Quality of life measurement in rosacea: position statement of the European Academy of Dermatology and Venereology Task Forces on Quality of Life and Patient Oriented Outcomes and Acne, Rosacea and Hidradenitis Suppurativa

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POSITION STATEMENT

Quality of life measurement in rosacea. Position statement of the European Academy of Dermatology and Venereology Task Forces on Quality of Life and Patient Oriented Outcomes and Acne, Rosacea and Hidradenitis Suppurativa

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Abstract
The European Academy of Dermatology and Venereology (EADV) Task Forces (TFs) on Quality of Life (QoL) and Patient-Oriented Outcomes and Acne, Rosacea and Hidradenitis Suppurativa (ARHS) do not recommend the use of any generic instrument as a single method of Health Related (HR) QoL assessment in rosacea, except when comparing quimp (quality of life impairment) in rosacea patients with that in other non-dermatologic skin diseases and/or healthy controls. The EADV TFs on QoL and Patient-Oriented Outcomes and ARHS recommend the use of the dermatology-specific HRQoL instrument the Dermatology Life Quality Index (DLQI) and the rosacea-specific HRQoL instrument RosaQoL in rosacea patients. The DLQI minimal clinically important difference may be used as a marker of clinical efficacy of the treatment and DLQI score banding of 0 or 1 corresponding to no effect on patients' HRQoL could be an important treatment goal. This information may be added to consensuses and guidelines for rosacea.

INTRODUCTION

Rosacea is a common chronic inflammatory skin disease that almost exclusively affects the central facial skin and rarely affects the extrafacial skin.[1] Worldwide, at least 20 million patients are estimated to have rosacea, although reliable statistics are lacking.[2] Clinically, the condition is characterized by prolonged flushing (transient erythema), persistent erythema, telangiectasia, papules, pustules and rhinophyma, often accompanied by burning, stinging or pain (cutaneous rosacea). The eyes can be also involved (ocular rosacea). Because of its obvious facial location, rosacea is associated with a significant disease burden and impaired health-related quality of life (HRQoL).[3] The pathophysiology of rosacea is still poorly understood.[4–10] Currently treatment modalities mainly aim to control the clinical signs and symptoms rather than target causes or prevent disease.[11–16] Consequently, the therapy of rosacea is still unsatisfactory, although advanced laser treatments, anti-inflammatory topical and systemic therapies have improved the control of rosacea, especially papules and pustules.[11–16] More problematic is prevention of the early stage of rosacea to a chronic manifestation, the prevention of rhinophyma and the long-term control of inflammatory lesions and ocular rosacea.[11–15] Therefore, it is important to develop guidelines and consensus about the management of the disease, which may vary in different countries based on different environments and health systems. Available consensus documents and guidelines recommend HRQoL measurement and recognize that improvement of HRQoL is an important treatment goal in patients with rosacea.[17–19]

The purpose of this paper organized jointly by the European Academy of Dermatology and Venereology (EADV) Task Force (TF) on QoL and Patient-Oriented Outcomes and the EADV TF on Acne, Rosacea and Hidradenitis Suppurativa (ARHS) is to present current knowledge about QoL assessment in rosacea, including data on rosacea-specific HRQoL instruments and influence of different treatment methods on HRQoL, and to make practical recommendations concerning the assessment of QoL in people with rosacea.

METHODS

Members of the EADV TFs on QoL and Patient-Oriented Outcomes and ARHS were invited to participate. A literature search was performed using the PubMed database, which was searched from the beginning to September 2022 using the key word combinations: "rosacea, quality of life". All publications written in English or those having English abstracts were considered. All those who volunteered were allocated a section of the identified articles to review.

Exclusion criteria:

- Review articles, guidelines, protocols
- Studies without HRQoL assessment
- Measurement of HRQoL in conditions other than rosacea
- Studies where HRQoL was studied in rosacea and other diseases but results on rosacea were not presented and/or discussed separately

All publications were independently assessed by two coauthors. The assessments were compared and discrepancies discussed and resolved. The remaining publications were analysed in detail and the QoL instruments used in rosacea were listed.

List of used abbreviations is presented in Table S1.

RESULTS

From the 207 articles identified in the literature search, 139 were excluded based on the exclusion criteria, leaving 68 publications[20–87] for the further analysis.

The generic HRQoL instrument the Short Form (SF)-36 was used five times.[40,59,75,84,85] Another generic HRQoL instrument EuroQoL (EQ)-5D[55,67] and its modifications EQ-5D-3L[76] and EQ-5D-visual analogue scale[77] were also used to assess quimp in rosacea. The dermatology-specific Dermatology Life Quality Index (DLQI) was used for quimp assessment in 45 studies on rosacea.[20–23,25,28–30,32,34,35,37,40–42,46,48–57,60,62–69,72–74,77,78,80,82,83,86,87]

Data on the DLQI scores from included articles is given in Figure 1. Another dermatology-specific instrument Skindex and its modifications Skindex-29 and Skindex-16 were used in one study each.[38,39,71] The rosacea-specific HRQoL instrument the RosaQoL was used in 16 studies.[24,27,33,34,36,37,44,45,61,68,70,71,75,84–86] A modified Chinese version of the RosaQoL questionnaire (without two items from the original RosaQoL) was developed and initially validated.[86] The Impact Assessment for Rosacea Facial Redness (IA-RFR) and its modification the Impact Assessment for Rosacea Facial Bumps or Pimples (IA-RFB) were used in one study each.[82,85] Untitled study-specific instruments with HRQoL elements were used in six studies.[31,43,47,58,79,85] Detailed information on rosacea-specific HRQoL instruments are presented in Table 1.

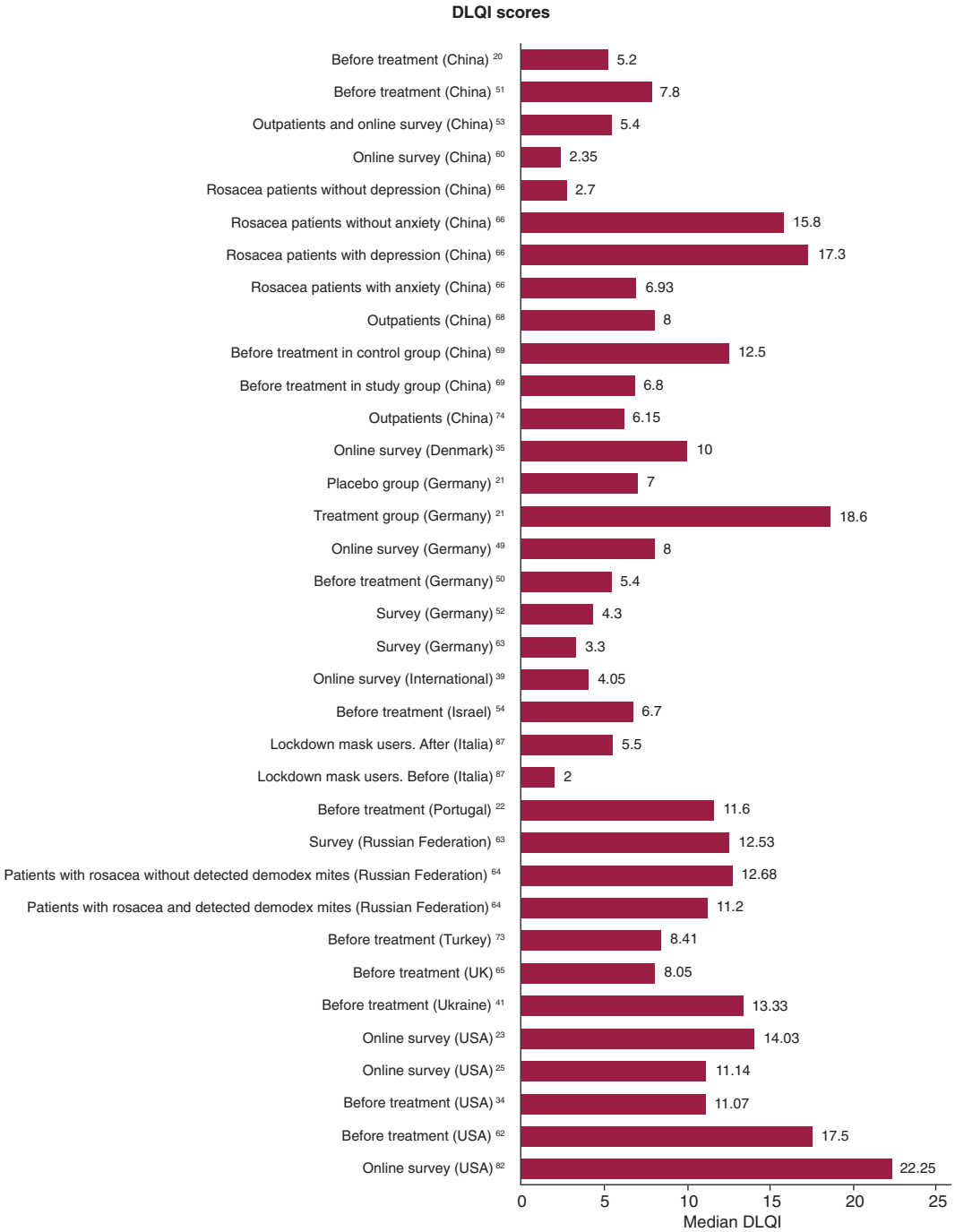

FIGURE 1 Mean DLQI scores of patients with rosacea from included studies.

TABLE 1 Rosacea-specific HRQoL instruments.

Title	Number of items	Scoring	Validation	Recall period
The rosacea-specific Quality of Life (RosaQoL)[71]	21 items Three subscales: symptoms, function and emotion	Each item has five response categories: never (1), rarely (2), sometimes (3), often (4) and all the time (5)	Reliability, responsiveness, discriminant validity	Past 4 weeks (?)
Modified RosaQoL (Chinese)[86]	19 items Three subscales: symptoms, function and emotion	Each item has five response categories: never (1), rarely (2), sometimes (3), often (4) and all the time (5)	Construct validity. Test–retest reliability. Convergent validity. Internal consistency.	Past 4 weeks (?)
Impact Assessment for Rosacea Facial Redness (IA-RFR)[82]	8 items Four domains (self-perception, emotional, grooming, and social)	5-point scale (0, no negative impact, to 4, high negative impact). The overall impact score for the IA-RFR was calculated as the mean of all individual item scores.	Test–retest reliability. Convergent validity. Internal consistency (Cronbach $a > 0.83$), with the exception of "personal grooming" (Cronbach $a = 0.018$).	Past week
The Impact Assessment for Rosacea Facial Bumps or Pimples (IA-RFB), an instrument adapted from the IA-RFR[85]	8 items	Individual items rated on a five-point adjectival scale from 0 to 4. Higher scores indicating higher negative impact. The overall impact score for the IA-RFB was calculated as the mean of all individual item scores.	No data on validation	Past week

HRQoL assessment in clinical trials

In rosacea patients treated for 4 months with either 0.25 mg/kg/day of oral isotretinoin or placebo Skindex scores indicated that isotretinoin-treated patients' HRQoL improved significantly more than placebo-treated patients.[39] Patients with rosacea who participated in a 16-week, randomized, single-blind pilot study of the effects of twice-daily monotherapy with 3% praziquantel ointment vs. placebo showed significant HRQoL improvement. Patients in the praziquantel group experienced a significantly higher improvement in comparison with those in the placebo group.[41] Two phase 3 multicenter, double-blind, parallel-group, placebo-controlled trials of identical design showed that at the end of the 12 weeks study significantly more patients in the ivermectin 1% group than in the vehicle reported no effect on their HRQoL, as measured by the DLQI. There was better improvement of RosaQoL in the ivermectin 1% groups.[37] A randomized, double-blind, vehicle-controlled, parallel-group, multicenter study showed significant HRQoL improvement measured by the DLQI and RosaQoL after use of azelaic acid foam 15% and placebo. A larger proportion of participants in the azelaic acid foam group achieved minimal clinically important difference (MCID) of the DLQI. Differences between treatment groups favoured the azelaic acid foam group for each of the following DLQI items: "embarrassment or self-consciousness"; "going shopping or looking after your home or garden"; "social or leisure activities"; "problems with your partner or any of your close friends or relatives".[34] In a randomized, double-blind, vehicle-controlled study both pimecrolimus and placebo showed equally significant improvement of patients' HRQoL.[21] Rosacea patients that received capsules containing 220 mg of zinc sulphate or placebo twice daily for 90 days showed no difference before and after between total RosaQoL scores and between RosaQoL domain scores, and also between the active treatment group and placebo group.[36] A randomized, double-blind, vehicle-controlled study of a topical formulation containing drug-free ultra-deformable phospholipid vesicles showed no significant changes in the total RosaQoL scores or RosaQoL function scores with either treatment. A significant reduction in RosaQoL emotion scores was recorded between baseline and week 1, and between weeks 4 and 5 in the active treatment group, but this did not differ significantly compared with the vehicle group.[33] A multicenter, randomized, investigator-blinded, parallel-group comparison of combination therapy ivermectin 1% cream and doxycycline 40-mg modified-release capsules, versus topical ivermectin 1% cream and placebo showed a decline of DLQI score from baseline, with the percentage of subjects experiencing no effect on their QoL ranging from less than 20% at baseline to higher than 65% at the last visit in both treatment arms. Mean changes in DLQI scores reached the MCID in both treatment arms.[48] In the study that compared skin care regimen with the use of placebo, the mean DLQI score decreased significantly in the treatment group but not significantly in the placebo group.[50]

A randomized, assessor-blinded clinical trial comparing oral doxycycline 40 mg and minocycline 100 mg for a 16-week period with 12 weeks of follow-up showed no significant differences in RosaQoL scores between treatment methods.[27] Oral doxycycline as monotherapy or in combination with topical therapy led to HRQoL improvement without significant differences between groups.[61] Treatment with ivermectin cream 1% once a day vs. metronidazole 0.75% showed an improved HRQoL in patients treated

with ivermectin from week 16 to week 52 measured by the DLQI and EQ-5D.[55] Post hoc subanalysis of patients with severe Investigator's Global Assessment Score grades from a previous study showed a greater reduction from baseline of the mean DLQI scores in the ivermectin group. After 16 and 52 weeks of treatment the proportion of subjects with a DLQI score of 0 or 1, representing no effect on QoL, was higher in the ivermectin group. Significantly more patients from the ivermectin group also reached the DLQI MCID.[67] Azelaic acid gel either alone or in combination with other standard treatment for rosacea showed significant improvement in all four components of the RosaQoL over the course of treatment, regardless of the type of therapy prescribed.[44] Comparison of oral clarithromycin 250 mg, twice a day for 6 weeks with clarithromycin combined with pulsed dye laser showed significant quimp improvement in both groups but greater improvement in the group with combined treatment regimen.[69]

In several open-label studies a significant improvement of QoL was reported after use of pulsed dye laser alone[62,65,78,79] and in combination with 1.064 nm neodymium-doped yttrium aluminium garnet laser[22] and non-ablative fractional 1440-nm laser therapy.[51] Intradermal botulinum toxin A injections improved quimp in patients with erythema telangiectasia rosacea with and without non-laser thermomechanical system.[20,54] After 12 weeks of open-label metronidazole topical gel 0.75% treatment all DLQI items except "work or study" and "problems with skin treatment" significantly improved.[28] Use of a skin care cream showed improvement of RosaQoL scores on day 29 in subjects with mild-to-moderate erythemato-telangiectatic rosacea.[70] Skin care regimens also significantly improved study-specific instrument total scores[47] or its separate items.[31] Surgical treatment of rhinophyma improved QoL, measured by an untitled study-specific questionnaire, in 67% of patients of whom 34% observed a significant improvement. No impact on HRQoL was reported in 33% of patients. None of the patients indicated a postoperative worsening of HRQoL.[26]

Comorbidities

DLQI scores were significantly correlated with Fibromyalgia Impact Questionnaire scores in the patients with rosacea.[80] Significantly higher DLQI, anxiety and depression scores were observed in the rosacea group compared to the control group. The total DLQI score of patients was positively related to anxiety and depression scores in the Hospital Anxiety and Depression Scale.[56] In the study by Chen et al.[66] the mean ± SD total DLQI score of patients who had anxiety and depression was 14.03 ± 7.51 and 13.34 ± 7.50, respectively, and 8.05 ± 6.35 and 8.41 ± 6.80 for the patients who did not have anxiety and those who did not have depression, respectively. In another study QoL measured by the EQ-5D-3L, anxiety, depression and sleep quality revealed no differences between rosacea patients and healthy controls.[76] According to the total Female Sexual Function Index (FSFI) scores, 49.4% of the rosacea patients had sexual dysfunction compared with 30.0% of the healthy controls. The total FSFI scores were negatively correlated with the values of the DLQI.[72] Patients with rosacea with detected demodex mites[64] and opisthorchiasis (a parasitic disease caused by Opisthorchis viverrini and Opisthorchis felineus)[32] had significantly higher quimp than rosacea patients without detected demodex mites and opisthorchiasis.

Comparison with other diseases

The DLQI in patients with rosacea was lower than in patients with atopic dermatitis and psoriasis.[52] Rosacea patients had higher levels of recorded symptoms and emotions than in patients with acne but lower levels of functioning.[38] Rosacea, vitiligo and acne-induced erythema patients reported significantly worse QoL compared to patients with lentigines or melasma, as evaluated by the DLQI. In this study rosacea patients reported the worst mental component scores of SF-36 and the scores were significantly worse than that of melasma patients.[40]

Different clinical types of rosacea

Rhinophyma had the worst QoL when compared to erythematotelangiectatic or papulopustular rosacea but there was no significant difference between erythematotelangiectatic and papulopustular rosacea.[45] Total DLQI scores showed that rosacea had negative impacts on HRQoL in respondents with mild to severe erythema, with greatest impacts observed in those with severe erythema.[82] Rosacea facial redness had a negative impact on all study participants for all domains of the IA-RFR questionnaire. In the papulopustular rosacea cohort, bumps and pimples had the greatest negative impact in the Emotional and Grooming domains of the IA-RFB questionnaire. Notably, in the papulopustular rosacea cohort, comparison of the overall impact of facial redness and of bumps and pimples indicated that the negative impact of facial redness was numerically greater. RosaQoL total scores and Emotion, Symptom and Functioning domain scores were similar within each cohort, with participants indicating responses of "rarely" to most of the questionnaire items. The papulopustular rosacea cohort had numerically higher mean scores than the erythematotelangiectatic rosacea cohort overall and in all RosaQoL domains, suggesting that papulopustular rosacea might have a slightly greater negative impact on QoL than erythematotelangiectatic rosacea. Results from the SF-36 questionnaire showed that both the erythematotelangiectatic rosacea and the papulopustular rosacea cohorts had lower scores than the United States general population both overall and for each individual domain within the questionnaire.[85] Total and individual domain IA-RFR scores (self-perception, emotional, grooming, social) showed a significant impact related to the severity of the erythema of rosacea, with an upward trend in both total

score and all individual domain scores with increasing levels of erythema severity.[82] RosaQoL emotional domain scores increased with erythema severity, but none of the SF-36 domain scores differed significantly between different levels of erythema severity.[75]

Miscellaneous

At the end of treatment among 1366 patients with rosacea, more 'clear' than 'almost clear' subjects had a clinically meaningful difference in DLQI and a final DLQI score of 0–1 indicating no effect on QoL.[30] One-month after a medical corrective make-up lesson, there was a significant DLQI score improvement in patients with rosacea. HRQoL significantly improved, independently of the initial score level of the DLQI.[57] DLQI scores significantly worsened after 6 weeks of COVID-19 quarantine. DLQI mean scores in rosacea patients increased from 7 to 10 (from 7 to 11 in papulopustular type of rosacea and from 6 to 9 in erythematotelangiectatic type).[87]

DISCUSSION

The DLQI was used in 66% of included publications (45/68). Rosacea-specific RosaQoL was used in 23.5% of included studies (16/68). The generic SF-36 was used in 7% of included publications (5/68). Other instruments were used only once or twice.

The DLQI is the most widely used HRQoL instrument in dermatology. The DLQI was reported to be sensitive to reflect rosacea severity grades.[82] In order to define when the change in a score becomes 'significant' to a patient, the MCID can be calculated. The MCID represents the smallest improvement considered worthwhile by a patient. The concept of an MCID is offered as the new standard for determining minimal effectiveness of a given treatment and for describing patient satisfaction in reference to that treatment.[88] In order to give clinically useful meaning to QoL scores, it is possible to define score band descriptors.[89] Detailed recommendations on treatment goals and changes of treatment approaches, based on a HRQoL questionnaire with a validated banding system (as for the DLQI), may be an important and promising approach.[90] For general inflammatory skin conditions, a change in DLQI score of at least four points is considered clinically important (MCID).[91] A DLQI of 0 or 1, corresponding to no effect on a patient's QoL, may be considered as an ideal treatment goal.[92,93] More 'clear' than 'almost clear' patients with rosacea reached the DLQI MCID and DLQI scores of 0 or 1, corresponding to no effect on patient's HRQoL.[30] The DLQI MCID has been used as an indicator of treatment efficacy in some clinical trials on rosacea.[34,48,55]

RosaQoL is the most frequently used rosacea-specific instrument: it was initially validated and used in several clinical trials and was shown to be more sensitive than generic instruments.[34,75] The modified Chinese version of the RosaQoL questionnaire (without two items from the original RosaQoL)[86] should be consider as a separate instrument and should not be used for direct comparison with scores from the original RosaQoL questionnaire and its various translations.

The IA-RFR and its modification of the IA-RFB have seldom been used. Having separate instruments for different clinical sub-types of a single disease may appear beneficial in theory but may be too complicated for real-life clinical use. Although modern dermatology practice pays attention to almost every aspect of patients' lives,[94] the basic aspects of people's lives that are affected by skin disease are largely the same, although with different emphases. The creation of a specific instrument for every skin condition would result in a confusing array of measures.[92]

Use of the generic EQ-5D-3L failed to detect differences between rosacea patients and healthy controls.[76] The rosacea-specific HRQoL instrument RosaQoL was more sensitive to erythema severity[75] and treatment changes[34] than the generic SF-36 and EQ-5D-5L instruments. However, in a study by Taieb et al.[55] EQ-5D scores showed greater improvement in patients treated with ivermectin cream once a day vs. metronidazole cream twice a day.

Oral isotretinoin,[39] topical azelaic acid,[34] ivermectin,[37] praziquantel[41] and skin care regimen[50] all showed a better effect on HRQoL improvement than placebo in clinical trials on rosacea. The significant HRQoL improvement in rosacea patients after use of topical placebo preparations recorded in most of the placebo-controlled trials[21,34,41] on the one hand, devalues the results of open uncontrolled studies and on another hand demonstrates a wider perspective of the use of medical cosmetics in rosacea. On another matter, a recent study demonstrated permeability barrier alterations in papulopustular rosacea and highlighted the importance of barrier repair.[95] Novel potential targets for rosacea treatment[96–98] may lead to new clinical trials that in turn may need reliable and sensitive HRQoL instruments as outcome measures. There is a need for new effective treatment methods of rosacea. There is a lack of well-designed clinical trials with sufficient number of patients and controls to confirm clinical efficacy and HRQoL improvement for many treatment methods that are currently used in patients with rosacea.

HRQoL in patients with rosacea was better than in patients with atopic dermatitis and in patients with psoriasis[52] but worse than in patients with melasma.[40] However, for the most reliable comparison, patients with different diseases should be assessed with different parameters (e.g. disease severity grading, age, sex).[99] Based on the analysis of the DLQI scores from those studies included in this review, it seems that HRQoL impairment is generally recorded as being higher in clinical settings than in online surveys and may significantly differ between countries. Similar results were previously reported for other skin diseases.[100–102] A promising approach is to develop HRQoL instruments simultaneously in different countries as in the case of the European

KIDSCREEN/DISABKIDS or the Infants and Toddlers Dermatology Quality of Life (InToDermQoL) and its epidermolysis bullosa-specific module.[92,103,104]

Protective mask use increased HRQoL impairment in patients with papulopustular and erythematotelangiectatic types of rosacea.[87] The full spectrum of equipment that is protective against COVID-19 may exacerbate rosacea and other skin diseases (acne, contact, allergic, seborrhoeic and atopic dermatitis, psoriasis and hand eczema).[105–110] There are recommendations from the EADV Task Force on Contact Dermatitis[111] and other professional organizations and from groups of experts on how to decrease the negative influence of protective equipment on patients' skin and to improve HRQoL.[112]

There are many reasons that HRQoL should be measured. The EADV TF on QoL and Patient-Oriented Outcomes has previously presented recommendations on the principles of HRQoL instrument selection and their use in different skin diseases.[100,112–126]

CONCLUSIONS

The EADV TFs on QoL and Patient-Oriented Outcomes and ARHS do not recommend the use of any generic instrument as a single method of HRQoL assessment in rosacea except where there is a need to compare quimp in rosacea patients with other non-dermatologic skin diseases or with healthy controls.

The EADV TFs on QoL and Patient-Oriented Outcomes and ARHS recommend the use of the dermatology-specific HRQoL instrument the DLQI and rosacea-specific HRQoL instrument RosaQoL in rosacea patients.

The DLQI MCID may be used as a marker of minimal clinical efficacy of treatment and an important treatment goal could be the DLQI score banding of 0 or 1, corresponding to 'no effect' on a patient's HRQoL. This information may be added to consensuses statements and guidelines for rosacea.

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None.

CONFLICT OF INTEREST STATEMENT

AYF is joint copyright owner of the DLQI. Cardiff University receives royalties from use of the DLQI: AYF receives a share under standard university policy. MS has performed consultancy services for which he received compensation from Pfizer, Sanofi, Regeneron, Lilly, Novartis, Galderma, Leo, Merck, Avon, Pierre-Fabre, L'Oreal, BMS, Maruho, Toray, Mitsubishi, Maruho, Kiniksa, ZymoGenetics, Almirall; he served on advisory board for Pfizer, Novartis, Galderma, Leo, Avon, Pierre-Fabre, L'Oreal, BMS, Maruho, Toray, Mitsubishi, Maruho, ZymoGenetics, Almirall; research (not associated with the submitted work) was supported by Pfizer, Novartis, Galderma, Leo, Avon, Pierre-Fabre, L'Oreal, BMS, Maruho, Toray, Mitsubishi, Maruho, ZymoGenetics, Almirall. AB had royalties for publications: Practical Psychodermatology wiley 2014 and Psychodeermatology in clinical practice Springer 2021; consulting fees from Abbvie, Almirall, Eli Lilly, Galderma, Novartis, Pfizer, UCB, Leo Pharma, Janssen, Sanofi; travel bursary from UCB and Abbvie. JCS received honorarium from AbbVie, Leo Pharma, Novartis, Sanofi-Genzyme, Vifor, Trevi, UCB, Janssen-Cilag, Eli-Lilly, Pierre-Fabre. CCZ had grants or contracts paid to employer, not associated with the submitted work from AbbVie, Astra Zeneca, Boehringer-Ingelheim, Celgene, GSK, Inflarx, Novartis, PPM, Relaxera, UCB; consulting fees, not associated with the submitted work from AccureAcne, Amgen, Almirall, Bayer, Biogen, Boehringer-Ingelheim, GSK/Stiefel, Incyte, Inflarx, Janssen, L'OREAL, Luvos, NAOS-BIODERMA, Novartis, Pierre Fabre, PPM, Regeneron, UCB, Viatris; lecture honoraria from AbbVie and UCB. Other authors reported no conflicts of interests.

DATA AVAILABILITY STATEMENT

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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