**Title: Hyperhidrosis Quality of Life Measures: Review and Patient Perspective**

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##### Hyperhidrosis Quality of Life Measures: Review and Patient Perspective

##### Abstract

***Purpose***

To identify the tools that have been used to measure quality of life in hyperhidrosis research and obtain patient insight on commonly used tools.

***Methods***

Twelve databases were searched to identify studies that reported measuring quality of life or described a quality of life tool in the context of hyperhidrosis. Data on the use of the tools were tabulated and hyperhidrosis-specific and dermatology-specific measures were summarised. A workshop was held to obtain the patients’ perspective on the most commonly used tools and the newly developed HidroQoL© tool.

***Results***

182 studies were included in the review. Twenty-two quality of life tools were identified; two or more tools were often used in combination. The most commonly used tools were the Hyperhidrosis Disease Severity Scale, the Dermatology Quality of Life Index and the Hyperhidrosis Quality-of-Life Questionnaire. Patient advisors preferred the new HidroQoL© tool, which was considered to be easy to complete and most relevant to hyperhidrosis patients.

***Conclusions***

There are several tools available for assessing quality of life in hyperhidrosis patients; disease specific measures are widely used and appear suitable. It is unclear which tool is the most reliable, although the HidroQoL© tool was preferred by a small group of patient advisors.

**Key words:** hyperhidrosis, quality of life, dermatology, review

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##### Introduction

Hyperhidrosis is characterised by uncontrollable excessive and unpredictable sweating. Primary hyperhidrosis has no discernible cause and is thought to affect approximately 1% of the UK population [1]. It most commonly involves the axillae, hands and feet, but may also involve other areas of the body. The symptoms of hyperhidrosis can significantly affect a patient’s quality of life, and can lead to social embarrassment, loneliness, anxiety and depression. Primary hyperhidrosis usually develops in childhood and adolescence. Teenagers may struggle to do schoolwork and exams, due to problems holding a pen and sweating ruining paperwork in classwork or in exams. Adults may find the condition affects employability. It may prevent individuals having personal relationships. The unpredictable and uncontrollable nature of the condition can make it very distressing for sufferers.

It is important that treatments used to manage hyperhidrosis symptoms not only reduce sweating, but also have a beneficial effect on patients’ quality of life. Therefore, health related quality of life should be assessed in clinical studies.

##### Objectives

To identify the tools that have been used to measure quality of life in hyperhidrosis research and obtain patient insight and perspective on commonly used tools.

##### Materials and methods

This review was undertaken as part of a broader project assessing the clinical and cost-effectiveness of interventions for the management of primary hyperhidrosis in secondary care [2]. The protocol for the broader project was registered on PROSPERO (number CRD42015027803).

To identify all the tools used for the assessment of quality of life in hyperhidrosis research we adopted two literature search strategies. Twelve electronic databases (including MEDLINE, EMBASE and PsycINFO) were searched in January 2016. The first search strategy was conducted as part of the broader project and combined relevant search terms for ‘hyperhidrosis’ with search terms for treatment types, e.g. ‘iontophoresis’. The second search strategy combined search terms for ‘hyperhidrosis’ with a recognised search filter for ‘quality of life’. No date or language limits were applied. The ‘quality of life’ specific search strategy developed for Ovid MEDLINE is presented as Appendix 1, together with the full list of electronic databases searched. Clinical advisors were consulted for additional potentially relevant studies and the reference lists of relevant reviews were manually searched. An update search of MEDLINE was performed in March 2018 to check for new studies of the HidroQol tool; none were found.

Two reviewers (RW and J J-D) single screened titles and abstracts obtained through the search, with a sample of 10% of records double screened to confirm agreement between the reviewers; the level of agreement between reviewers was 96.2%. Full manuscripts of potentially relevant studies were obtained and independently screened by two reviewers (RW and J J-D), using pre-defined eligibility criteria. Disagreements were resolved through discussion or consultation with a third reviewer.

All studies that reported measuring quality of life or described a quality of life tool in the context of primary hyperhidrosis were included. These studies were identified at the abstract screening stage or from the full papers ordered for the review of effectiveness. It is acknowledged that some papers excluded from the effectiveness review at the abstract stage may have mentioned quality of life in the full paper: such studies will have been missed. However, we consider that it is unlikely that any important quality of life tools have been missed, owing to the large number of studies screened.

Data extraction into Microsoft Excel comprised of details of the quality of life tool or tools used; whether the tool was disease specific for hyperhidrosis, disease specific for skin disease, or a generic quality of life tool; and any description of the validity of the tool was also extracted, where available. Data were extracted by a single reviewer and checked by a second reviewer (RW and J J-D).

The included studies were not quality assessed as they were not necessarily studies evaluating the effectiveness of interventions, nor was the information extracted effectiveness data. Whilst the COSMIN quality checklist suggests it could be useful when selecting a measurement instrument, it was found that it could not be readily used as it requires a high level of detailed information about how a tool was developed, far more than was available for this review; the studies found did not provide sufficient information to enable such a detailed assessment of methodological quality.

Data on the use of the quality of life tools were tabulated and hyperhidrosis-specific and dermatology-specific measures were summarised in a narrative synthesis. The aim of the review was to provide an overview of tools used in hyperhidrosis. As a formal validation of each tool was beyond the remit of this review no statistical analysis was undertaken.

##### Results

The searches identified 337 publications in total, of which 182 studies were relevant for inclusion in the review. Twenty-two individual tools for measuring quality of life were identified, summarised in Table 1. Some studies reported using more than one tool, hence the total number of studies in which the tools were reported is 208.

###### A brief description of the hyperhidrosis and dermatology specific measures is presented below.

###### **Hyperhidrosis specific measures**

###### Hyperhidrosis Disease Severity Scale (HDSS)

The HDSS was identified as the most commonly used tool; it was used in 63 studies in total, in both surgical and medical hyperhidrosis research. The HDSS was often used in combination with the Dermatology Life Quality Index (DLQI), with 18 studies using both tools.

The HDSS is a disease specific tool considered important for diagnostic use in clinical practice and for research to identify and quantify the severity of disease in patients with hyperhidrosis and also to assess treatment effects over time [3,4]. The HDSS allows researchers to measure the impact hyperhidrosis has on those suffering from excessive sweating using a four point scale:

1. My sweating is never noticeable and never interferes with my daily activities.

2. My sweating is tolerable but sometimes interferes with my daily activities.

3. My sweating is barely tolerable and frequently interferes with my daily activities.

4. My sweating is intolerable and always interferes with my daily activities.

The tool’s simple design has raised questions of its value as a tool to measure patient reported quality of life and a consensus exercise by the Canadian Hyperhidrosis Advisory Committee selected the HDSS more as a measure of disease severity [3]. However, an assessment of the validity and reliability of the HDSS found that HDSS score four weeks post treatment correlated well with the DLQI and relevant activity items from the Hyperhidrosis Impact Questionnaire (HHIQ) (r=0.35 to 0.77; p=<0.001) [4].

###### Hyperhidrosis Quality-of-Life Questionnaire (HQLQ)

The HQLQ was designed by De Campos and colleagues in 2003 as a disease specific tool to assess the effect of surgical interventions for patients with hyperhidrosis [5]. The design built upon the previous validation work of Amir and colleagues [6], described below, and tested the tool on a patient sample (n=378) with the aim of replacing more generic quality of life measures.

The HQLQ questionnaire consists of a single question to start ‘*how would you rate your quality of life before and after treatment’* and the patient is asked to enter a score between 1 (excellent/much better) and 5 (very poor/much worse). This is followed by twenty questions selected for relevance from the 35 items in the Amir questionnaire [6], again scored between 1 and 5. The final score for quality of life has a range from 20 (excellent/much better after surgery) to 100 (very poor/much worse after surgery). No validation or reliability statistics or cross-validation with other tools was reported.

###### Keller Hyperhidrosis Scale (Keller et al. 2001)

The Keller Hyperhidrosis Scale was designed by Keller and colleagues in 2001 to measure preoperative and postoperative quality of life scores of patients receiving bilateral endoscopic thoracic sympathectomy for palmar and plantar hyperhidrosis [7]. The tool measures quality of life on a scale of 0 (mild) to 10 (severe). The validation work compared patient scores against the Short Form 36 (SF-36) and validation work reported a strong level of reliability (Cronbach’s α = 0.89).

###### Hyperhidrosis Impact Questionnaire (HHIQ)

The HHIQ was designed by Teale and colleagues in 2002 to assess the impact of hyperhidrosis on the daily lives of patients and measure the effect of treatment [8]. The development of the tool was industry funded and its relative popularity is predominantly an effect of its use in Allergan research trials. The design of the tool was informed by a review of the literature and interviews with key stakeholders (patients and physicians in the UK and Germany) and then a pilot study with the same stakeholders tested the validity and linguistic equivalence of the questionnaire [8]. The questionnaire contained four sections i) disease and treatment background, ii) direct impact on medical and non-medical resource utilisation, iii) indirect impact on employment and productivity and iv) intangible impacts on emotional status. Forty one questions measured baseline impact of the disease with 10 further questions for follow up assessments. The final design of the HHIQ was validated against the Short Form 12 (SF-12) health survey and the DLQI using a population of 345 patients and 145 non-hyperhidrosis controls. A test-retest of the 10 follow up questions using a cohort of clinical patients found consistent reliability and responsiveness.

###### Disease-specific health-related questionnaire for hyperhidrosis (Amir et al. 2000)

This tool was designed and validated by Amir and colleagues in Israel for a patient population who were considering surgery for hyperhidrosis. The tool was designed to assist with clinical decision making and to measure the efficacy of surgical interventions on sweat reduction [6].

The Amir tool was designed with 35 questions separated into the five domains with a seven point Likert scale for each response, where a score of 6 to 7 indicated a very low quality of life, 3 to 5 a medium level of quality of life and 1 to 2 a high level of quality of life. The validation exercise found a high level of reliability (Cronbach’s α = 0.84). However, a limitation of the validation work noted by the authors is that only patients waiting for surgery were used in the survey and therefore may represent only patients whose symptoms were more severe [6]. In addition, the tool was designed and validated in Israel and reported in studies conducted in Brazil, both countries have a very hot climate that could have an impact on the patient population and subsequent patient reported outcome measures.

*Hyperhidrosis Quality Of Life Index (HidroQoL©)*

The HidroQoL© is a recently developed tool, identified via publications describing its design and extensive validation [9-11].

The tool was developed as a disease specific aid to both clinical practice and research to assist with hyperhidrosis patient/clinician communication. In 2012 Kamudoni and colleagues recruited an online cohort of 71 patients from a number of social networking sites to participate in initial interviews [9]. This led to the development of a pilot tool containing 47 questions answered using a 6-point scale. Further work in 2015 [11] used modern test theory to examine differential item functioning. The second stage of validation involved a cross-sectional cohort of 595 patients who completed a number of questionnaires for comparison (HDSS, DLQI and Skindex-17). The HidroQoL© correlated well with the DLQI (r=0.6, p<0.01) and HDSS (r=0.59, p<0.001) and showed correlation to the Skindex-17 scale but to a lesser extent. Reliability, tested using baseline measures and a test-retest method, showed strong reproducibility (internal consistency, Cronbach's α overall scale = 0.89; test-retest reliability, intra-class correlation = 0.93, p<0.001).

An online longitudinal study involved 260 patients completing the tool on three separate occasions; the results indicated that the tool was responsive at identifying slight changes or small responses to treatment over time.

###### Hyperhidrosis Questionnaire (HQ)

The design and validation of the HQ was described by Kuo and colleagues in 2004 [12]. The tool’s development was informed by a review of the literature, followed by interviews with patients, nursing staff and clinicians. The pilot questionnaire contained 34 questions answered using a scale of 1 (least disturbance) to 5 (most disturbance). The study included 85 patients suffering from a combination of plantar, palmar, axilla or generalised hyperhidrosis attending a thoracic surgery outpatient clinic in Southern Taiwan between April 2002 and March 2003. Internal reliability and construct validity was reported (Cronbach’s α 0.95, range 0.71 to 0.94 across domains), but no cross-validation with other scales was reported. The final questionnaire contained 29 questions across 5 domains: functional; psychological; social; affective; and physical.

###### **Dermatology specific measures**

###### Dermatology Life Quality Index (DLQI) includes children’s version (CDLQI)

The DLQI was the most commonly used dermatology specific tool, used in 48 studies. As mentioned previously, it was often used alongside the HDSS in hyperhidrosis research. The DLQI is a concise tool (10 questions) often used in the management of chronic skin disorders [13]. Developed and validated by Finlay and Khan (1994) to provide a patient centred method for comparison between different types of skin disease, the questionnaire records the impact the disease has on a patient’s quality of life and the relative effectiveness of treatment [13].

A review of the DLQI in 2004 reported that repeatability, internal consistency and sensitivity to change have all been demonstrated for this tool and it has been cross-validated against a number of other dermatology tools, mainly for psoriasis and acne [14]. However, more recently, detailed Rasch analysis has highlighted several problems with the scale, particularly when combining DLQI scores for individuals with different types of skin condition [15].

###### Skindex - Quality of life measure for people with skin disease

The Skindex suite of tools includes the original Skindex questionnaire, Skindex-29, Skindex-17 and Skindex-16. The tool’s development was based on findings from a review of the literature and focus group interviews with patients and clinicians to construct the initial framework for the ways in which patients are affected by skin disease. The original tool was a 61-question survey developed and validated by Chren and colleagues in 1996 [16], this was refined to a 29-item questionnaire (Skindex-29) to reduce completion time and improve the tool’s evaluative properties [17]. Further refinement resulted in a 16-item questionnaire (Skindex-16) [18] for use in longitudinal research to measure changes over time in patient quality of life in addition to reducing the tool to one page. The final version of the tool (Skindex-17) was created in 2006, using a response theory model to address issues such as response order and differential item functioning [19].

In a study of 201 patients, Skindex tool scores were reproducible after 72 hours and were internally consistent (Cronbach’s α = 0.76 to 0.86). Construct validity was also demonstrated. However, physicians’ judgement of disease severity did not consistently correspond with Skindex scores and Skindex does not appear to have been cross-validated against other quality of life measures.

###### VQ-Dermato scale - A French language scoring instrument validated for chronic skin diseases

The VQ-Dermato scale was designed and validated by Grob and colleagues in 1999 to provide a French language dermatology-specific instrument for routine use to assess the quality of life of patients with ‘chronic skin disorders’ [20]. The VQ-Dermato scale is a 28-item instrument developed from interviews with patients. The tool was validated on a population of 231 hospital and private practice patients in France suffering from chronic skin conditions. A strong correlation was reported between the VQ-Dermato scale and the SF-36 (Cronbach’s α = 0.67 to 0.88).

###### Freiburg Life Quality Assessment (FLQA)

The FLQA was designed and validated as a set of dermatology-specific modules, the first module addressed the core issues of all skin diseases. The additional questions were more specific to distinct diseases. The tool was found to have satisfactory discriminatory power and validation data was published in 2004 [21].

###### Patient Benefit Index (PBI)

The PBI, developed by Augustin and colleagues in 2009, is an instrument used to identify patient reported needs and benefits of dermatology research and treatment. Assessment is a two-step process; the first to capture data on the patients’ needs prior to treatment, followed by an assessment of improvement after treatment. The result is an index of patient benefit in response to treatment. The measure was validated in 2009 using a large cohort of patients (n=500) with many different skin diseases, including hyperhidrosis (n=50) [22].

##### Patients’ perspective

The patients’ perspective was collected to complement the narrative review of quality of life measures used in hyperhidrosis research. A workshop was held at Harrogate District Hospital with four patient advisors and one dermatologist (AL). All four patients had moderate to severe hyperhidrosis for over 5 years; two patients had hyperhidrosis of the axilla and two had hyperhidrosis of the hand and axilla. Three patients were female and one was male and patients’ ages ranged from their 20s to 50s. Prior to the workshop the patient advisors were sent copies of four quality of life tools: the three most commonly used tools (HDSS, DLQI and HQLQ) and the newly developed HidroQoL© tool, and asked to consider a short list of questions about the tools (see Appendix 2). At the workshop the review of quality of life tools used in hyperhidrosis research was described and patients were asked to comment on the four tools.

All patient advisors agreed that the HidroQoL© tool was superior to the other three tools. They commented that it covers everything important to patients with hyperhidrosis and is easy to complete. The DLQI was considered to be too general and too focussed on the skin, with questions that were not applicable to hyperhidrosis patients. The HDSS was considered to be too basic and, depending on different situations, patients could easily fluctuate between an HDSS score of 2 or 3. More generally the patient advisors considered that measuring the actual amount of sweat produced (e.g. by gravimetry) was less important than measuring quality of life, and it should only be considered as a secondary outcome. They also stated that single measurements in time could give the wrong impression of the severity of hyperhidrosis and do not necessarily reflect the patient’s overall condition. The patient advisors considered that the HidroQoL© tool should be the primary outcome in future studies of interventions for hyperhidrosis.

##### Discussion

The aim of this review was to identify the tools used to measure quality of life in hyperhidrosis research. The review identified a number of tools; the HDSS, the DLQI and the HQLQ were used more often than any other tool for measuring quality of life in hyperhidrosis research. The HDSS appears to have value for researchers assessing the clinical effectiveness of treatments for hyperhidrosis; it is often used to measure response to treatment. It is unclear from the literature what measures were used to design or validate the tool and it is not highly regarded as a comprehensive tool for measuring quality of life. The DLQI has a patient centred approach but it is criticised in the context of quality of life measures for hyperhidrosis for being too general and its inability to capture hyperhidrosis specific problems or concerns [11]. UK and American studies commonly used the HDSS and DLQI in combination for both surgical and medical hyperhidrosis intervention studies. The HQLQ was designed specifically for surgical interventions for hyperhidrosis making it a popular choice for surgical studies although the majority of users were in Brazil where the tool was originally developed, with none of the studies being UK based.

Of interest is the new HidroQoL© tool, developed by UK researchers as a scoring system with more focus on patient relevant measures than most quality of life tools used in hyperhidrosis research, for both research and clinical practice [10,11]. This tool was not found in any studies assessing interventions for hyperhidrosis identified for the review although this may be because the tool is still relatively new.

In summary, there are a number of tools available for assessing quality of life in patients with hyperhidrosis. Disease specific measures are widely used and appear appropriate, although with the lack of standardisation in method of development and validation it is not clear from this review which tool is the most reliable. Some of the commonly used tools, such as the HDSS, appear to lack any form of published validation during development. The combined use of two or more tools is common, but again there is a lack of clear standardisation for which combinations should be used or work best together. The type of intervention (surgical or medical) and geographical location may also be a factor in tool selection and it was not uncommon to find colleagues using the same tool. The HidroQoL© is the most recent tool to be designed and validated for measuring the quality of life of patients with hyperhidrosis and was preferred by our small group of patient advisors.

##### Conclusions

Health related quality of life should be a key outcome in future studies of interventions for hyperhidrosis. There are several tools available; disease specific measures are widely used and appear suitable. It is unclear which tool or tools are the most reliable for measuring quality of life in hyperhidrosis patients. The newly developed HidroQoL© tool has been extensively validated and was preferred by a small group of patient advisors to this project. The HidroQoL© tool should be tested alongside established tools, such as the HDSS and DLQI, to establish its reliability and patient/clinician acceptability in clinical practice and hyperhidrosis research.

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Table 1: Frequency data for the use of quality of life measures in 182 studies of hyperhidrosis

|  |  |  |
| --- | --- | --- |
| **Quality of Life measure (tool)** | **Acronym/**  **abbreviation** | **Total number of studies in which reported** |
| **Hyperhidrosis specific measures** |  |  |
| Hyperhidrosis Disease Severity Scale [3,4] | HDSS | 63 |
| Hyperhidrosis Quality-of-Life Questionnaire [5] | HQLQ | 31 |
| Keller Hyperhidrosis Scale [7] | Keller, 2001 | 10 |
| Hyperhidrosis Impact Questionnaire [8] | HHIQ | 8 |
| Disease-specific health-related questionnaire for hyperhidrosis [6] | Amir, 2000 | 5 |
| Hyperhidrosis Quality of Life Index [9-11] | HidroQoL© | 3 |
| Hyperhidrosis Questionnaire [12] | HQ | 2 |
| **Dermatology specific measures** |  |  |
| Dermatology Quality of Life Index (includes children’s version CDLQI) [13] | DLQI | 48 |
| Skindex - Quality of life measure for people with skin disease [23] | Skindex | 6 |
| VQ-Dermato scale - A French language scoring instrument validated for chronic skin diseases [20] | VQ-Dermato scale | 1 |
| Freiburg Life Quality Assessment [21] | FLQA | 1 |
| Patient Benefit Index [22] | PBI | 1 |
| **Generic quality of life tools** |  |  |
| Short Form 36 health status survey [24] | SF-36 | 13 |
| Short Form 12 health status survey [25] | SF-12 | 7 |
| Illness Intrusiveness Rating Scale [26] | IIRS | 2 |
| Leibowitz social anxiety scale [27] | Liebowitz, 1987 | 1 |
| Questionnaire of Quality of Life (adapted from the Caregiver Questionnaire) [28] | QQL | 1 |
| University of California loneliness scale [29] | UCLA V3 | 1 |
| Nottingham Health Profile [30] | NHP | 1 |
| The Everyday Life Questionnaire [31] | EDLQ | 1 |
| State-Trait Anxiety Inventory [32] | STAI | 1 |
| International quality of life assessment [33] | EuroQoL 5D-5L (EQ-5D) | 1 |