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Systematic Review

A systematic review of 454 randomized controlled trials using the Dermatology Life Quality Index: experience in 69 diseases and 43 countries

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Abstract

Background Over 29 years of clinical application, the Dermatology Life Quality Index (DLQI) has remained the most used patient-reported outcome (PRO) in dermatology due to its robustness, simplicity and ease of use.

Objectives To generate further evidence of the DLQI's utility in randomized controlled trials (RCTs) and to cover all diseases and interventions.

Methods The methodology followed PRISMA guidelines and included seven bibliographical databases, searching articles published from 1 January 1994 until 16 November 2021. Articles were reviewed independently by two assessors, and an adjudicator resolved any opinion differences.

Results Of 3220 screened publications, 454 articles meeting the eligibility criteria for inclusion, describing research on 198 190 patients, were analysed. DLQI scores were primary endpoints in 24 (5.3%) of studies. Most studies were of psoriasis (54.1%), although 69 different diseases were studied. Most study drugs were systemic (85.1%), with biologics comprising 55.9% of all pharmacological interventions. Topical treatments comprised 17.0% of total pharmacological interventions. Nonpharmacological interventions, mainly laser therapy and ultraviolet radiation treatment, comprised 12.2% of the total number of interventions. The majority of studies (63.7%) were multicentric, with trials conducted in at least 42 different countries; 40.2% were conducted in multiple countries. The minimal clinically importance difference (MCID) was reported in the analysis of 15.0% of studies, but only 1.3% considered full score meaning banding of the DLQI. Forty-seven (10.4%) of the studies investigated statistical correlation of the DLQI with clinical severity assessment or other PRO/quality of life tools; and 61–86% of studies had within-group scores differences greater than the MCID in 'active treatment arms'. The Jadad risk-of-bias scale showed that bias was generally low, as 91.8% of the studies had Jadad scores of ≥ 3; only 0.4% of studies showed a high risk of bias from randomization. Thirteen per cent had a high risk of bias from blinding and 10.1% had a high risk of bias from unknown outcomes of all participants in the studies. In 18.5% of the studies the authors declared that they followed an intention-to-treat protocol; imputation for missing DLQI data was used in 34.4% of studies.

Conclusions This systematic review provides a wealth of evidence of the use of the DLQI in clinical trials to inform researchers' and clinicians' decisions for its further use. Recommendations are also made for improving the reporting of data from future RCTs using the DLQI.

What is already known about this topic?

- The Dermatology Life Quality Index (DLQI) has been used in clinical practice and research for 29 years and continues to be the most frequently used patient-reported outcome (PRO) tool for dermatology.
- Previous systematic reviews of the DLQI have focused on psoriasis, biologics or validation of the DLQI.

What does this study add?

- This systematic review covers RCTs in 68 diseases and a wide range of interventions in 68 diseases.
- Details of study settings and countries, numbers of patients recruited, ages and DLQI score changes and assessment periods are summarized.

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- Studies where the minimal clinically important difference was achieved are identified and analysed, with a comprehensive analysis of bias.
- DLQI scores were the primary endpoints in 24 (5.3%) of the RCTs.
- The results inform future users of the DLQI, confirm the extensive experience of its use in dermatology RCTs and demonstrate the DLQI as the patient-reported outcome measure of choice.
- Evidence is provided to aid researchers and clinicians in the use of the DLQI in routine clinical practice.

The Dermatology Life Quality Index (DLQI) is the most widely used dermatology patient-reported outcome (PRO) measure in routine practice and clinical trials,[1,2] because of the simplicity of reporting and application, a single meaningful summary score, its ease of completion in 2 min,[3] comparability between studies and over time due to there being only a single version of the tool, and wide language accessibility.[4] It is embedded in national guidelines and disease registries in more than 45 countries and is available in 138 translations.[5] However, users of the DLQI need structured access to evidence concerning its use. This should include the score changes seen (and to be expected) in intervention studies, and the range of diseases where it has been of value as an outcome measure.

Previous reviews of the DLQI focused on its use in psoriasis,[6–8] biologics[7,9–11] or validation[2,12–14] and clinical results.[15] This systematic review is the first to investigate the use of the DLQI from its inception in 1994 to 2021 in randomized controlled trials (RCTs) covering all diseases and both pharmacological and nonpharmacological interventions, and whether DLQI outcomes show beneficial effects of the interventions by statistically significant or clinically significant improved scores.

Materials and methods

Data sources

The study followed the 2020 PRISMA guidelines and checklist for the reporting of systematic reviews.[16] The study protocol and detailed search strategy were registered in PROSPERO (CRD42021290587) and are provided in Table S1 (see Supporting Information).[17] The MEDLINE (Ovid), Embase, Cochrane Library, CINAHL (EBSCO), Web of Science, SCOPUS and PsycINFO databases were searched independently by two authors (J.V. and J.R.J.) from 1 January 1994 (DLQI creation) to 16 November 2021, and the results corroborated. Search terms included 'DLQI' and 'Dermatology Life Quality Index'. Database-specific 'article type/study type' keywords, language keywords (English) and age selection keywords were also used to search the required types of study to be included (e.g. medical subject heading terms for RCT). Duplicates were excluded.

Search strategy/selection

The eligibility criteria for included studies are provided in Table 1. The search results were imported into EndNote20®, to keep track of references.[18] Two authors (J.V. and J.R.J.) independently compared the study titles and abstracts retrieved by searches against the inclusion and exclusion criteria and examined full texts that potentially met the criteria but whose abstracts lacked sufficient information. Rejected studies were recorded with reasoning. A third author (F.M.A.) resolved and recorded any study selection disagreements. The PRISMA flowchart gives search counts for inclusions and exclusions, and reasons for exclusions (Figure 1).[16]

Studies that did not include new DLQI data and previously published analyses were excluded, as were publications with no DLQI data (but use mentioned) and studies that combined previously randomized treatment arms, so that only single-arm (no longer randomized) DLQI data were presented.

Outcome measures extracted

Information recorded included the study aim, disease studied, disease severity, systemic/topical drugs or other interventions, DLQI data collection duration, the research setting (e.g. trial, hospital, clinic or community), whether it was single

Table 1 Eligibility criteria for study selection

Variable	Inclusion	Exclusion
Patients	Adults ≥ 18 years, any gender, ethnicity, setting, country Any inflammatory and noninflammatory dermatological conditions	
Methods	Interventional RCTs published as full papers in peer-reviewed journals (including crossover trials and trials with OLEs if initial treatment was continued after study completion)	Not in English language
	Published between 1 January 1994 and 16 November 2021	'Grey' literature, including dissertations, conference abstracts, conference proceedings, reports, editorials, letters to editors, commentaries, protocols and reviews
	Interventions included any drug, therapeutic intervention and alternative medicines, e.g. acupuncture, fire needle, Chinese traditional (herbal) medicine, Ayurvedic, and educational or lifestyle interventions	
Outcomes	DLQI was primary or secondary outcome	No DLQI data provided

DLQI, Dermatology Life Quality Index; OLE, open-label extension; RCT, randomized controlled trial.

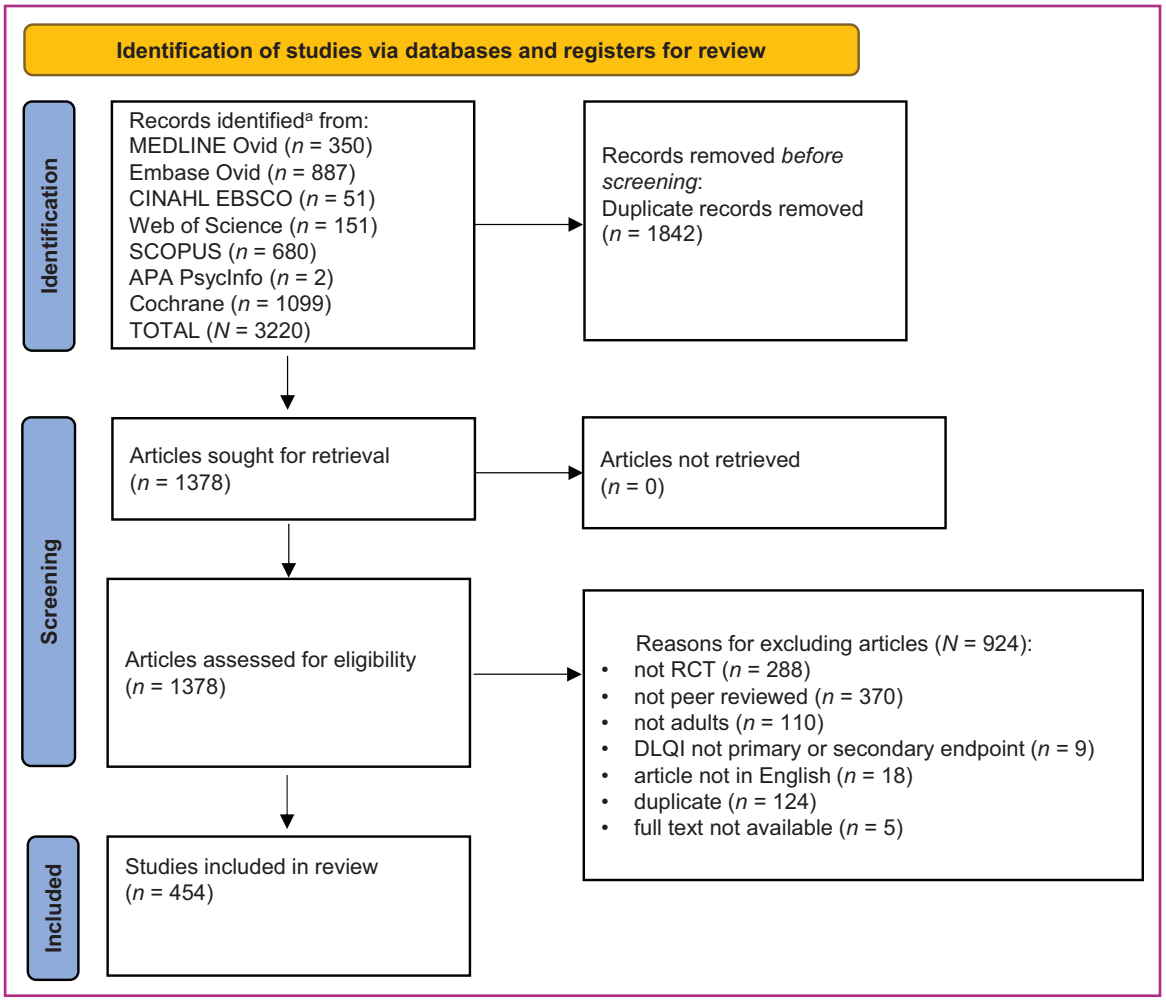

Figure 1 PRISMA flow diagram of article selection. DLQI, Dermatology Life Quality Index; RCT, randomized controlled trial. [a]Inclusion criteria applied by search engine, where applicable (i.e. RCT, adult, English language, journal article and peer reviewed).

or multicentred (number of sites), patient demographics (mean or median age, gender, ethnicity stated, country), the number of participants randomized to each intervention group, and whether DLQI score was a primary or secondary endpoint.

Data were extracted from up to three arms for each study: generally, a control or placebo/comparator arm and up to two intervention arms. Where studies reported multiple dosage strengths for the same drug, only data from the highest dosage arms were extracted. Therapeutic, nonpharmaceutical interventions were also recorded.

If studies did not report primary data but extracted data from previously published RCTs and performed post hoc-style analysis, data were obtained from the original RCTs, particularly on methodology and study design. Sometimes these elements and DLQI score data were supplied in supplementary data files, which were also consulted. Drug registrations (e.g. National Institutes of Health and ClinicalTrials.gov) were consulted for data on study protocols, particularly the location of studies and number of sites used, if not provided in the articles themselves.

Outcomes recorded that were related to the DLQI were total or median scores at baseline and study endpoint, or score differences (if given) for each arm. Evidence of statistically significant and/or clinically significant change [based on minimal clinically important difference (MCID)] were noted, and whether the DLQI was correlated with other PRO or quality of life (QoL) instruments. Using several PRO measures in combination and/or with disease severity scales in a study may achieve a better understanding of patient outcomes (e.g. capture difference aspects of QoL), or identify disease-specific, as well as general outcome aspects. Thus, other PRO tools or QoL measures used in combination with the DLQI were recorded to inform those seeking to use the DLQI (or one of the other outcome measures we captured).

Data extraction and synthesis

For data extraction, we followed the guidance of the Cochrane Handbook for Systematic Reviews of Interventions.[19] A REDCap database (a secure web application for building/managing online surveys and databases)[20–22] was created based on the Cochrane Handbook version 6.2 and the updated guidance recommendations.[19,23] J.V. and J.R.J. independently extracted data from the included publications to parallel REDCap database tables, and an adjudicator (F.M.A.) resolved any disagreements over data extraction. Missing data were noted in the data templates, but none was sufficiently important to contact the original authors

about. Data were extracted from REDCap to Microsoft EXCEL for analysis of totals, means and percentages.

The two reviewers independently assessed the risk of bias (quality) of the included studies, using the Jadad scale.[24,25] Assessment of bias was made at the individual study level. The domains included in bias analysis were bias arising from the randomization process, bias due to blinding and bias due to not accounting for all patients. The appropriate reporting of baseline (i.e. imbalances in study arms) and whether any corrections were made in the analysis to account for baseline imbalance were also noted.

Results

A total of 3220 studies were retrieved from the online database search. There were 1842 duplicates; the remaining 1378 underwent full-text assessment. Of these, 454 described research on 198 190 patients meeting the inclusion eligibility criteria (Figure 1). Published RCTs that used the DLQI are increasing exponentially, with 68 new studies reported in 2021 (Figure 2).

Study sites and settings

One-third ($n=154$; 33.9%) of the RCTs were single-site studies; the majority ($n=289$; 63.7%) were multicentre studies, with 11 (2.4%) study locations being indeterminate. Sixty-four (14.1%) trials were conducted at two sites, 15 (3.3%) at 3–5 sites, 12 (2.6%) at 6–10 sites, 19 (4.2%) at 11–20 sites, 72 (15.9%) at 21–50 sites, 54 (11.9%) at 51–200 sites, 36 (7.9%) at 101–200 sites and 6 (1.3%) at >200 sites.

Although the majority of studies ($n=253$; 55.7%) failed to report the study setting(s), 97 (21.4%) studies were conducted in hospitals, 30 (6.6%) in clinics, 22 (4.8%) in trial centres, 23 (5.1%) in outpatient/ambulatory care and 29 (6.4%) in other settings.

Trials were conducted in at least 43 different countries, although 177 (39.0%) reported multiple countries without listing details (Table S2; see Supporting Information). The majority of studies conducted in a single country were mainly in Europe (excluding the UK; $n=73$ studies, 16.1% of all studies), while 16 studies (3.5%) were conducted in the UK alone and 31 (6.8%) in the USA alone (Figure 3). The ethnicity of participants was explicitly mentioned in 207 (45.6%) studies.

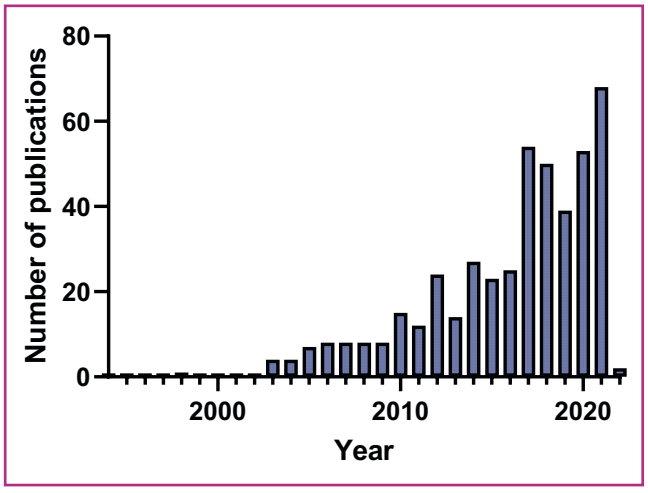

Figure 2 Number of randomized control trial studies that have used the Dermatology Life Quality Index over time.

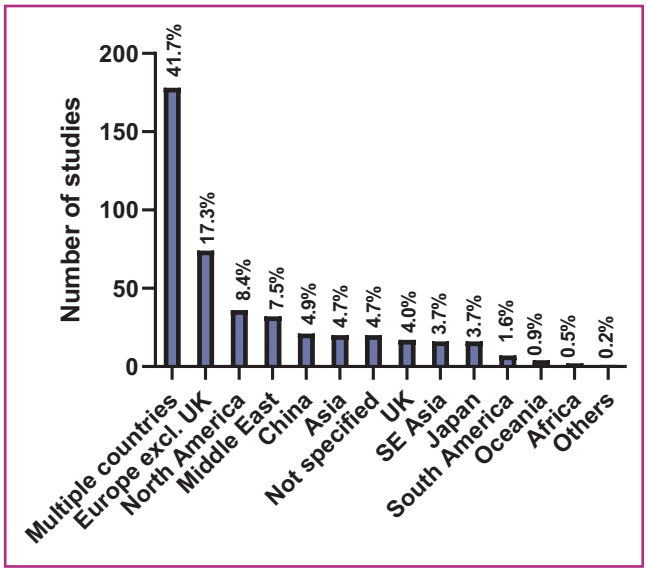

Figure 3 Location of the included randomized controlled trials. SE, South East.

The majority of studies ($n=412$; 90.7%) recruited both male and female participants; 14 (3.1%) recruited only males, 21 (4.6%) only females, 5 (1.1%) did not record participants' gender and 2 (0.4%) recorded a separate category for gender as 'other'. Studies that recruited only females concerned oligomenorrhoea and amenorrhoea in women with polycystic ovary syndrome (PCOS), hirsutism in PCOS, acne, striae distensae, systemic lupus erythematosus with permanent facial skin damage, axillary hyperhidrosis (three studies), plaque psoriasis, rosacea, breast cancer (three studies), xerosis in dialysis patients, hand–foot syndrome, vulvovaginal candidiasis, alopecia, cellulite, hyperpigmentation, periorbital pigmentation and melasma. Studies that recruited only males concerned hyperpigmented lips, plaque psoriasis (five studies), psoriatic arthritis, chronic skin lesions due to mustard gas (three studies), actinic keratosis, hidradenitis suppurativa and lichen sclerosus (two studies). The mean age of the participants (where given) of all study arms across all studies was 45 (range 22–81) years.

Disease profile

Sixty-eight different diseases were studied (Table 2).[26–479] Most studies were of psoriasis ($n=251$; 55.3%), followed by atopic dermatitis ($n=26$; 5.7%), urticaria ($n=20$; 4.4%), psoriatic arthritis ($n=17$, 3.7%), eczema/hand eczema ($n=16$; 3.5%) and hidradenitis suppurativa ($n=11$; 2.4%).

Overall, studies recruited patients with mild ($n=77/757$; 10.2%), moderate ($n=288/757$; 38.0%) and severe ($n=258/757$; 34.1%) disease, with 134/757 (17.7%) having unspecified disease severity. Psoriasis studies recruited patients with mild ($n=46/453$; 10.2%), moderate ($n=202/453$; 44.6%) and severe ($n=183/453$; 40.4%); 22 (4.9%) patients had unspecified disease severity.

Table 2 Diseases ($n=69$) studied in 454 studies included in this systematic review

Disease type	Disease	No. of studies (%)	Reference(s)
Inflammatory	Psoriasis	251 (55.3)	26–276
	AD	26 (5.7)	277–302
	Urticaria	20 (4.4)	303–322
	Eczema/hand eczema	16 (3.5)	203,323–338
	PsA	17 (3.7)	339–355
	HS	11 (2.4)	356–365,479
	Acne	10 (2.2)	366–375
	Rosacea	7 (1.5)	376–382
	Palmoplantar pustulosis	4 (0.9)	383–386
	Nail psoriasis	3 (0.7)	53,214,215
	Palmoplantar psoriasis	3 (0.7)	50,52,104
	Perioral dermatitis	2 (0.4)	387,388
	Psoriasis and PsA	2 (0.4)	94,117
	Seborrhoeic dermatitis	2 (0.4)	389,390
	Bullous disease	1 (0.2)	391
	HS and psoriasis	1 (0.2)	115
	Lichen planus	1 (0.2)	392
	Lupus erythematosus	1 (0.2)	393
	PV	1 (0.2)	394
	Psoriasis and AD	1 (0.2)	61
	Sarcoidosis	1 (0.2)	395
	Scleroderma skin fibrosis	1 (0.2)	396
Skin disorders caused by external agents	AK	4 (0.9)	397–400
	Radiodermatitis	3 (0.4)	401–403
	Chemotherapy-induced cutaneous symptoms	2 (0.4)	404,405
	Chronic actinic dermatitis and PLE	1 (0.2)	406
	Chronic sulfur mustard-induced cutaneous complications	1 (0.2)	407
	Contact dermatitis	1 (0.2)	408
	Disseminated superficial actinic porokeratosis	1 (0.2)	409
	Erlotinib-induced rash	1 (0.2)	410
	Parthenium dermatitis	1 (0.2)	411
	Photoaging	1 (0.2)	412
	PLE	1 (0.2)	413
	Scalp psoriasis	1 (0.2)	45
	Schnitzler syndrome	1 (0.2)	414
Benign and malignant tumours	Cutaneous leiomyomas	1 (0.2)	415
	Metastatic adenocarcinoma of the colon	1 (0.2)	416
	Metastatic colorectal cancer	1 (0.2)	417
	Oesophageal cancer	1 (0.2)	418
	Skin care in breast cancer	1 (0.2)	419
Infections and infestations	Viral warts	3 (0.7)	420–422
	Hand/foot syndrome	1 (0.2)	423
	Herpes zoster	1 (0.2)	424
	Leprosy	1 (0.2)	425
	Tinea cruris/corporis	1 (0.2)	426
	Tinea pedis	1 (0.2)	427
	Vaginal candidiasis	1 (0.2)	428
Other	Pruritus	10 (2.2)	429–438
	Hyperhidrosis	8 (1.7)	439–446
	Lichen sclerosus	3 (0.6)	447–449
	Alopecia	2 (0.4)	450,451
	Cellulitis	2 (0.4)	452,453
	Hirsutism in PCOS	2 (0.4)	454,455
	Hyperpigmentation	2 (0.4)	456,457
	Uraemic pruritus	2 (0.4)	458,459
	Vitiligo	2 (0.4)	460,461
	Xerosis	2 (0.4)	462,463
	Dry skin	1 (0.2)	464
	Erythrokeratoderma	1 (0.2)	465
	Leg ulcers	1 (0.2)	466
	Lymphoedema due to podoconiosis	1 (0.2)	467
	Melasma	1 (0.2)	468
	Oligomenorrhoea and amenorrhoea	1 (0.2)	469
	Palmar hyperhidrosis	1 (0.2)	470
	Periorbital pigmentation	1 (0.2)	471
	Prurigo nodularis (nonatopic)	1 (0.2)	472
	Pyoderma gangrenosum	1 (0.2)	473
	Stasis dermatitis	1 (0.2)	474
	Striae distensae	1 (0.2)	475
	'Any skin disease'	3 (0.7)	476–478

Some studies are mentioned more than once as they may have covered more than one disease. AD, atopic dermatitis; AK, actinic keratosis; HS, hidradenitis suppurativa; PCOS, polycystic ovarian syndrome; PLE, polymorphous light eruption; PsA, psoriatic arthritis; PV, pemphigus vulgaris.

Clinical severity and patient-reported outcomes assessment

Clinical severity assessment tools used included a mixture of dermatology-specific and generic measures. Psoriasis Area and Severity Index (PASI) was employed in 227 (50.0%) studies,[480] along with the Physicians' Global Assessment in 101 (22.2%),[481] Investigator Global Assessment in 53 (11.7%),[482] Nail Psoriasis Severity Index in 26 (5.7%),[483] Eczema Area and Severity Index in 20 (4.4%),[484] body surface area affected in 19 (4.2%)[485] and the SCOring Atopic Dermatitis (SCORAD) in 16 (3.5%). The PRO/QoL tools employed included the Medical Outcomes Study 36-item Short-Form health survey in 54 (11.9%),[486] the Hospital Anxiety and Depression Scale in 21 (4.6%)[487] and the EuroQol EQ-5D-5L in 17 (3.7%).[488] Many other clinical severity assessment and PRO/QoL tools were also used (Table S3; see Supporting Information).

Interventions using the Dermatology Life Quality Index in randomized clinical trials

Summary data – including disease; systemic, topical and nonmedicinal interventions; total number of participants randomized; mean or median age for each intervention arm; DLQI assessment period; clinical setting; most commonly used QoL tools; country of study; and Jadad score and domains from every included study – are provided in Table S4 (see Supporting Information).

Most study drugs were systemic ($n=452/529$; 85.4%), with biologics (growth factors, immunomodulators, monoclonal antibodies, and products derived from human blood and plasma) comprising 253/529 (47.8%) of all pharmacological interventions. Topical treatments used in 76 studies comprised 17.0% of the total pharmacological interventions (Table 3).

Thirty-two different biologics were used in the studies, the most common being etanercept, ustekinumab, adalimumab, secukinumab and ixekizumab for psoriasis and psoriatic arthritis (Table 4).

The dominant nonpharmacological interventions ($n=62$) were laser treatment ($n=10/62$; 16.1% of the total nonpharmacological interventions), followed by ultraviolet radiation (UVR) treatments ($n=6$; 9.7%), educational intervention ($n=5$; 8.1%), Chinese (traditional) herbal medicines ($n=4$; 6.5%), digital applications ($n=3$; 4.8%), low-energy diets ($n=2$; 3.2%), microneedle ($n=2$; 3.2%) and platelet-rich plasma ($n=2$; 3.2%), with a further 28 nonpharmacological interventions used in single studies (45.2%). Nonpharmacological interventions comprised only 12.2% of the total number of interventions ($n=591$).

Dermatology Life Quality Index scores

The DLQI was reported as a primary endpoint in 24 (5.3%) studies. Primary outcomes focused on clinical determinations of disease severity and progression, the most common being PASI. Generally, DLQI scores were reported as mean baseline and endpoint scores (from which we calculated differences), or as mean difference scores, or both. Mean DLQI baseline and endpoint scores were reported in arm 1 (control) in 26.0% of studies, arm 2 (intervention) in 27.5% of studies and arm 3 (intervention) in 11.0% of studies. Some studies reported only median scores.

Reported difference scores often differed from differences calculated from reported baseline and endpoint mean scores, having been calculated on a per-patient basis rather than as the difference of the group means. There was a trend to report differences when these were deemed significant; otherwise, baseline and endpoint scores were reported. Table 5 and Figure 4 give the DLQI score differences.[489]

Sixty-eight studies (15.0%) used MCID in their analysis, but only 6 (1.3%) considered full-score meaning banding of the DLQI scale.[490] Many studies also used the proportion of patients who achieved a final total DLQI score of 0 or 1 as an endpoint. In addition, 47 (10.4%) studies investigated statistical correlation of DLQI with other PRO/QoL tools.

Study bias

Randomization was mentioned in 444 studies (97.8%); however, the method was only appropriate in 317 studies (69.8%). Blinding was mentioned without further detail in 77 studies (17.0%), 290 (63.9%) described appropriate blinding, 21 (4.6%) used an inappropriate blinding method, blinding was not mentioned in the methodology sections of 38 studies (8.4%) and in 25 studies (5.5%) the design made blinding irrelevant. Baseline data demographics were described across the study arms in 418 studies (92.1%); adjustments were made during analysis for baseline imbalances in three (0.7%) and were not mentioned in 27 studies (5.9%). Figure 5 shows the distribution of Jadad scores and summarizes the risk of bias.

In 84 (18.5%) studies, the authors stated that they followed an intention-to-treat protocol. Imputation for missing DLQI data was used in 156 (34.4%) studies. Several imputation methods were used, including fixed imputation (last observation carried forward) ($n=76$; 16.7%), nonresponder imputation ($n=47$; 10.4%) and multiple imputation ($n=19$; 4.2%). Eighty-three studies (18.3%) used no imputation and the method was not stated in 151 (33.3%).

Discussion

This systematic review represents 27 years of the global implementation of the DLQI in RCTs, compiling a wealth of information in a one-stop resource. The global reach of the DLQI is demonstrated by its use in 43 different countries and by 40.2% of studies using it in multiple countries. Furthermore, 41.2% of studies were conducted at >10 sites; only 33.9% were conducted at a single site.

The number of studies that assessed systemic drugs ($n=307/454$; 67.6%) is a result of the large number of new biologics ($n=307/529$; 58.0% of total drugs assessed) being developed, mainly for the treatment of psoriasis, psoriatic arthritis, atopic dermatitis, urticaria and hidradenitis suppurativa. Topical treatments only comprised 17.6% ($n=93$ studies) of the pharmacological interventions studied. A recent systematic review has confirmed that biologics can significantly improve DLQI scores in patients with psoriasis.[9] However, 69 different diseases were studied, emphasizing the generic strengths of the DLQI as a dermatology-specific

Table 3 Pharmacological interventions ($n=529$) by drug type in 454 randomized controlled trials included in the systematic review

Systemic intervention			Topical intervention		
	No. of uses (%)[a]	Reference(s)		No. of uses (%)[a]	Reference(s)
Biologics	253 (55.7)	See Table 4			
Analgesics	4 (0.8)	424,430,458,459			
Antidiabetics	4 (0.8)	79,93,136,150			
Antihistamine	11 (2.1)	305,309,311,312,315,316,320,321,458			
Antiviral (valaciclovir)	1 (0.2)	424			
DMARD	2 (0.4)	252,350			
Fusion toxin (DAB389IL-2)	1 (0.2)	43			
Muscarinic agonist (pilocarpine)	1 (0.2)	443			
Selective NK1R antagonist (serlopitant)	1 (0.2)	438			
PDE4 inhibitor (apremilast)	8 (1.5)	50, 134,183,201,202,276,362			
Antidepressant	2 (0.4)	430,459	Antidepressant (doxepin)	1 (0.2)	433
Selective CRTh2 receptor antagonist (AZD1981)	1 (0.2)	322	Antifungal	6 (1.1)	389,426–428
Anti-infectives	5 (1.0)	304,380,391,405,410	Anti-infectives	9 (1.7)	366,369,374,376,377,379,380,382,388
Antimuscarinic agent (methantheline bromide)	1 (0.2)	442	Antimuscarinic agent (oxybutynin)	1 (0.2)	443
Corticosteroid (prednisolone)	3 (0.6)	333,391,473	Corticosteroid	27 (5.1)	68,95,119,121,144–146, 163,185,188,235,242,324,329,331, 334,338,403,407,416,429,433,435,472,474
EGFR TKi (icotinib)	1 (0.2)	396	EGFR TKi (icotinib)	1 (0.2)	272
			Humectant (hyaluronic acid)	1 (0.2)	400
Immunosuppressants	20 (3.8)	39,48,66,88,113,134–136, 186,199,217,221,260,268,269,287, 333,394,473	Immunosuppressants	4 (0.8)	387,390,437,472
JAKi	16 (3.0)	26,41,51,63,86,110,155,178,251,296,299,302,347	JAKi (tofacitinib)	1 (0.2)	176
Muscarinic antagonist (oxybutynin)	1 (0.2)	443	Muscarinic antagonist (oxybutynin)	1 (0.2)	446
Natural products and supplements	7 (1.3)	221,271,282,348,375,424,434	Natural products and supplements	4 (0.8)	151,398,404,451
NSAID	6 (1.1)	190,199,229,240,241	NSAID	2 (0.4)	248,400
Retinoids	9 (1.7)	150,225,271,368,373,399,412,449	Retinoids	3 (0.6)	95,235,412
Statins	4 (0.8)	28,69,121,466	Statins (atorvastatin)	1 (0.2)	331
Tyrosine kinase 2 inhibitors	2 (0.4)	236,410	TRPM8 agonists (menthoxypropanediol)	1 (0.2)	436
Vitamin D3/vitamin D derivatives	3 (0.6)	119,120,411	Vitamin D3/vitamin D derivatives	9 (1.7)	144,145,150,185,188,189,263,351
Others	7 (1.3)	357,415,421,441,445	Others	5 (1.0)	242,367,457,465,470

CRTh2, prostaglandin D2 receptor 2; DMARD, disease-modifying antirheumatic drug; EGFR, epidermal growth factor receptor; JAKi, Janus kinase inhibitor; NK1R, neurokinin 1 receptor; NSAID, nonsteroidal anti-inflammatory drug; PDE4, phosphodiesterase-4; TKI, tyrosine kinase inhibitor; TRPM8, transient receptor potential cation channel subfamily M member 8. [a]Number of uses refers to the number of studies that used a particular drug of that type. Some studies used multiple drugs of that type (e.g. both bilastine and levocetirizine as antihistamines in the same study), so the number of references may not match the number of uses.

instrument and a broader interest within the research community.

Nonpharmacological interventions ($n=62$; 10.5% of total interventions) were mainly laser therapy ($n=10$; 16.1%) and UVR treatment ($n=6$; 9.7%), as well as various nonpharmacological interventions used in single studies (45.2% of nonpharmacological interventions). The low number of traditional medicine interventions may be due to the required complexity of clinical trials; novel laser or UVR treatments have commercialization potential, whereas widely used traditional medicines cannot receive patent protection.

The results showed that 26.0%, 27.5% and 11.0% of studies reported DLQI score differences for arms 1, 2 and 3, respectively. In addition, in 57.9%, 63.2% and 24.4% of studies of arms 1, 2 and 3, respectively, a score difference could be calculated from provided baseline and end-of-study DLQI scores. Furthermore, 61–86% of studies in the 'active arms' had within-group score differences greater than the MCID,[489] representing differences for the control/placebo arm of >33%. Such a result might be expected as studies usually included only more severely affected patients (most often in psoriasis, screened using the PASI).

Risk of bias was generally low; 91.8% of studies had Jadad scores of ≥3, 0.4% of studies showed a high risk from randomization, only 13.4% had a high risk of bias from blinding and 10.1% had a high risk due to the unknown fate of all participants. Although it might be expected that older studies had more potential for bias, this review showed no correlation between publication date and Jadad score (Spearman rank $r^2=0.028$). Allocation concealment,[491] although now considered an important element in study bias, was barely mentioned. Most studies (92.1%) checked

Table 4 Interventions ($n=529$) using biologics in 454 randomized controlled trials included in the systematic review

Biologic	No. of uses (% of total pharmacological interventions)	Disease(s) studied	Reference(s)
Etanercept	42 (7.9)	HS, pruritus, psoriasis	27,41,46,71,74,83,91,94,98,108,109,112,114,117,124,130–132,141,152,154,160,162,168,175,182,184,195,201,202,208,213,226,232,238,247,251,255,267,269,356,432
Ustekinumab	37 (7.0)	AD, psoriasis	39,40,42,44,52,55,58,59,70,92,102,111,114,118,127,130,131,137–140,143,156,167,177,186,194,196,209,212,237,245,246,259,275,291,343,352
Adalimumab	36 (6.8)	Cutaneous sarcoidosis, HS, psoriasis, PsA	32,33,56,64,70,85,107,126,128,149,157,164,169,179,182,186,191–193,197,198,200,203,204,217,218,227,257,340,341,347,351,360,365,395,479
Secukinumab	31 (5.9)	PPP, psoriasis, PsA	27,30,38,42,44,58,59,74,80,92,103,104,114,117,129–131,165,171,194,205,210,215,229,232,237,256,349,354,383
Ixekizumab	23 (4.4)	Psoriasis, PsA	30,53,55,97,108,112,124,141,147,148,184,195,196,199,207,209,220,261,266,267,274,341,342
Guselkumab	15 (2.8)	PPP, psoriasis	32,56,107,140,149,170,197,198,200,203,204,240,384,386
Brodalumab	11 (2.1)	Psoriasis	99,137,138,156,166,174,177,190,224,254,259
Infliximab	8 (1.5)	Psoriasis	48,77,81,82,206,243,244,262
Dupilumab	6 (1.1)	AD	277,279,283,293,294,297
Efalizumab	4 (0.8)	Psoriasis	101,158,159,172
Risankizumab	4 (0.8)	Psoriasis	40,102,180,241
Alefacept	3 (0.6)	Psoriasis	75,84,87
Bimekizumab	3 (0.6)	HS, psoriasis	57,257,479
Omalizumab	3 (0.6)	Urticaria	317–319
Tralokinumab	3 (0.6)	AD	292,300,301
Abatacept	2 (0.4)	PsA	346,353
Brikinumab	2 (0.4)	Psoriasis	100,181
Canakinumab	2 (0.4)	Schnitzler syndrome, urticaria	314,414
CPZ	2 (0.4)	Psoriasis	249,250
Cetuximab	2 (0.4)	Oesophageal cancer, radiodermatitis of head and neck cancer	401,418
Lebrikizumab	2 (0.4)	AD	284,295
Tildrakizumab	2 (0.4)	Psoriasis	60,208
Bermekimab	1 (0.2)	HS	358
Clazakizumab	1 (0.2)	PsA	345
Cytokines (IL-4, IL-10, IL-11)	1 (0.2)	Psoriasis	219
Golimumab	1 (0.2)	PsA	344
IFN-γ	1 (0.2)	Chronic sulfur mustard-induced cutaneous complications	407
Itolizumab	1 (0.2)	Psoriasis	133
Mirikizumab	1 (0.2)	Psoriasis	211
Nemolizumab	1 (0.2)	AD	290
Panitumumab	1 (0.2)	Metastatic colorectal cancer	417
Rituximab	1 (0.2)	PV	394
Total	253 (90)		

AD, atopic dermatitis; CPZ, certolizumab pegol; HS, hidradenitis suppurativa; IFN, interferon; IL, interleukin; PPP, palmoplantar pustulosis; PsA, psoriatic arthritis; PV, pemphigus vulgaris.AD, atopic dermatitis; CPZ, certolizumab pegol; HS, hidradenitis suppurativa; IFN, interferon; IL, interleukin; PPP, palmoplantar pustulosis; PsA, psoriatic arthritis; PV, pemphigus vulgaris.

Table 5 Dermatology Life Quality Index (DLQI) score differences across 454 randomized controlled trials included in the systematic review

	Arm 1 difference[a]	Arm 2 difference[a]	Arm 3 difference[a]	Arm 1 calculated difference[b]	Arm 2 calculated difference[b]	Arm 3 calculated difference[b]
No. of studies with DLQI difference scores	118	125	50	263	287	111
% studies with DLQI difference scores	26.0	27.5	11.0	57.9	63.2	24.4
No. of studies with no data available	336	320	404	191	167	343
No. of studies with score difference > MCID of 4.0[489]	33	76	31	181	219	95
No. of studies with score difference < MCID of 4.0[489]	84	48	17	82	68	16
% of studies with score difference > MCID of 4.0[489]	28.2	61.3	64.6	68.8	76.3	85.6

MCID, minimal clinically important difference. [a]Arm 1, arm 2 and arm 3 differences are published DLQI differences as reported. [b]Arm 1, arm 2 and arm 3 calculated differences were determined from differences between reported baseline and endpoint DLQI scores, where reported.

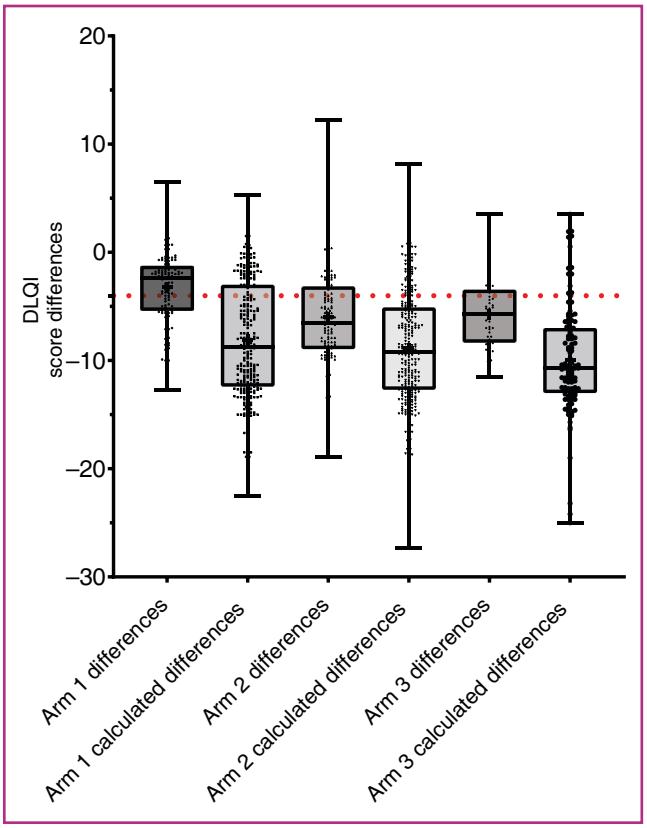

Figure 4 Published and calculated Dermatology Life Quality Index (DLQI) score differences for all interventions (n=469). Arm 1, arm 2 and arm 3 differences are published DLQI differences as reported. Arm 1, arm 2 and arm 3 calculated differences were determined from differences between reported baseline and endpoint DLQI scores, where reported. Arm 1 is generally a control, with arms 2 and 3 being increasing dosages of the same drug or greater potency of alternative treatments (i.e. expectedly increasingly more effective treatments). Whiskers show maximum and minimum values. Bars show means. Dotted horizonal line shows the DLQI minimal clinically important difference.

for baseline equivalence between study arms, although older studies often neglected to do so and few indicated any baseline correction being performed during analysis.

The assessment of bias was made at the level of an individual result, rather than at a study or outcome level. The domains included in the risk-of-bias analysis were bias arising from the randomization process, bias due to blinding and bias due to not accounting for all patients in the trial. The appropriate reporting of baseline (i.e. imbalances in study arms) and whether any corrections were made in the analysis to account for baseline imbalance were also noted.

This systematic review had some limitations. Although only articles written in English were reviewed, they often reported on RCTs carried out using different translations of the DLQI. The reports generally amalgamated DLQI data and did not report score distribution for each language. It would be of interest to analyse the raw data, to identify possible interpretation differences.

We only examined studies with extractable DLQI data and did not capture all pharmacological interventions for complex studies involving multiple arms (>3), pretreatments, multiple phases, crossover studies and so on, and those that separately analysed multiple RCTs within the one study. However, all other data in our capture template for these studies were obtained. We did not capture all dosage regimens or administration routes, this being beyond the study's scope. Limited data were available to describe the study settings in most publications. Some studies published invalid data, for example scores greater than the maximum possible for the DLQI and these data were therefore not included.

Patients may respond 'not relevant' to DLQI questions for a variety of reasons. The exceptional circumstances of the COVID-19 pandemic may have resulted in greater use of this response, as the pandemic restricted many aspects of people's lives. However, considering the time from data collection to publication of a RCT, it is unlikely that any publications included in our study were based on trials conducted during the pandemic.

The DLQI has been widely used in dermatology clinical trials due to its robustness, simplicity and ease of use.[3] The DLQI developers constantly engage in enhancing the utility of the DLQI, and this review of its use in clinical trials is the most comprehensive to date. This review allows structured access to inform future users of the DLQI, confirms the extensive experience of the DLQI in RCTs in dermatology and demonstrates the utility of the DLQI as the PRO measure of choice over the last 20 years. The use of the DLQI as a primary outcome measure in 24 RCTs represents

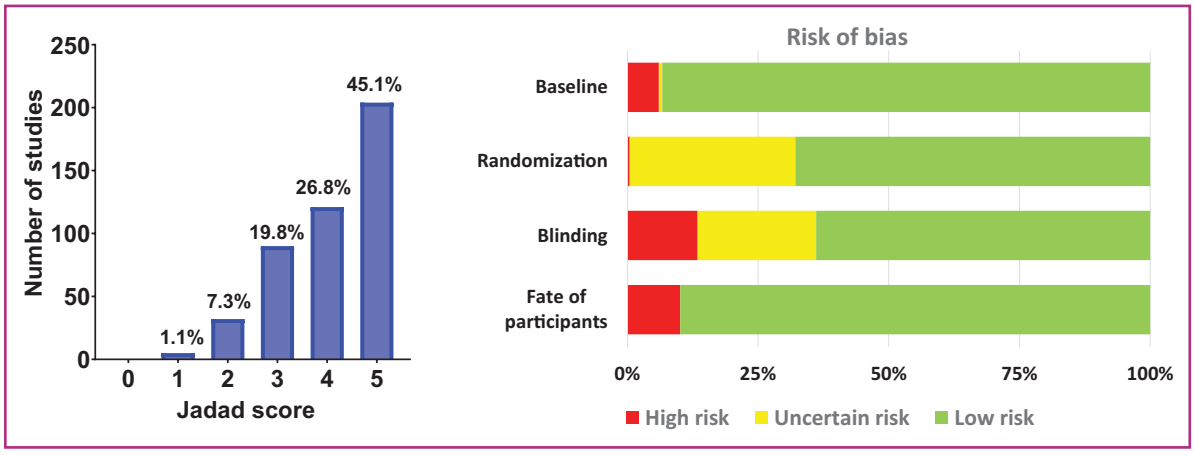

Figure 5 Distribution of Jadad scores and risk of bias.

a paradigm shift in the status accorded to PROs in dermatology. Traditionally researchers used only sign/symptom severity measures as primary endpoints in RCT protocols. PROs were secondary endpoints, despite more extensive validation. The use of the DLQI as a primary endpoint, with PROs' precision similar to those of clinical/biomedical parameters, indicates growing confidence in giving PROs such status to be used for labelling in marketing authorization of new health technologies, as well as an aid to treatment decision-making.

Although the majority of RCTs included in this study reported data in appropriate detail, some publications had deficiencies, particularly reporting DLQI data. The following recommendations are made: (i) publications reporting clinicals trials should include details of study settings, gender, ethnicity, and mean and range participant age; (ii) sample size calculation, randomization and blinding methods, including allocation concealment, should be clearly stated, and correct baseline characteristics and comparisons of patients presented; (iii) patient numbers should be reported, whether an intention-to-treat or per-protocol analysis was implemented, and the method(s) used for the imputation of missing data; (iv) DLQI baseline and final data collection point mean and median scores with interquartile range, as well as score differences, should be published, even when the DLQI outcome may be the percentage of 0 or 1 scores at the final data collection point – the presentation of percentage score changes should be discouraged; (v) authors should analyse their DLQI data using MCID and use score severity bands to interpret results.

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Conflicts of interest

J.V. has participated in an Advisory Board for Amgen, has received payment or honoraria from L'Oréal and support from UCB Pharma for attending meetings. F.M.A. has received honoraria from AbbVie, Janssen, LEO Pharma, Lilly Pharmaceuticals, L'Oréal, Novartis and UCB. His department receives income from royalties from the Dermatology Life Quality Index (DLQI) and related instruments. J.R.I. receives a stipend as Editor-in-Chief of the *British Journal of Dermatology* and an authorship honorarium from UpToDate. He is a consultant for Boehringer Ingelheim, ChemoCentryx, Citryll, Novartis and UCB Pharma, and has served on advisory boards for Insmed, Kymera Therapeutics and Viela Bio. He is co-copyright holder of HiSQOL, Investigator Global Assessment and Patient Global Assessment instruments for hidradenitis suppurativa. His department receives income from royalties from the DLQI and related instruments. S.S. has received an unrestricted educational grant from GSK, is a consultant for Novo Nordisk and produces educational materials for AbbVie. A.Y.F. is joint copyright owner of the DLQI. Cardiff University receives royalties from some use of the DLQI; A.Y.F. receives a proportion of these under standard university policy.

J.R.J. and R.K.S. report no conflicts of interest.

Data availability

All data are incorporated into the article and the Supporting Information.

Ethics statement

Not applicable.

Supporting Information

Additional Supporting Information may be found in the online version of this article at the publisher's website.

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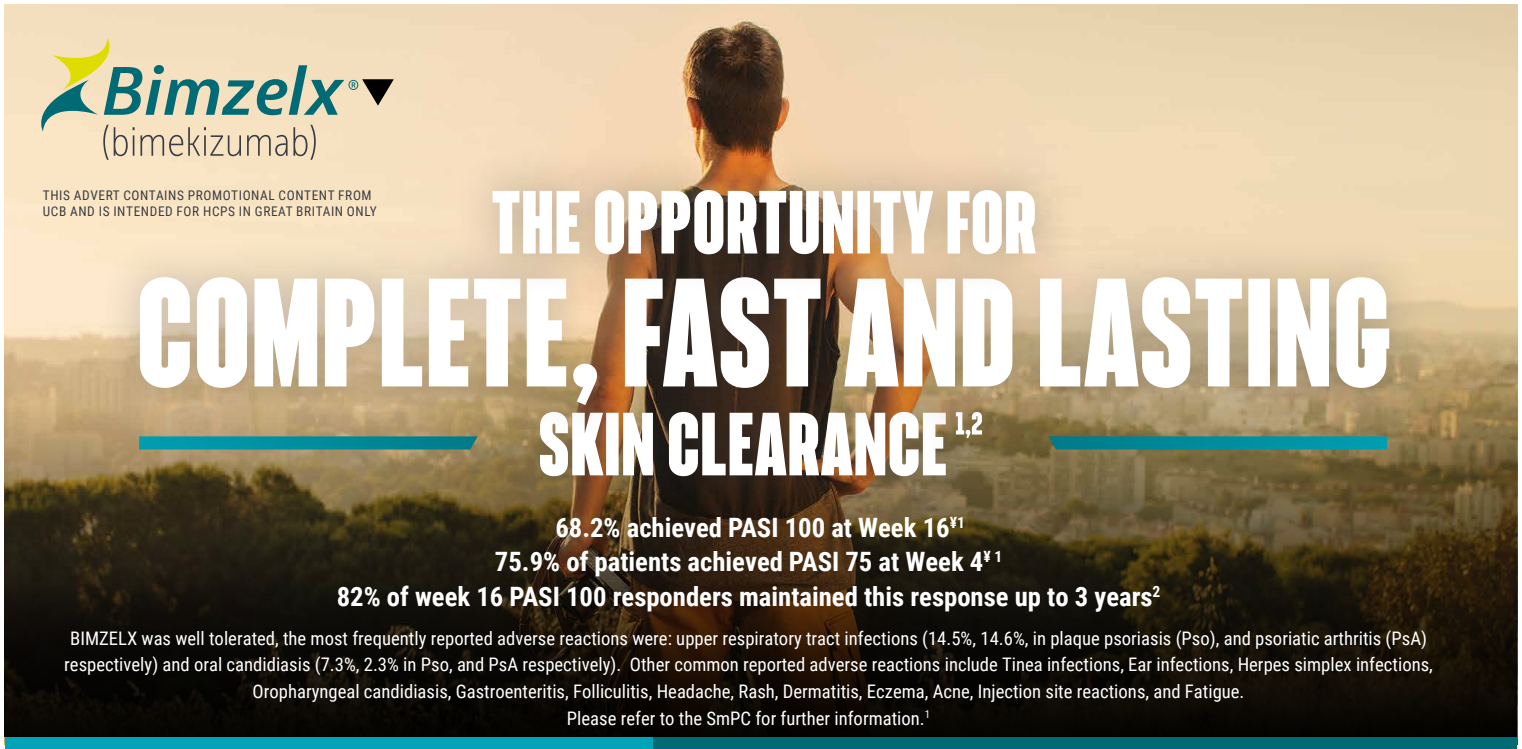
Bimzelx® ▼
(bimekizumab)

THIS ADVERT CONTAINS PROMOTIONAL CONTENT FROM UCB AND IS INTENDED FOR HCPS IN GREAT BRITAIN ONLY



THE OPPORTUNITY FOR COMPLETE, FAST AND LASTING SKIN CLEARANCE[1,2]

68.2% achieved PASI 100 at Week 16[¥1]
75.9% of patients achieved PASI 75 at Week 4[¥1]
82% of week 16 PASI 100 responders maintained this response up to 3 years[2]

BIMZELX was well tolerated, the most frequently reported adverse reactions were: upper respiratory tract infections (14.5%, 14.6%, in plaque psoriasis (Pso), and psoriatic arthritis (PsA) respectively) and oral candidiasis (7.3%, 2.3% in Pso, and PsA respectively). Other common reported adverse reactions include Tinea infections, Ear infections, Herpes simplex infections, Oropharyngeal candidiasis, Gastroenteritis, Folliculitis, Headache, Rash, Dermatitis, Eczema, Acne, Injection site reactions, and Fatigue.
Please refer to the SmPC for further information.[1]

Challenge expectations in plaque psoriasis[1,2]

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Footnotes: ¥co-primary endpoints PASI 90 and IGA 0/1 at Week 16

Pso - Plaque Psoriais; PsA - Psoriatic Athritis

BIMZELX® (Bimekizumab) is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. Bimzelx, alone or in combination with methotrexate, is indicated for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs). Please refer to the SmPC for further information.[1]

PRESCRIBING INFORMATION FOR HCP'S IN GREAT BRITAIN

BIMZELX® ▼ (Bimekizumab) is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy; and for active psoriasis arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs), alone or in combination with methotrexate.[1] (Please consult the Summary of Product Characteristics (SmPC) before prescribing).

Active Ingredient: Bimekizumab – solution for injection in pre-filled syringe or pre-filled pen: *160 mg of bimekizumab in 1 mL of solution (160mg/mL).* **Indications:** Moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. Alone or in combination with methotrexate, for active psoriatic arthritis in adults who have had an inadequate response or intolerant to one or more disease-modifying antirheumatic drugs (DMARDs). Adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) who have responded inadequately or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs). Adults with active ankylosing spondylitis who have responded inadequately or are intolerant to conventional therapy. **Dosage and Administration:** Should be initiated and supervised by a physician experienced in the diagnosis and treatment of conditions for which Bimzelx is indicated. **Recommended dose:** Plaque Psoriasis: 320 mg (given as two subcutaneous injections of 160 mg each) at week 0, 4, 8, 12, 16 and every 8 weeks thereafter. Psoriatic arthritis: 160 mg (given as 1 subcutaneous injection of 160 mg) every 4 weeks. For psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis, the recommended dose is the same as for plaque psoriasis. After 16 weeks, regular assessment of efficacy is recommended and if a sufficient clinical response in joints cannot be maintained, a switch to 160 mg every 4 weeks can be considered. Axial spondyloarthritis (nr-axSpA and AS): 160 mg (given as 1 subcutaneous injection) every 4 weeks. For patients with plaque psoriasis (including psoriatic arthritis with coexistent moderate to severe psoriasis) and a body weight ≥ 120 kg who did not achieve complete skin clearance at week 16, 320 mg every 4 weeks after week 16 may further improve treatment response. Consider discontinuing if no improvement by 16 weeks of treatment. Renal or hepatic impairment: No dose adjustment needed. Elderly: No dose adjustment needed. Administer by subcutaneous injection to thigh, abdomen or upper arm. Rotate injection sites and do not inject into psoriatic plaques or skin that is tender, bruised, erythematous or indurated. Do not shake pre-filled syringe or pre-filled pen. Patients may be trained to self-inject. **Contraindications:** Hypersensitivity to bimekizumab or any excipient; Clinically important active infections (e.g. active tuberculosis). **Warnings and Precautions:** Record name and batch number of administered product. *Infection:* Bimekizumab may increase the risk of infections e.g. upper respiratory tract infections, oral candidiasis. Caution when considering use in patients with a chronic infection or a history of recurrent infection. Must not be initiated if any clinically important active infection until infection resolves or is adequately treated. Advise patients to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops an infection, the patient should be carefully monitored. If the infection becomes serious or is not responding to standard therapy do not administer bimekizumab until infection resolves. *TB:* Evaluate for TB infection prior to initiating bimekizumab – do not give if active TB. While on bimekizumab, monitor for signs and symptoms of active TB. Consider anti-TB therapy prior to bimekizumab initiation if past history of latent or active TB in whom adequate treatment course cannot be confirmed. *Inflammatory bowel disease:* Bimekizumab is not recommended in patients with inflammatory bowel disease. Cases of new or exacerbations of inflammatory bowel disease have been reported. If inflammatory bowel disease signs/symptoms develop or patient experiences exacerbation of pre-existing inflammatory bowel disease, discontinue bimekizumab and initiate medical management. *Hypersensitivity:* Serious hypersensitivity reactions including anaphylactic reactions have been observed with IL-17 inhibitors. If a serious hypersensitivity reaction occurs, discontinue immediately and treat. *Vaccinations:* Complete all age appropriate immunisations prior to bimekizumab initiation. Do not give live vaccines to bimekizumab patients. Patients may receive inactivated or non-live vaccinations. **Interactions:** A clinically relevant effect on CYP450 substrates with a narrow therapeutic index in which the dose is individually adjusted e.g. warfarin, cannot be excluded. Therapeutic monitoring should be considered. **Fertility, pregnancy and lactation:** Women of child-bearing potential should use an effective method of contraception during treatment and for at least 17 weeks after treatment. Avoid use of bimekizumab during pregnancy. It is unknown whether bimekizumab is excreted in human milk, hence a risk to the newborn/infant cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Bimzelx therapy. No data available on human fertility. **Driving and use of machines:** No or negligible influence on ability to drive and use machines. **Adverse Effects:** Refer to SmPC for full information. Very Common *(≥ 1/10):* upper respiratory tract infection; Common *(≥ 1/100 to < 1/10):* oral candidiasis, tinea infections, ear infections, herpes simplex infections, oropharyngeal candidiasis, gastroenteritis, folliculitis; headache, rash, dermatitis and eczema, acne, injection site reactions, fatigue; Uncommon *(≥ 1/1,000 to < 1/100):* mucosal and cutaneous candidiasis (including oesophageal candidiasis), conjunctivitis, neutropenia, inflammatory bowel disease. Storage precautions: Store in a refrigerator (2°C – 8°C), do not freeze. Keep in outer carton to protect from light. Bimzelx can be kept at up to 25°C for a single period of maximum 25 days with protection from light. Product should be discarded after this period or by the expiry date, whichever occurs first.

Legal Category: POM

Marketing Authorisation Numbers: PLGB 00039/0802 (Pre-filled Syringe), PLGB 00039/0803 (Pre-filled Pen).

UK NHS Costs: £2,443 per pack of 2 pre-filled syringes or pens of 160 mg each.

Marketing Authorisation Holder: UCB Pharma Ltd, 208 Bath Road, Slough, Berkshire, SL1 3WE, United Kingdom.

Further information is available from: UCB Pharma Ltd, 208 Bath Road, Slough, Berkshire, SL1 3WE. Tel: 0800 2793177 Email: ucbcares.uk@ucb.com

Date of Revision: August 2023 (GB-P-BK-AS-2300047)

Bimzelx is a registered trademark.

Adverse events should be reported. Reporting forms and information can be found at http://www.mhra.gov.uk/yellowcard. Adverse events should also be reported to UCB Pharma Ltd at ucbcares.uk@ucb.com or 0800 2793177.

References: 1. BIMZELX (bimekizumab) SmPC. Available at: https://www.medicines.org.uk/emc/product/12834/smpc. Accessed September 2023 **2.** Strober et al. [BE BRIGHT open label extension] Br J Dermatol. 2023. 188(6): 749-759.

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