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Title Page

Title: Correlation of Dermatology Life Quality Index (DLQI) with psychiatric measures in randomized controlled trials: a systematic review

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AYF is joint copyright owner of the DLQI and Cardiff University and AYF receive royalties.

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Abstract**Background**

Skin conditions may have a major impact on the psychological well-being of patients, ranging from depression to anxiety. The Dermatology Life Quality Index (DLQI) is the most commonly used quality of life tool in dermatology, though it has yet to be correlated with psychiatric measures used in clinical therapeutic trials.

Objectives

We conducted a systematic review to determine whether there is any correlation between the DLQI and psychiatric measure scores, potentially allowing the DLQI to be used as a surrogate measure for depression or psychiatric screening.

Methods

Six databases were searched using the keywords: 'DLQI', 'Dermatology Life Quality Index', 'Psych*', 'depression', 'anxiety', 'stress' and 'trial*'. All randomised trials where full DLQI and psychiatric scores were provided were included. PRISMA guidelines were followed.

Results

462 records were screened but only seven met inclusion criteria. Hospital Anxiety and Depression Scale (HADS) was the most commonly used psychiatric measure; the 'depression' component score changes correlated strongly with the DLQI ($r=0.715$).

Conclusions

There needs to be guidance on psychiatric measurement and reporting in clinical trials. Though the DLQI correlated well with the 'depression' domain of the HADS scale, interviews and screening for depression are still vital for full assessment of patient psychological well-being as well as for fully understanding the wider impact of skin disease on patients

Introduction

Skin conditions may have significant implications on a patient's quality of life (QoL) affecting various aspects of their day-to-day living¹. This includes routine activities, household chores, social interactions and relationships. There is a well-documented impact on psychological well-being, often manifesting in psychiatric problems ranging from depression to anxiety². Several studies have examined the relationship between psychiatric morbidity and skin diseases³⁻⁷. Psoriasis is associated with psychological disorders with sexual and sleep complaints being the most prevalent³. Anxiety and depression are strongly correlated in conditions such as alopecia areata⁴, vitiligo⁵, rosacea⁶ and hirsutism⁷.

The Dermatology Life Quality Index⁸ (DLQI, score range 0-30) has been used in many skin conditions and across a wide range of disease severities^{9,10}. It has high patient acceptability¹¹, short completion time, and extensive validation⁹, resulting in its widespread use in clinical settings as well as clinical therapeutic research trials globally¹². Furthermore, the psychosocial aspects captured by the DLQI are well documented¹⁰. Despite this, the DLQI has yet to be compared and correlated with other psychiatric morbidity measures in randomized controlled trials.

We aimed to conduct a systematic review to identify the different validated psychiatric measures that have been utilized in conjunction with the DLQI in randomized controlled trials (RCTs), and whether there is any correlation between the scores that would potentially allow the DLQI to be used as a surrogate measure for depression or psychiatric screening.

Materials and Methods

Data sources

Six computerized bibliographical databases were searched up to 19 May 2016:

OVID MEDLINE, MEDLINE In-Process & Other Non-Indexed Citations, EMBASE, WEB OF SCIENCE Core Collection, SCOPUS and PsycInfo. The search was not restricted by language and was conducted using PRISMA guidelines (Prospero registration no: XXX).

Keywords used were: 'DLQI', 'Dermatology Life Quality Index', 'Psych*', 'depression', 'anxiety', 'stress' and 'trial*'.

Search filters are given in the Supplementary Material. We ran supplementary searches and reviewed trial registers and grey literature. Reference lists of all included studies and of recent reviews were also assessed. Electronic publications in advance of print were also included.

Selection criteria

We included all randomised controlled trials for any condition where the DLQI was used. This included cross-over trials and trials with open-label extensions, in all languages studying the adult population (aged 18 and over) of either sex and of any ethnicity. Only papers where the absolute scores or change in scores for the DLQI and for psychiatric measures were provided were included.

Exclusion criteria

The exclusion criteria for the systematic review were as follows: studies which included any patient less than 18 years of age, and articles where the change in scores could not be reliably calculated for the DLQI or any psychiatric morbidity scale (including graphical representation). Abstracts and posters where further data was not available upon contacting the author were also excluded.

Outcome measures extracted

Primary Outcome

Data recorded included DLQI scores and which psychiatric morbidity scale was utilised. Scores for these measures were recorded at baseline, treatment and follow-up endpoints, as well as the change in these scores attributed to treatment. For studies with an open label extension, the data was only extracted for the period of the study while it was randomised and controlled.

Secondary Outcomes

Correlation between the sensitivity of the DLQI and psychiatric measures to change.

Data extraction and synthesis

Two reviewers (FA and NJ) extracted data independently from all eligible published studies, discussed any disagreements and, if necessary involved a third reviewer (Dr. Jui Vyas, Cardiff University) for resolution. We adapted a form, which included the Cochrane Risk of Bias tool, for recording data¹³ that included study design, details of administration, methodological quality and duration of treatment and follow-up. Article quality was quantitatively rated using the JADAD score¹⁴.

Results

Characteristics and attributes of the studies selected

462 records were screened from the initial database search, of which only seven interventional RCTs met the inclusion criteria; six studies were for psoriasis and one for atopic dermatitis. One study, for which results were available, was identified by searching trial registries (Fig. 1). The data describes results from 5578 adult patients, with an average age of 45 years. Approximately 63.8% of the study population was male. The studies identified

by the systematic review and their extracted attributes are summarised in Table 1.

The most common psychiatric tools used alongside the DLQI were: Beck Depression Inventory (BDI, 2 studies) and the Hospital Anxiety and Depression Scale (HADS, 5 studies). The BDI, published in 1961²², is a 21-item patient reported outcome measure (score range 0-63) and is commonly used in studies to assess the severity of depression. The inventory covers various aspects of mental health and depression as well as physical symptoms and relationships. The HADS scale was developed in 1983²³ as a screening tool and consists of 14 items (score range 0-21). The questions encapsulate two domains: anxiety (HADS-A) and depression (HADS-D), each containing seven questions with a four-level response system. Scores ranging from 0-7 are considered 'normal', 8-10 'borderline abnormal' and 11-21 'abnormal'.

DLQI and the psychiatric measures scores

Mean scores at baseline ranged from 6.6-13.8 for the DLQI, 8.1-12.3 for the BDI, 5.0-6.6 for HADS-D and 6.8-8.3 for the HADS-A. At treatment endpoint, the scores ranged from 2.6-6.1 for the DLQI, 5.8-10.5 for BDI, 3.1-5.00 for HADS-D, 4.3-6.1 for HADS-A (Table 2) In five studies the DLQI was measured more frequently than the psychiatric scores throughout the study duration. However, only measurement scores for simultaneous assessment points of the two measures (i.e. DLQI, HADS or BDI) were examined.

Relationships between the DLQI and psychiatric measures

Change in score for these measures at treatment endpoint were recorded, or calculated where needed from the absolute data provided. As the HADS was the most commonly used tool (5 out of 7 studies), DLQI scores were correlated with this measure (Figure 2a and 2b). The HADS-Depression index was more closely correlated to the DLQI ($R^2=0.715$) than the HADS-Anxiety index ($R^2=0.423$).

Relevance of accumulative change of scores for the DLQI and HAD Scale

Table 2 demonstrates a mean HADS-D score across all studies of 5.76 ('normal' according to the HADS-D scoring index²³) and a mean HADS-A score of 7.39 ('borderline abnormal'). The expected DLQI score change per HADS-D point is 4.59 and 4.29 for the HADS-A. This suggests.....

Discussion

Depression and other psychiatric issues continue to be significant problems experienced by dermatology patients, potentially affecting treatment compliance, leading to premature treatment discontinuation and alteration of the disease course²⁴. The implications extend beyond QoL for concerned individuals, with concurrent economic repercussions through lost productivity and sick leave^{25,26}. Researchers therefore often administer QoL tools which encompass a psychological component alongside psychiatric measures where appropriate to gather holistic efficacy data, though these are predominantly cited as secondary outcomes. This systematic review

highlights the need for more frequent psychiatric assessment in RCTs, particularly where quality of life is measured; several studies had to be excluded from this review as a result. Full scores for psychiatric measures are not always provided, with researchers favouring clinical data instead. Though primary outcomes are centred around these clinical parameters, it is imperative psychiatric morbidity is not sidelined given its prevalence in this population²⁻⁷.

Although the HADS is commonly used to assess symptoms of depression and anxiety, it is most appropriate as a screening tool with routine clinical psychiatric assessment considered as the primary diagnostic method²⁷. The DLQI contains questions on various aspects of quality of life, including 'embarrassment' and 'self-consciousness', but does not overtly record data on depression or anxiety⁸. Nevertheless, the total DLQI score correlated well with score changes in the Depression component of the HADS, though not as well as with the Anxiety component (Figures 2a/b). It may be possible to consider depression and anxiety in patients using DLQI scores, especially in the absence of an appropriate psychiatric measure; a DLQI score change 4.59 and 4.29 results in a point change for the HADS-D and HADS-A respectively. However, a significant limitation of this systematic review is that there was very little data in interventional trials where both DLQI and HADS values were provided, thereby necessitating further work on more expansive datasets for more accurate and refined correlation values.

Several studies used inappropriate or non-validated scales to assess psychiatric morbidity, which led to their exclusion in this systematic review. The frequency at which this data was recorded compared to quality of life also varied across studies, despite majority of the identified studies belonging to the same intervention group. Generic and disease-specific QoL questionnaires may capture elements of depression and other mental health disorders, though these have not been validated as such for their primary purpose. Where psychiatric scores were provided, on occasion the authors omitted commenting on the results and therefore deducing worthwhile conclusions. We suggest guidelines to ensure routine and correct measurement of psychiatric symptoms using appropriate measures, alongside QoL assessment. The diverse and inconsistent nature of the data-reporting limits the potential to analyse and compare data between trials, whilst potentially missing cases of depression or other significant mental health issues. Almost all the studies identified in this review assessed psoriasis, a condition commonly linked with psychological distress²⁸. In such cases, psychotherapy may be a significant adjuvant to traditional topical and systemic dermatological treatment, further highlighting the need for full and accurate reporting of psychological data.

There are several limitations to this review. Though the focus was primarily on interventional studies, to capture more extensive correlation data, observational studies could also have been included. We only studied DLQI data given its widespread implementation¹²; further research correlating other QoL measures may highlight other patterns of data reporting. The mean baseline HADS-D score of 5.8 is rated 'normal' according to the screening

cut-off²³, and 7.4 'borderline abnormal' for the HADS-A. This highlights that mostly patients without, or with minimal, psychiatric morbidity were recruited, emphasising the limited availability of such data in trials. Perhaps if data with patients suffering with more significant psychiatric morbidity were available for RCTs, we might see higher score changes in the HAD scale, and subsequently more sensitive DLQI correlation values (Table 2).

The results of this systematic review echo our recent calls for guidance on the reporting of QoL scores¹²; we extend these suggestions for psychiatric morbidity reporting. Patients often suffer with depression and suicidal ideation²⁷ and if appropriate measures are not administered, these potentially-serious symptoms may be missed, perhaps leading to avoidable detrimental consequences.

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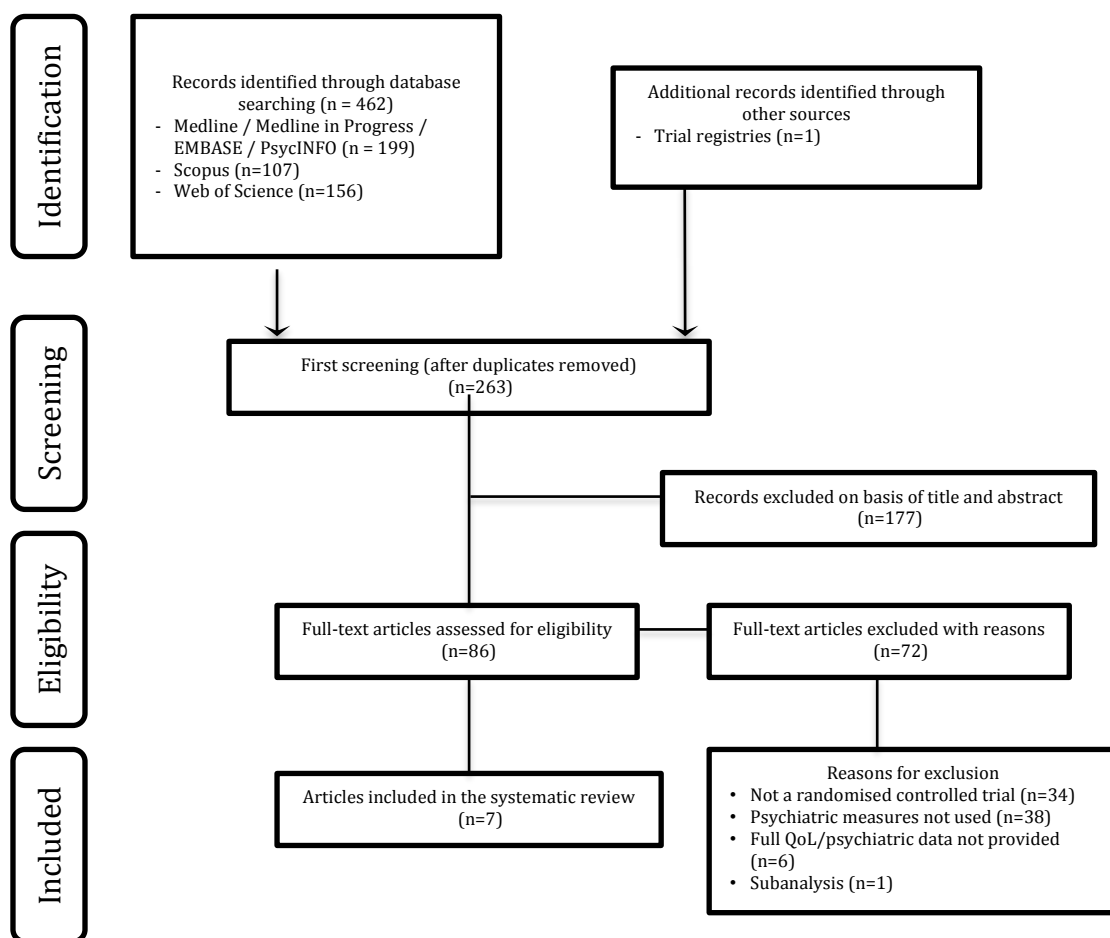
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Figure 1 Flow diagram of article selection



Figures 2a & b

- a) Correlation between change in DLQI scores and HADS-D scores
- b) Correlation between change in DLQI scores and HADS-A scores

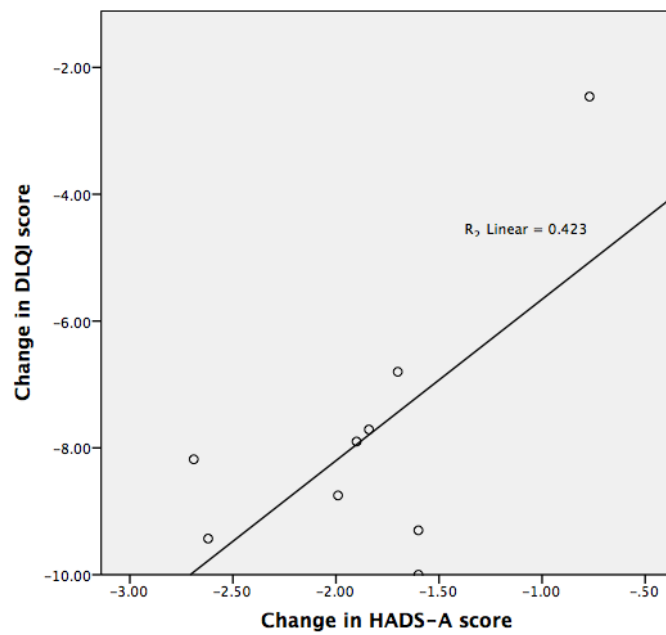
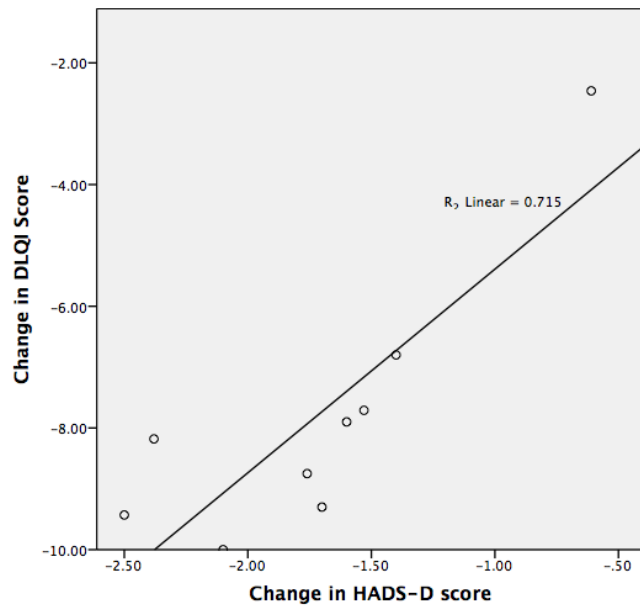


Table 1 Table of included studies, basic demographic information and psychiatric measures used

| Author, Year | JADAD score | Interventional study arm | Condition | Study duration (weeks) | Average participant age | Total no. of study participants | Psychiatric measure |
|---|-------------|-----------------------------|-------------------|------------------------|-------------------------|---------------------------------|---------------------|
| Bostoen 2012¹⁵ | 4 | Educational Programme | Atopic dermatitis | 12 | 38.5 | 16 | BDI |
| Bundy 2013¹⁶ | 2 | eTIPS* | Psoriasis | 6 | 45.8 | 61 | HADS |
| Dauden 2009¹⁷ | 1 | Etanercept (Continuous) | Psoriasis | 54 | 44.8 | 352 | HADS |
| | | Etanercept (Paused) | | | 45.2 | 359 | |
| Gelfand 2008¹⁸ | 1 | Etanercept (Continuous) | Psoriasis | 12 | 45.8 | 1272 | BDI |
| | | Etanercept (Interrupted) | | | 44.9 | 1274 | |
| Gniadecki 2012¹⁹ | 3 | Etanercept BIW [†] | Psoriasis | 12 | 46.1 | 379 | HADS |
| | | Etanercept QW ^{††} | | | 46.9 | 373 | |
| Langley 2010²⁰ | 4 | Ustekinumab 45 mg | Psoriasis | 52 | 45.1 | 409 | HADS |
| | | Ustekinumab 90 mg | | | 46.6 | 411 | |
| Trial No: NCT01309737²¹ | N/A | CP-690,550 5 mg | Psoriasis | 52 | 45.9 | 331 | HADS |
| | | CP-690,550 10 mg | | | 44.3 | 341 | |

* eTIPS, electronic Targeted Intervention for Psoriasis

[†] BIW, twice weekly

^{††} QW, once weekly

Table 2 Baseline scores and change in scores after treatment as reported in each study

| Author, Year | Interventional study arm | Baseline score HADS-D | Baseline score HADS-A | Baseline score DLQI | Change in score HADS-D | Change in score HADS-A | Change in score DLQI | Expected DLQI score change for 1 HADS-D point |
|---|-----------------------------|-----------------------|-----------------------|---------------------|------------------------|------------------------|----------------------|---|
| Bundy 2013¹⁶ | eTIPS* | 5.00 | 7.60 | 6.60 | -0.61 | -0.77 | -2.46 | 4.03 |
| Dauden 2009¹⁷ | Etanercept (Continuous) | 5.70 | 7.21 | 12.80 | -1.76 | -1.99 | -8.75 | 4.97 |
| | Etanercept (Paused) | 6.20 | 7.67 | 13.80 | -1.53 | -1.84 | -7.71 | 5.04 |
| Gniadecki 2012¹⁹ | Etanercept BIW [†] | 6.60 | 8.30 | 12.30 | -1.60 | -1.90 | -7.90 | 4.94 |
| | Etanercept QW ^{††} | 6.40 | 8.00 | 12.30 | -1.40 | -1.70 | -6.80 | 4.86 |
| Langley 2010²⁰ | Ustekinumab 45 mg | 4.90 | 6.80 | 12.20 | -1.70 | -1.60 | -9.30 | 5.47 |
| | Ustekinumab 90 mg | 5.40 | 6.90 | 12.60 | -2.10 | -1.60 | -10.00 | 4.76 |
| Trial No: NCT01309737²¹ | CP-690,550 5 mg | 6.00 | 7.05 | 13.22 | -2.38 | -2.69 | -8.18 | 3.44 |
| | CP-690,550 10 mg | 5.64 | 6.94 | 12.69 | -2.50 | -2.62 | -9.43 | 3.77 |
| Mean (SD) | | 5.76 (0.59) | 7.39 (0.53) | 11.1 (2.16) | -1.73 (0.57) | -1.86 (0.57) | -7.84 | 4.59 |
| Range | | 4.90 to 6.60 | 6.80 to 8.30 | 6.60 to 13.80 | -2.50 to -0.61 | -2.69 to -0.77 | -10.00 to -2.46 | 3.44 to 5.4 |

* eTIPS, electronic Targeted Intervention for Psoriasis

[†] BIW, twice weekly

^{††} QW, once weekly