)	428	70 (16.4%)	274 (64.0%)	44 (10.3%)	23 (5.4%)	17 (4.0%)
Item 10 (treatment difficulties)	428	9 (2.1%)	201 (47.0%)	113 (26.4%)	66 (15.4%)	39 (9.1%)

N/A=not applicable
DLQI= Dermatology Life Quality Index

Table 3 Associations between DLQI, PASI, EQ-5D and EQ VAS and the number of 'not relevant' responses on the DLQI

Number of 'not relevant' responses	N (%)	Mean (SD)			
		DLQI (0-30)	PASI (0-72)	EQ-5D-3L (-0.594 to 1)	EQ VAS (0-100)
0	262 (61.2%)	6.5 (8.0)	7.1 (3.5)	0.79 (0.25)	71.8 (19.9)
1	84 (19.6%)	7.2 (6.6)	9.3 (9.7)	0.71 (0.29)	68.2 (22.2)
≥2	82 (19.2%)	7.3 (6.0)	11.3 (10.5)	0.60 (0.32)	61.5 (21.7)
Multivariate p-value*		*0.049*	*<0.001*	*<0.001*	*<0.001*
Pairwise p-value**	0 vs. 1	0.240	0.064	*0.023*	0.714
	0 vs. ≥2	0.111	*0.000*	*0.000*	*0.000*
	1 vs. ≥2	1.000	0.358	0.053	0.085

*Kruskal-Wallis test, where p<0.05 was considered statistically significant.
** Dunn-Bonferroni post-hoc test, where p<0.05 was considered statistically significant.
On DLQI and PASI, higher scores refer to a worse health state, while on EQ-5D and EQ VAS, higher scores correspond to a better health state.
DLQI= Dermatology Life Quality Index; PASI = Psoriasis Area and Severity Index

Table 4 Multivariate logistic regression on providing at least one 'not relevant' response on the DLQI

	Regression coefficient (β)	SE	OR (95% CI)	p-value
Constant	-1.668	0.599	0.189	0.005
Gender (female)	0.498	0.235	1.646 (1.039-2.608)	0.034
Age	0.048	0.009	1.049 (1.031-1.068)	0.000
PASI score	0.030	0.012	1.030 (1.006-1.055)	0.014
Education				
Secondary school	-0.905	0.337	0.405 (0.209-0.784)	0.007
College/university	-1.071	0.377	0.343 (0.164-0.717)	0.004
Full-time job	-0.746	0.250	0.474 (0.290-0.774)	0.003

Note: n=428, dependent variable: zero 'not relevant' responses = 0; ≥1 'not relevant' response =1, Nagelkerke R^2=0.286.

SE= standard error; OR = odds ratio; CI= confidence interval

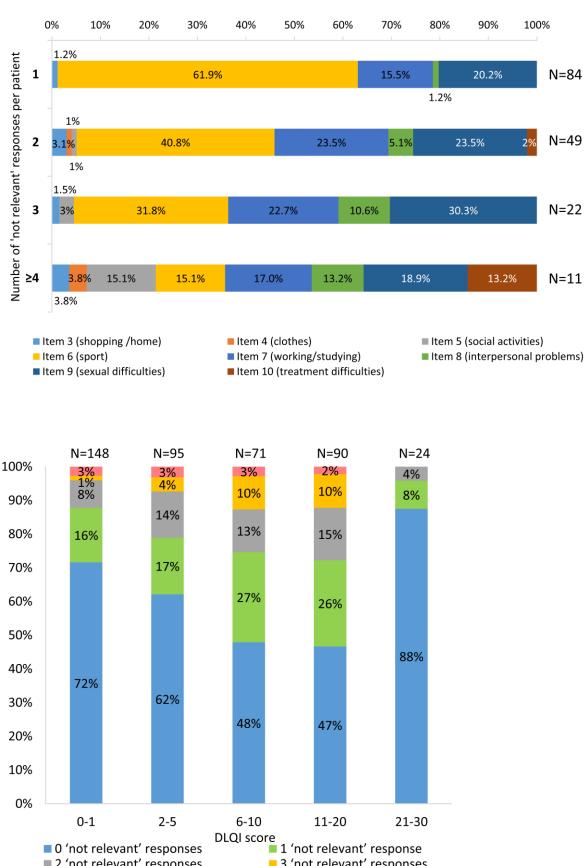**Table 5 Association between gender and frequencies of 'not relevant' responses per item**

DLQI items	'Not relevant' responses (N, %)		p-value*
	Male (N=278)	Female (N=150)	
Item 1 (sore, itchy, painful)	N/A	N/A	-
Item 2 (embarrassment)	N/A	N/A	-
Item 3 (shopping/home)	6 (2.2%)	1 (0.7%)	0.244
Item 4 (clothes)	1 (0.4%)	2 (1.3%)	0.252
Item 5 (social activities)	3 (1.1%)	8 (5.3%)	*0.008*
Item 6 (sport)	70 (25.3%)	51 (34.0%)	0.056
Item 7 (working/studying)	35 (12.6%)	25 (16.6%)	0.258
Item 8 (interpersonal problems)	9 (3.2%)	11 (7.3%)	0.058
Item 9 (sexual difficulties)	31 (11.2%)	39 (26.0%)	*<0.001*
Item 10 (treatment difficulties)	3 (1.1%)	6 (4.0%)	*0.044*
Total	93 (33.5%)	73 (48.7%)	*0.002*

N/A=not applicable

DLQI= Dermatology Life Quality Index

*Chi-square test, where a p-value of <0.05 was considered statistically significant.

Number of 'not relevant' responses per patient

1 — 1.2%, 61.9%, 15.5%, 1.2%, 20.2% — N=84

2 — 1%, 3.1%, 1%, 40.8%, 23.5%, 5.1%, 23.5%, 2% — N=49

3 — 1.5%, 3%, 31.8%, 22.7%, 10.6%, 30.3% — N=22

≥4 — 3.8%, 3.8%, 15.1%, 15.1%, 17.0%, 13.2%, 18.9%, 13.2% — N=11

- ■ Item 3 (shopping /home)
- ■ Item 4 (clothes)
- ■ Item 5 (social activities)
- ■ Item 6 (sport)
- ■ Item 7 (working/studying)
- ■ Item 8 (interpersonal problems)
- ■ Item 9 (sexual difficulties)
- ■ Item 10 (treatment difficulties)

DLQI score

- ■ 0 'not relevant' responses
- ■ 1 'not relevant' response
- ■ 2 'not relevant' responses
- ■ 3 'not relevant' responses
- ■ ≥4 'not relevant' responses