A systematic review of 457 randomised controlled trials using the Dermatology Life Quality Index: experience in 68 diseases and 42 countries

Running Head: Systematic review of treatment/intervention using the DLQI.

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John Ingram 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 HS. His department receives income from royalties from the Dermatology Life Quality Index (DLQI) and related instruments.
Sam Salek has received an unrestricted educational grant from GSK, is a consultant for Novo Nordisk and produces educational materials for Abbvie.
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Data availability: All data are incorporated into the article and its online supplementary material.

Ethics statement: Not applicable.

What is already known about this topic?

The 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 of 457 randomized controlled trials describing research on 198,587 patients provides information covering 68 diseases and a wide range of interventions to which the DLQI has been applied. Details of study settings and countries, numbers of patients recruited, ages, and DLQI assessment periods are summarised. Longitudinal studies where the minimal clinically important difference (MCID) was achieved have been identified and analysed, with a comprehensive analysis of bias. DLQI scores were primary endpoints in 24 (5.3%) studies.

What are the clinical implications of this work?

This systematic review allows structured access to inform future users of the DLQI, confirms the very extensive experience of the DLQI in RCTs in dermatology and demonstrates the utility of the DLQI as the patient reported outcome measure of choice over the last two decades. This systematic review provides valuable evidence to aid researchers and clinicians in its further use and help its continued implementation into routine clinical practice.

Abstract

Background: Over 29 years of clinical application, the Dermatology Life Quality Index (DLQI) has remained the most used PRO in dermatology due to its robustness, simplicity and ease of use.
Objectives: This systematic review aimed to generate further evidence of its utility in randomised controlled trials and is the first to cover all diseases and interventions.
Methods: The methodology followed PRISMA guidelines and included seven bibliographic databases, searching articles published from January 1 1994 until November 16, 2021. Articles were reviewed independently by two assessors, and an adjudicator resolved any opinion differences.
Results: Of 3220 screened publications, 457 articles meeting eligibility criteria for inclusion, describing research on 198,587 patients, were analysed. DLQI scores were primary endpoints in 24 (5.3%) of studies. Most studies were of psoriasis (53.2%), although 68 different diseases were studied. Most study drugs were systemic (84.3%), with biologics 55.9% of all pharmacological interventions. Topical treatments comprised 17.1% of total pharmacological interventions. Non-pharmacological interventions were 13.8% of the total interventions, mainly laser therapy and UV treatment. 63.6% of studies were multicentre, with trials conducted in at least 42 different countries, and 41.7% were conducted in multiple countries. Minimal importance difference (MID) was reported in analysis of 15.1% of studies, but only 1.3% considered full score meaning banding of DLQI. 61 (13.4%) of studies investigated statistical correlation of DLQI with clinical severity assessment or other PRO/QoL tools. 62% to 86% of studies had within group scores differences greater than the MID in "active treatment arms". The JADAD risk of bias scale showed that bias was generally low, as 91.4% of studies had JADAD scores of ≥3; only 0.44% of studies showed high risk from randomisation, 13.8% high risk from blinding and 10.4% high risk from unknown outcome of all participants in the studies. 18.3% of studies declared that they followed an intention-to treat (ITT) protocol, and imputation for missing DLQI data was used in 34.1% of studies.
Conclusions: This systematic review provides a wealth of evidence for use of the DLQI in clinical trials to inform researchers' and clinicians' decision for its further use. Recommendations are also made for improving the reporting of data from future RCT trials using DLQI.

Introduction

The Dermatology Life Quality Index (DLQI)[1] is the most widely used dermatology patient reported outcome (PRO) measure in routine practice and clinical trials[2], because of the simplicity of reporting and application, a single meaningful summary score, its ease of completion in two minutes[3], comparability between studies and over time due to there being only a single version of the tool, and accessibility in over 139 different translations.[4] It is embedded in national guidelines and disease registries in >45 countries[5] and is available in 138 translations. 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 focussed on its use in psoriasis[6-8], biologics[7,9-11] or validation[2,12-14] and clinical results.[15] This systematic review (SR) is the first to investigate the use of the DLQI from its inception in 1994 to 2021 in randomised controlled trials (RCTs) covering all diseases and both pharmacological/non-pharmacological interventions and whether DLQI outcomes show beneficial effects of the interventions by statistically significant or clinically significant improved scores.

Materials and Methods

Data sources

This study follows 2020 PRISMA guidelines for reporting systematic reviews and checklist[16]. The study protocol and detailed search strategy was published on PROSPERO International Prospective Register of Systematic Reviews[17] (https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=290587) and is provided in the Supplementary Table 5. Medline (Ovid), Cochrane Library, EMBASE, Web of Science, SCOPUS, CINAHL(EBSCO) and PsycINFO online databases from 1st January 1994 (DLQI creation) to 17th November 2021 were searched independently by two authors (JJ, JV), and 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. MESH terms for RCT. Duplicates were excluded.

Search strategy/Selection

Table 1 gives the eligibility criteria for included studies.

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

Studies not including new DLQI data, and previously published analyses were excluded, as were publications with no DLQI data (but use mentioned), and studies that combined previously randomised treatment arms, so that only single arm (no longer randomised) DLQI data was 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, community, single or multi-centred (number of sites), patient demographics (mean or median age, gender, ethnicity stated, country), the number of subjects randomised to each intervention group, and whether DLQI was a primary or secondary endpoint.

Data was 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, non-drug interventions were also recorded.

If studies did not report primary data but extracted data from previously published RCT trials and performed post-hoc style analysis, data was obtained from the original published RCTs, particularly about methodology and study design. Sometimes these elements and DLQI score data were supplied in supplementary data files that were also consulted. Drug registrations e.g. NIH, U.S. National Library of Medicine: clinicaltrials.gov, were consulted for data on study protocols, particularly location of studies and number of sites used, if not provided in the articles.

Outcomes recorded relating 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) were noted, and whether the DLQI was correlated with other PRO/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, additionally, other PRO tools/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, guidance of the Cochrane Handbook for Systematic Reviews of Interventions was followed[19]. A RedCAP database[20-22] (a secure web application for building/managing online surveys and databases) was created based on the Cochrane Handbook Version 6.2 [23] and the updated guidance[19] recommendations. The authors JJ and JV independently extracted data from the included publications to parallel RedCap database tables, and an adjudicator (FA) resolved any disagreements in data extraction. Missing data were noted in the data templates, but none was sufficiently important to contact original authors. Data was extracted from RedCap to MS-Excel for analysis of totals, means and percentages.

The two reviewers independently assessed the risk of bias (quality) of 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 randomisation 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 provided by online database searching. There were 1842 duplicates and the remainder 1378 were assessed from the articles' full text, of which 457 described research on 198,243 patients meeting the inclusion eligibility criteria (Figure 1). Publications of RCTs using DLQI are increasing exponentially, with 72 new studies reported in 2021 (Figure 2).

Study sites and settings

One-third (155, 33.9%) of the RCT trials were single site studies; the majority (291, 63.7%) were multicentre, with 11 (2.4%) study locations being indeterminate. Sixty-four (14.0%) trials were conducted at two sites, 16 (3.5%) at three to five sites, 12 (2.6%) at 6-10 sites, 19 (4.2%) at 11-20 sites, 72 (15.8%) at 21-50 sites, 54 (11.8%) at 51-200 sites, 36 (7.9%) at 101-200 sites and six (1.3%) at >200 sites.

Although the majority of studies (n=255, 55.8%) failed to report the study setting(s), 97 (21.2%) studies were conducted in hospitals, 31 (6.8%) in clinics, 22 (4.8%) in trial centres, 23 (5.0%) in outpatient/ambulatory care and 29 (6.3%) in other settings.

Trials were conducted in at least 42 different countries, although 178 (40.2%) reported multiple countries without listing details (Supplementary Table1). The majority of studies conducted in a single

country were mainly in Europe (excluding the UK) (n=74, 16.7%) while 16 studies (3.6%) were conducted in the UK alone and 30 studies (6.8%) in the USA alone (Figure 3). Ethnicity of subjects was explicitly mentioned in 208 (45.7%) studies.

A great majority of the studies (n=415; 90.8%) recruited both male and female subjects, 14 (3.1%) recruited only male, 21 (4.6%) only female, five (1.1%) studies recorded no gender and two (0.4%) studies recorded gender as 'other'. Studies recruiting only females were concerning oligomenorrhoea and amenorrhoea in women with polycystic ovary syndrome (PCOS), hirsutism (PCOS), acne, striae distensae, systemic lupus erythematosus with permanent facial skin damage, axillary hyperhidrosis (n=3), plaque psoriasis, rosacea, breast cancer (n=3), xerosis in dialysis patients, hand-foot syndrome, vulvovaginal candidiasis, alopecia, cellulite, hyperpigmentation, periorbital pigmentation and melasma. Studies recruiting only males concerned hyperpigmented lips, plaque psoriasis (n=5), psoriatic arthritis, chronic skin lesions due to mustard gas (n=3), actinic keratosis, hidradenitis suppurativa, and lichen sclerosus (n=2). Participants' average age (where given) of all study arms across all studies was 45 years (range 22-81 years).

Disease profile

Sixty-eight different diseases were studied (Table 2). Most studies were of psoriasis (n=243, 53.2%), followed by atopic dermatitis (n=26, 5.7%), urticaria (n=20, 4.4%), eczema (n=17, 3.7%), psoriatic arthritis (n=17, 3.7%), eczema/hand eczema (n=17, 3.7%) and hidradenitis suppurativa (n=11, 2.4%).

Overall, studies recruited patients with mild (n=78, 10.2%), moderate (n=289, 38.0%) and severe (n=259, 34.0%) disease, with 136 (17.8%) unspecified. Psoriasis studies recruited mild (n=47, 10.3%), moderate (n=203, 44.4%), and severe (n=184, 40.3%) patients with 23 (5.0%) unspecified.

Clinical severity and patient-reported outcomes assessment

Clinical severity assessment tools used included a mixture of dermatology-specific and generic measures. The Psoriasis Area and Severity Index (PASI)[485] was employed in 224 (39.6%) studies, along with Patient Global Assessment (PGA)[486] 17.1%, Investigator Global Assessment (IGA)[487] 9.0%, Nail Psoriasis Severity Index (NAPSI)[488] 4.6%, Eczema Area and Severity Index (EASI)[489] 3.5%, affected Body Surface Area (BSA)[490] 3.4% and the Scoring Atopic Dermatitis (SCORAD) 2.8%. The PRO/Qol tools employed included the 36-Item Short Form Survey RAND Corporation (SF-36)[491] 9.4%, the Hospital Anxiety and Depression Scale (HADS)[492] 3.7% and the EuroQol EQ-5D[493] 3.0%. Many other clinical severity assessment and PRO/QoL tools were also used (Supplementary Table2).

Interventions using DLQI in randomised clinical trials

Summary data including disease, systemic, topical and non-medicinal interventions, total subjects randomised, mean or median age for each intervention arm, DLQI assessment period, clinical setting, most commonly used QoL tools, country of the study and JADAD score and domains from every included study are given in Supplementary Table3.

Most study drugs were systemic (n=373, 85.1%), with biologicals (growth factors, immune modulators, monoclonal antibodies, and products derived from human blood and plasma) comprising 251 (55.8%) of

all pharmacological interventions. Topical treatments used in 77 studies comprised 17.1% of the total pharmacological interventions (Table 3).

32 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 non-pharmacological interventions were laser treatment (n=10, 15.9% of the total non-pharmacological interventions), followed by ultraviolet treatments (n=6, 9.5%), educational intervention (n=5, 7.9%), Chinese (traditional) herbal medicines (n=4, 6.3%), digital applications (n=3, 4.8%), motivational interviewing (n=2, 3.2%), low energy diets (n=2, 3.2%), microneedle (n=2, 3.2%) and platelet-rich plasma (n=2, 3.2%) with another 27 non-pharmacological interventions used in single studies (42.9%). Non-pharmacological interventions comprised only 12.3% of the total interventions.

DLQI Scores

The DLQI was reported as a primary endpoint in 24 (5.3%) of 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 arm1 (control) by 26.3% of studies, arm2 (intervention) by 27.8%, and arm3 (intervention) by 10.9% 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 per patient basis rather than 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.

Sixty-nine studies (15.1%) used minimal importance difference (MID) in their analysis, but only six (1.3%) considered full score meaning banding[499] of the DLQI scale. Many studies also used the proportion of patients achieving a final total DLQI score of 0 or 1 as an endpoint. In addition, 49 (10.7%) studies investigated statistical correlation of DLQI with other PRO/QoL tools.

Study bias

Randomisation was mentioned in 447 studies (97.8%), however the method was appropriate in only 318 studies (69.6%). Blinding was mentioned without further details in 77 studies (16.9%), 291 studies (63.8%) described appropriate blinding, 21 studies (4.6%) used an inappropriate blinding method, in 39 studies (8.6%) blinding was not mentioned under methodology, and in 26 studies (5.7%) study design made blinding irrelevant. Baseline data demographics were described across the study arms in 420 studies (92.3%), adjustments were made during analysis for baseline imbalances in three studies (0.7%) and were not mentioned in 28 studies (6.2%). Figure 5 gives the distribution of JADAD scores and summarises risk of bias.

Eight-four studies (18.4%) stated that they followed an intention-to treat (ITT) protocol. Imputation for missing DLQI data was used in 157 (34.4%) studies. Several imputation methods were used, including fixed imputation (last observation carried forward) (n=76, 16.6%), non-responder imputation (n=47, 10.3%) and multiple imputation (n=20, 4.4%). Eighty-four studies (18.4%) used no imputation and the method was not stated in 151 (33.%).

Discussion

This systematic review represents 27 years of global implementation of DLQI in RCTs compiling a wealth of information in this one-stop source. The global reach of the DLQI is demonstrated by its use in 42 different countries and by 40.2% of studies using it in multiple countries. Furthermore, 40.9% of studies were conducted at >10 sites and only 34% were conducted at a single site.

The number of studies assessing systemic drugs (n=373, 85.1%) results from the large number of new biologics (n=251, 55.8% total drugs assessed) being developed, mainly for treatment of psoriasis, psoriatic arthritis, atopic dermatitis, urticaria and hidradenitis suppurativa. Topical treatments only comprised 17.1% (n=77 studies) of the pharmacological interventions studied. A recent systematic review has confirmed that biologics can significantly improve DLQI scores in patients with psoriasis[6,9]. However, 68 different diseases were studied, emphasising the generic strengths of the DLQI as a dermatology-specific instrument and a broader interest within the research community.

Non-pharmacological interventions (n=63, 13.8% of total interventions) were mainly laser therapy (n=10, 15.9%) and UV treatment (n=6, 9.5%) as well as various non-pharmacological interventions used in single studies (42.9% of non-pharmacological interventions). The low number of traditional medicine interventions may be due to the required complexity of clinical trials, and novel laser or UV treatments have commercialisation potential whereas widely used traditional medicines cannot receive patent protection.

Results showed that 25.6%, 28.7% and 12.0% of studies reported DLQI scores difference for arm1, arm2 and arm3, respectively. In addition, in 59.3%, 65.2% and 25.4% of studies for arm1, arm2 and arm3 respectively, a score difference could be calculated from provided baseline and end of the study DLQI scores. Furthermore, 61% to 86% of studies in the "active arms" had within group scores differences greater than the MID[498] representing differences for the control/placebo arm of 35%. Such a result might be expected as studies usually included only more severely affected patients (most often, in psoriasis, screened using PASI).

Risk of bias was generally low, as 91.6% of studies have JADAD scores of 3 or above, 0.44% of studies showed high risk from randomisation, only 13.6% having high risk of bias from blinding and 10.1% high risk from unknown fate of all participants in the studies. 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= 0.022). Allocation concealment[500], although now considered an important element in study bias, was barely mentioned. Most studies (92.6%) did check for baseline equivalence between study arms, although older studies often neglected to do so and very few indicated any baseline correction being performed during analysis.

Assessment of bias was made at the level of an individual result, rather than at a study or outcome level. The domains included in bias analysis were bias arising from the randomisation 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 has some limitations. Although only English language articles were reviewed, these articles often reported on RCTs carried out using many different DLQI translations. The reports

generally amalgamated DLQI data and did not report score distribution for each language. It would be of interest if it were possible to analyse the original raw data to identify possible interpretation differences.

We examined and only studies with extractable DLQI data and did not capture all pharmacological interventions for complex studies involving multiple arms (>3), pre-treatments, multiple phases, cross-over studies etc. and those which 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 was available to describe study settings in most studies. 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 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. The review allows structured access to inform future users of the DLQI, confirms the very 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 two decades. The use of the DLQI as a primary outcome measure in 24 RCTs represents 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 often 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 authorisation of new health technologies as well as an aid to treatment decision making.

Recommendations

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:

1. Publications reporting clinicals trials should include details of study settings, genders, ethnicity, and mean and range of participants' age.
2. The sample size calculation, randomisation and blinding methods, including allocation concealment should be clearly stated, and correct baseline characteristics and comparisons of subjects presented.
3. Patient numbers should be reported, whether intention to treat or per protocol analysis was implemented, and the method(s) for data imputation of missing data.
4. 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. Presentation of percentage score changes should be discouraged.
5. Authors should analyse their DLQI data using MID and use score severity bands in interpreting results.

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Figure legends

Figure 1 PRISMA 2020 Flow diagram of article selection.

Figure 2 Number of randomised control trial studies using the DLQI over time.

Figure 3. Location of randomised controlled trial studies.

Figure 4. Published and calculated DLQI score differences for all interventions (N=469). Arm1,2,3 differences are published DLQI differences as reported. Arm1,2,3 calculated differences were determined from differences between reported baseline and endpoint DLQI scores, where reported. Arm1 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 MID.

Figure 5. Distribution of JADAD scores and risk of bias.

1 Table 1. Eligibility criteria for study selection.

Variable	Inclusion	Exclusion
Patients	- Adults ≥ 18 years, any gender, ethnicity, settings, countries - Any inflammatory and non-inflammatory dermatological conditions	
Methods	- Interventional RCTs published as full papers in peer-reviewed journals (including cross-over trials and trials with open-label extensions if initial treatment was continued after study completion) - Published between 1 January 1994 and 17 November 2021 - Interventions included any drug, therapeutic intervention and alternative medicines e.g. acupuncture, fire needle, Chinese traditional (herbal) medicine, Ayurvedic, and educational or lifestyle interventions	- Not in English language -'Grey' literature including dissertations, conference abstracts, reports, editorials, letters to editors, commentaries, protocols, reviews, conference abstracts, conference proceedings, and dissertations
Outcomes	- DLQI is primary or secondary outcome	- No DLQI data given

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1 Table 2. Diseases studied

Disease type	Disease	Number of studies	%	Ref
Inflammatory	Psoriasis	243	53.2	26-136,137-281
	Atopic dermatitis	26	5.7	282-307
	Urticaria	20	4.4	308-327
	Eczema/Hand eczema	17	3.7	328-344
	Psoriatic arthritis	17	3.7	204,345-361
	Hidradenitis suppurativa	11	2.4	362-371
	Acne	10	2.2	372-381
	Rosacea	7	1.5	382-388
	Palmoplantar pustulosis	4	0.9	389-392
	Nail psoriasis	3	0.7	53,215,216
	Palmo-plantar psoriasis	3	0.7	50,52,105
	Perioral dermatitis	2	0.4	393,394
	Psoriasis and psoriatic arthritis	2	0.4	94,118
	Seborrheic dermatitis	2	0.4	395,396
	Bullous disease	1	0.2	397
	Hidradenitis suppurativa and psoriasis	1	0.2	116
	Lichen planus	1	0.2	398
	Lupus erythematosus	1	0.2	399
	Pemphigus vulgaris	1	0.2	400
	Psoriasis and atopic dermatitis	1	0.2	61
	Sarcoidosis	1	0.2	401
	Scleroderma skin fibrosis	1	0.2	402
Skin disorders caused by external agents	Actinic keratosis	4	0.9	403-406
	Radio-dermatitis	3	0.7	407-409
	Chemotherapy-induced cutaneous symptoms	2	0.4	410,411
	Chronic actinic dermatitis and polymorphous light eruption (PLE)	1	0.2	412
	Chronic sulphur mustard-induced cutaneous complications	1	0.2	413
	Contact dermatitis	1	0.2	414
	Disseminated superficial actinic porokeratosis	1	0.2	415
	Erlotinib induced rash	1	0.2	416
	Parthenium dermatitis	1	0.2	417
	Photoaging	1	0.2	418
	Polymorphic light eruption	1	0.2	419
	Scalp psoriasis	1	0.2	45
	Schnitzler syndrome	1	0.2	420
Benign and Malignant tumours	Cutaneous leiomyomas	1	0.2	421
	Metastatic adenocarcinoma of the colon	1	0.2	422
	Metastatic colorectal cancer	1	0.2	423
	Oesophageal cancer	1	0.2	424
	Skin care in breast cancer	1	0.2	425
Infections and infestations	Viral warts	3	0.7	426-428
	Hand/foot syndrome	1	0.2	429
	Herpes zoster	1	0.2	430
	Leprosy	1	0.2	431
	Lymphoedema due to podoconiosis	1	0.2	432
	Tinea cruris/corporis	1	0.2	433
	Tinea pedis	1	0.2	434
	Vaginal candidiasis	1	0.2	435
Other	Pruritus	10	2.2	436-445

	Hyperhidrosis	8	1.8	446-453
	Lichen sclerosus	3	0.7	454-456
	Alopecia	2	0.4	457,458
	Cellulitis	2	0.4	459,460
	Hirsutism in polycystic ovarian syndrome (PCOS)	2	0.4	461,462
	Hyperpigmentation	2	0.4	463,464
	Uremic pruritus	2	0.4	465,466
	Vitiligo	2	0.4	467,468
	Xerosis	2	0.4	469,470
	Dry skin	1	0.2	471
	Erythrokeratoderma	1	0.2	472
	Leg ulcers	1	0.2	473
	Melasma	1	0.2	474
	Oligomenorrhoea and amenorrhoea	1	0.2	475
	Palmar hyperhidrosis	1	0.2	476
	Peri-orbital pigmentation	1	0.2	477
	Prurigo nodularis (non-atopic)	1	0.2	478
	Pyoderma gangrenosum	1	0.2	479
	Stasis dermatitis	1	0.2	480
	Striae distensae	1	0.2	481
	“Any skin disease”	3	0.7	482-484

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1 Table 3. Pharmacological interventions by drug type

Systemic				Topical			
	# uses	%	Refs		# uses	%	Refs
Biologics	252	56.0	See Table 4				
Analgesics	4	0.89	430,437,465,466				
Anti-diabetics	4	0.89	79,93,137,151				
Antihistamine	11	2.4	310,314,316,317,321,325,326,465,494				
Antiviral (valacyclovir)	1	0.22	430				
Disease-modifying anti-rheumatic drug (DMARD)	2	0.44	256,339				
Fusion Toxin (DAB389IL-2)	1	0.22	43				
Muscarinic agonist (pilocarpine)	1	0.22	450				
Selective NK1-R antagonist (serlopitant)	1	0.22	445				
Selective phosphodiesterase-4 (PDE4) inhibitor (apremilast)	9	2.0	184,202,203,368				
Antidepressant	2	0.44	437,466	Antidepressant (doxepin)	1	0.22	440
Selective CRTh2 receptor antagonist (AZD1981)	1	0.22	327	Antifungal	6	1.3	395,433-435
Anti-infectives	5	1.1	309,386,397,411,416	Anti-infectives	9	2.0	372,375,380,382,383,385,386,388,394
Antimuscarinic agent (methantheline bromide)	1	0.22	495	Antimuscarinic agent (oxybutynin)	1	0.22	450
Corticosteroid (prednisolone)	3	0.67	355,397,479	Corticosteroid	27	6.10	68,95,120,122,145-147,164,186,189,239,246,346,351,353,356,361,409,413,422,436,440,442,478,480
Epidermal growth factor receptor tyrosine kinase inhibitor (icotinib)	1	0.22	402	Epidermal growth factor receptor tyrosine kinase inhibitor (icotinib)	1	0.22	277
				Humectant (hyaluronic acid)	1	0.22	406
Immunosuppressants	20	4.4	39,48,66,88,114,135-137,187,200,218,222,265,273,274,292,355,400,479	Immunosuppressants	4	0.89	393,396,444,478
Janus kinase (JAK) inhibitors	16	5.8	26,41,51,63,86,111,156,179,255,301,304,307,336	Janus kinase (JAK) inhibitors (tofacitinib)	1	0.22	177
Muscarinic antagonist (oxybutynin)	1	0.22	450	Muscarinic antagonist (oxybutynin)	1	0.23	453

Natural Products and Supplements	7	1.6	222,276,287,337,381,430,441	Natural Products and Supplements	4	0.89	152,404,410,458
NSAID	6	1.3	191,200,233,244,245	NSAID	2	0.44	252,406
Retinoids	9	2.0	151,227,276,374,379,405,418,456	Retinoids	3	0.67	95,239,418
Statins	4	0.89	28,69,122,473	Statins (atorvastatin)	1	0.22	353
Tyrosine kinase 2 inhibitors	2	0.44	240,416	TRPM8 agonists (menthoxypropanediol)	1	0.22	443
Vitamin D3/Vitamin D derivatives	3	0.67	120,225,417,496	Vitamin D3/Vitamin D derivatives	9	2.0	145,146,151,186,189,190,268,340
Others	6	1.3	363,421,427,448,452	Others	5	1.1	246,373,464,472,476

Note: #uses refers to number of studies using 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.

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1 Table 4. Interventions using biologicals

Biologicals	Number of uses	% of total pharmacological interventions	Diseases studied	References
etanercept	42	9.31	hidradenitis suppurativa, pruritus, psoriasis	27,41,46,71,74,83,91,94,98,109,110,113,115,118,125,131-133,142,153,155,161,163,169,176,183,185,196,202,203,209,214,228,236,242,251,255,260,272,274,362,439
ustekinumab	37	8.20	atopic dermatitis, psoriasis	39,40,42,44,52,55,58,59,70,92,103,112,115,119,128,131,132,138-141,144,157,168,178,187,195,197,210,213,241,249,250,264,280,296,332,341
adalimumab	34	7.54	cutaneous sarcoidosis, hidradenitis suppurativa, psoriasis, psoriatic arthritis	32,33,56,64,70,85,108,127,129,150,158,165,170,180,183,187,192-194,198,199,201,204,205,218,219,229,262,329,330,336,340,366,371,401,497
secukinumab	32	7.10	palmoplantar pustulosis, psoriasis, psoriatic arthritis	27,30,38,42,44,58,59,74,80,92,104,105,115,118,130-132,166,172,195,206,211,215,216,233,236,241,261,281,338,343,389
ixekizumab	23	5.10	psoriasis, psoriatic arthritis	30,53,55,97,109,113,125,142,148,149,185,196,197,200,208,210,221,266,271,272,279,330,331
guselkumab	15	3.33	palmoplantar pustulosis, psoriasis	32,56,108,141,150,171,198,199,201,204,205,244,390,392
brodalumab	11	2.44	psoriasis	99,138,139,157,167,175,178,191,226,258,264
Infliximab	8	1.77	psoriasis	48,77,81,82,207,247,248,267
dupilumab	6	1.33	atopic dermatitis	282,284,288,298,299,302
efalizumab	4	0.89	psoriasis	102,159,160,173
risankizumab	4	0.89	psoriasis	40,103,181,245
alefacept	3	0.67	psoriasis	75,84,87
bimekizumab	3	0.67	hidradenitis suppurativa, psoriasis	57,262,497
omalizumab	3	0.67	urticaria	322-324
tralokinumab	3	0.67	atopic dermatitis	297,305,306
abatacept	2	0.44	psoriatic arthritis	335,342
brikinumab	2	0.44	psoriasis	100,182
canakinumab	2	0.44	Schnitzler syndrome, urticaria	319,420
certolizumab pegol (CPZ)	2	0.44	psoriasis	253,254
cetuximab	2	0.44	oesophageal cancer, radiodermatitis of head and neck cancer	407,424
lebrikizumab	2	0.44	atopic dermatitis	289,300
tildrakizumab	2	0.44	psoriasis	60,209
bermekimab	1	0.22	hidradenitis suppurativa	364
clazakizumab	1	0.22	psoriatic arthritis	334
Cytokines (cytokines IL4, IL10 and IL11)	1	0.22	psoriasis	220
golimumab	1	0.22	psoriatic arthritis	333

IFN-γ	1	0.22	chronic sulfur mustard-Induced cutaneous complications	413
itolizumab	1	0.22	psoriasis	134
mirikizumab	1	0.22	psoriasis	212
nemolizumab	1	0.22	atopic dermatitis	295
panitumumab	1	0.22	metastatic colorectal cancer	423
rituximab	1	0.22	Pemphigus vulgaris	400
Total	252	55.86		

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1 Table 5. DLQI score differences (n=458)

	Arm1 diff	Arm2 diff	Arm3 diff	Arm1 calculated diff	Arm2 calculated diff	Arm3 calculated diff
Number of studies with DLQI difference scores	123	131	53	270	296	114
% studies with DLQI difference scores	25.6	28.7	12.0	59.3	65.2	25.4
Number of studies with no data available	337	330	407	181	168	346
No. of studies score diff >MID of 4.0[498]	34	78	32	182	219	95
No. of studies score diff <MID of 4.0[498]	86	49	18	84	70	16
% of studies with score diff >MID of 4.0[498]	28.3	61.4	64.0	68.4	75.8	85.6

Notes: Arm1,2,3 differences are published DLQI differences as reported. Arm1,2,3 calculated differences were determined from differences between reported baseline and endpoint DLQI scores, where reported.

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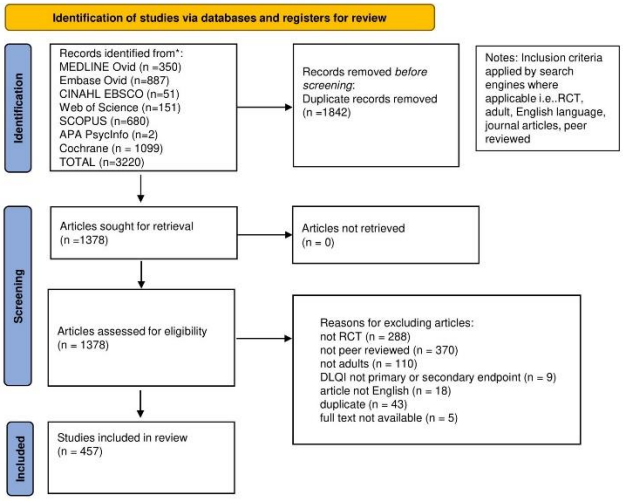

Figure 1
159x90 mm (x DPI)

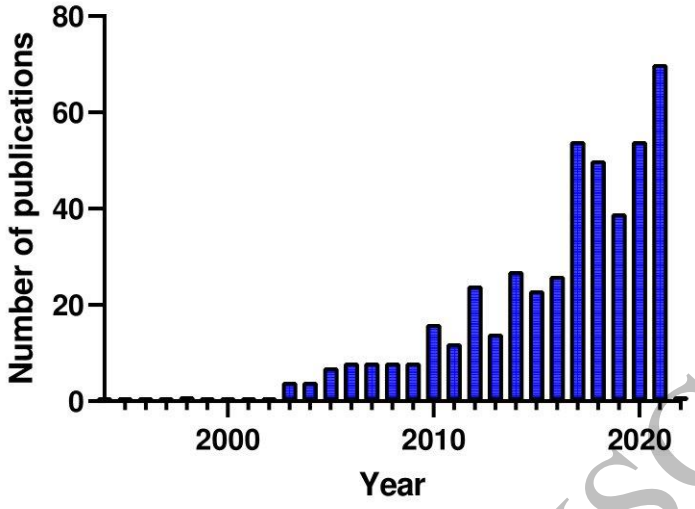

Figure 2
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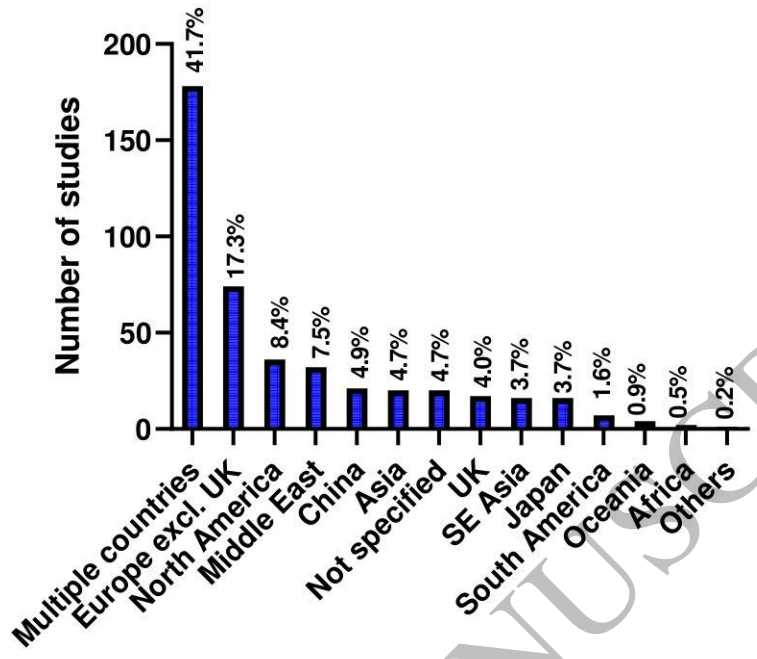


Figure 3
108x92 mm (x DPI)

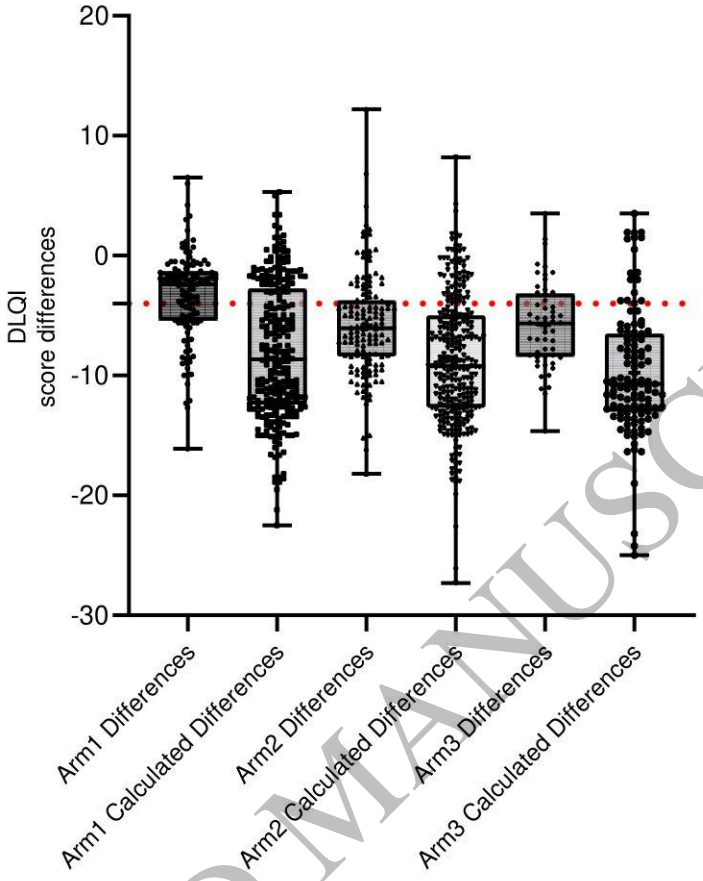
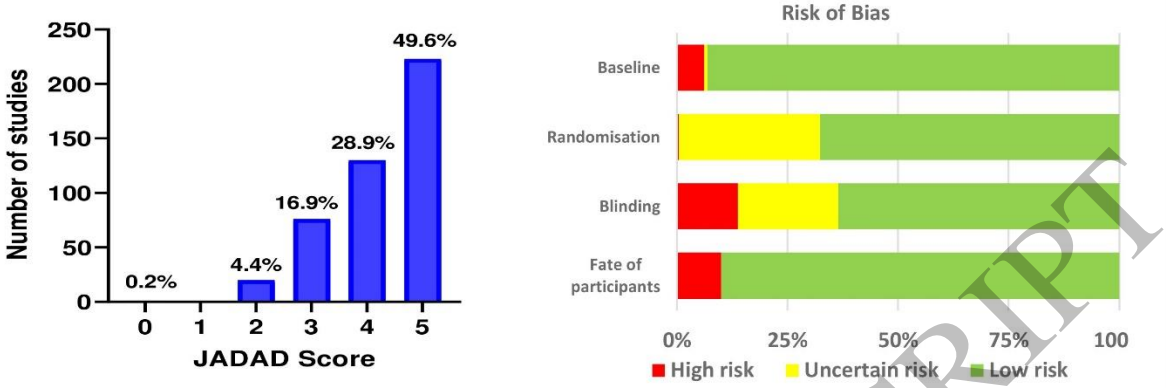


Figure 4
105x123 mm (x DPI)



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2 *Figure 5*

3 *159x90 mm (x DPI)*