Health-related quality of life in dermatology: measurement, interpretation and application
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GENERAL DISCUSSION
INTRODUCTION

In the last decades, a lot has changed in the management of patients with chronic skin diseases. The introduction of health-related quality of life (HRQoL) in dermatology by Professor A.Y. Finlay and Dr G.K. Khan in 1994 has played an important role in this development. Putting the patient in the center of health care management and, thereby, aiming to improve patient care and shared decision making, requires reliable, valid, and interpretable patient-reported outcome measures (PROMs).

The overall aim of this thesis was to contribute to the improvement of HRQoL of patients with a chronic skin disease. The focus of the thesis was on (i) the measurement of HRQoL in dermatology, (ii) the interpretation of HRQoL data, and (iii) the application of a HRQoL intervention in daily clinical practice. First, in order to contribute to the quality of the measurement of HRQoL in dermatologic research and clinical practice, understanding of the concept HRQoL and the related methodology are prerequisites (chapter 2.1). Second, to effectively use HRQoL data in clinical practice, insight into the interpretation of HRQoL scores, or differences in scores, is required (chapters 3.1 through 3.4). Third, to support the application of a HRQoL intervention in clinical practice, it is essential that clinicians recognize and acknowledge the relevance of HRQoL measurement and the application of HRQoL data in their patient consultations (chapter 4.1). Finally, to enhance the implementation of a HRQoL intervention during patient consultations, the effectiveness of such an intervention in a clinical setting should be established (chapter 4.2 and 4.3).

The chapters of the thesis are summarized (chapter 5). This final chapter (chapter 6) reflects on the main findings and limitations, and concludes with a discussion on future perspectives.

WHERE ARE WE?

Measurement of health-related quality of life in dermatology

To contribute to the quality of HRQoL measurement in dermatology, in chapter 2.1 we presented a review article on the measurement of HRQoL in dermatological research and clinical practice. An introduction to the concept and methodology of HRQoL was provided, an overview of the most commonly used HRQoL instruments in dermatology was presented, background information was provided on the psychometric quality of these instruments, and a suggestion for the selection of a HRQoL instrument was given.

This review article, which was written on behalf of the European Academy of Dermatology and Venereology (EADV) Taskforce on Quality of Life, was intended for clinicians and junior researchers who are relatively unfamiliar with HRQoL measurement in dermatology. Therefore, less attention was given to modern test theory models. However, as modern test theory models are today generally acknowledged as a step forward in HRQoL instrument development and testing, it was highly recommended that instruments based on classical test theory models, as well as future instruments, are being (re-)analyzed according to modern test theory models. It was suggested that the EADV Taskforce should pay specific attention to modern test theory models in a subsequent article.

In addition, it was discussed that to date there is no univocal consensus among researchers and clinicians as to which particular HRQoL instrument should be used in dermatology. Hence,
similar outcomes will continuously be measured with different instruments. Agreement on a preferred HRQoL instrument, however, would enable adequate comparison of scores and syntheses of data across studies.

**Interpretation of health-related quality of life scores**

To effectively use HRQoL data in clinical practice, insight into the interpretation of HRQoL scores, or differences herein, are important prerequisites. In chapters 3.1 and 3.2, we presented clinically meaningful cut-off scores for the Skindex-29, using an anchor-based method. The established Skindex-29 domain and overall cut-off scores are indicative for patients with a mildly, moderately, or severely impaired HRQoL. With these cut-off scores, we were able to facilitate the interpretation of Skindex-29 scores. This may aid in understanding what these scores mean to dermatological patients whose HRQoL might be affected by their skin diseases. Relatively similar cut-off scores were found for mild and moderate impairment on the Symptoms domain. This resulted from the lower correlation of the particular anchor question with the corresponding Skindex-29 domain score and the lower discriminating capacity between patients who experienced a mildly or moderately impaired HRQoL. In addition, the established cut-off scores were generally higher compared to the ranges of scores that were established by a distribution-based method, presented by Professor T.E.C. Nijsten and colleagues. This may be the result of different methods used, differences in the distribution of diagnosis, and/or HRQoL scores of the samples.

In a commentary by Dr F. Sampogna and Dr D.D. Abeni, our cut-off scores were compared to ranges of scores of Professor T.E.C. Nijsten and colleagues. They showed that the use of different methods in different study populations does result in different categorizations of scores and, as a consequence, may have different clinical implications. In chapter 3.3 we reflected on this commentary. We suggested performing a future study to investigate the interpretability of Skindex-29 scores by combining anchor-based and distribution-based methods in a single study population. This would allow an adequate comparison of the categorization of scores.

In addition to the categorization of Skindex-29 scores, in chapter 3.4 we presented clinically meaningful differences in scores, using an extension of an item response theory (IRT) model, the one-parameter logistic model (OPLM). With the results of this study, we provided an answer to the question which score difference represents a clinically meaningful difference on item level in terms of complaints.

By applying Skindex-29 data to the OPLM, not only the clinical meaningfulness of differences in Skindex-29 scores could be determined, it also provided additional insight into the psychometric characteristics of the Skindex-29. It became very clear that the Skindex-29 consists of two instead of three domains, namely a Psychosocial and a Symptoms domain. In addition, it was confirmed that the original scale is not truly uni-dimensional, which is in agreement with the results found by Professor T.E.C. Nijsten and colleagues. In contrast with this study on the development of the Skindex-17, which is a Rasch reduced version of the Skindex-29, we found both clinical and psychometric arguments for maintaining all 29 items in the questionnaire. In addition, our results also suggested that Skindex-29 items clearly differed in their discriminating capacity and, thus, needed weighting before calculating domain scores.
The Skindex-29 in its current format does not meet the current high standards of instrument development. It was therefore suggested to perform confirmative and conclusive research on the original scoring system of the Skindex-29.

Health-related quality of life application in clinical practice

To support the use of HRQoL measurement in clinical practice, in chapter 4.1 we presented an overview of the relevance and application of the measurement of HRQoL in dermatological practice. We described why the measurement of HRQoL is important, which patients might benefit from it, and how HRQoL measurement can be applied in clinical practice. However, to successfully implement HRQoL measurement in clinical practice, valid conclusions with regard to the added value of a HRQoL intervention are essential.

Previous randomized controlled trials (RCTs) measuring the efficacy of patient reported outcome (PRO) interventions in other medical specialties have been highly heterogeneous in setting, patients, intensity and content of the PRO intervention. A diversity of outcomes was reported that makes it very difficult to interpret the evidence on the effectiveness of such interventions in clinical practice. Although Dr. J.M. Valderas and colleagues could not draw valid conclusions regarding the effectiveness of such interventions,6 the possible impact of PRO measurement in clinical practice included the detection of physical or psychological problems that might otherwise be overlooked, the monitoring of disease progression,7-10 the facilitation of doctor-patient communication and shared decision making,11 and the potential of enhancing patient-centered care.12

In dermatology, empirical data on the effectiveness of a HRQoL intervention in clinical practice is missing. In chapter 4.2 we described the rationale and design of a RCT investigating the efficacy of a HRQoL intervention on, primarily, patients’ HRQoL and doctor-patient communication and, secondary, on health status and disease severity in patients with moderate to severe psoriasis. In chapter 4.3 we presented the results of this RCT. We did not find evidence of efficacy of a HRQoL intervention in dermatological practice on the primary and secondary study outcomes. These results are in contrast with a study performed by Professor G. Velikova and colleagues,13 but consistent with other findings.14-20 Nevertheless, we observed a positive effect on patients’ and physicians’ satisfaction with the process of care, and the discussion of HRQoL aspects during the patient consultations was enhanced. The intended effect of the HRQoL intervention was reflected by the number of HRQoL aspects discussed, but at the expense of a longer consultation time. These results are in agreement with other studies,14,19,21 with the exception of the prolonged consultation.13,14 The discussion of HRQoL aspects may provide valuable information that can be used in patient management. Herewith, the HRQoL intervention may serve as a tool for improving patient care, which should be evaluated by future research.

WHERE SHOULD WE BE GOING?

The application of HRQoL measurement in dermatological practice and the use of HRQoL data may still interfere with current routine clinical practice, and outcomes research in dermatology remains challenging. In addition, insight into and knowledge of instrument development and testing has evolved.
Consensus on the preferred outcome measure

In the absence of consensus on a preferred HRQoL instrument in dermatology, the selection of an instrument remains a trade-off between, among others, the quality of an instrument, the research question, and target population. However, uniformity in PRO measurement, data collection and reporting will overcome limitations such as inconsistencies in the outcomes reported and difficulties in the interpretation, comparability, and synthesis of these outcomes.\(^\text{22}\)

The importance of uniformity is being recognized by several international project groups. The International Society for Quality of Life Research (ISOQOL) developed standards for the design and selection of PROMs to be used in patient-centered outcomes research and comparative effectiveness research.\(^\text{23,24}\)

The COnsensus-based Standards for the selection of health status Measurement Instruments (COSMIN) Initiative aims to improve the selection of instruments, and developed a checklist containing standards for evaluating the methodological quality of studies on the psychometric characteristics of instruments (www.cosmin.nl/). Further, the Harmonising Outcome Measures for Eczema (HOME) Initiative in dermatology (www.homeforeczema.org/) and the Outcome Measures in Rheumatology (OMERACT) Initiative (www.omeract.org/) are developing consensus-based sets of outcomes to be measured in clinical research. In addition, the Core Outcome Measures in Effectiveness Trials (COMET) project group undertakes different initiatives to support the development and application of agreed standardized sets of outcomes (www.comet-initiative.org/). These project groups are closely connected and are currently investigating which outcomes should be measured and reported as a minimum in all clinical trials of a specific condition. A subsequent next step would be how to measure these outcomes; i.e., which instruments should be used.

In the absence of consensus on a preferred instrument, consensus-based methods, such as (international) Delphi studies, are useful methods to establish consensus on the instrument of choice. These methods are used to synthesize data from experts, based on expertise and scientific background.\(^\text{24,25}\)

With an international Delphi study it would be possible to achieve consensus on the (type of) HRQoL instrument to be used in dermatology.

Modern test theory models

The preferred instrument to measure HRQoL should be of high methodological quality, that is, developed and tested according to modern test theory models. On either clinical or methodological grounds, the present dermatology-specific HRQoL instruments in their current formats do not meet these higher standards of instrument development and testing.\(^\text{5,26,27}\)

Together with the absence of consensus on the preferred HRQoL instrument, we are currently standing on a crossroad. Outcomes researchers and clinicians should decide which direction to take: further refinement of existing HRQoL instruments and addressing the suggestions for future research, or developing new instruments according to innovative and promising methods.

An ultimate next step in the evolution of PRO measurement in dermatology would be the development and/or validation of (existing) item banks for (domains of) HRQoL. Item banks are based on IRT models and are sets of items with their associated calibrations (i.e., hierarchy) that measure a certain construct. Item banks enable computer-adaptive testing (CAT). CAT is a method of administering an item bank by computer: the questions that are asked, adapt to the patient’s response to the previous question (i.e., ability level). With this,
item banks and CAT provide tailored measurements that reduce the test burden of both patients and clinicians, and provide efficient, precise, valid, and responsive instruments that can be adapted to different health conditions. Because of the hierarchy of the items, scores can be compared and data can be synthesized. For example, the Patient-Reported Outcome Measurement Information System (PROMIS) Network, funded by the National Institutes of Health, is developing series of item banks and provide clinicians and researchers access to these item banks (www.nihpromis.org). The development of item banks and CAT is innovative and considered to be the next step in the development of PROMs. 28

**Future perspectives**

In dermatology, future research should focus on the development and validation of item banks for (domains of) HRQoL to meet the current high quality standards for PRO measurement. This may ultimately add to the application of standardized and uniform PROMs in dermatological research and clinical practice.

**CONCLUSIONS**

In the changing management of patients with chronic skin diseases, the culture of outcomes research and clinical practice in dermatology need to alter as well. It is well known that the severity of a skin disease is not fully reflected by the characteristics of the skin disease only; it is also illustrated and reflected by aspects that can only be determined by PROs. 29 A good understanding of these aspects, as well as a positive attitude towards HRQoL measurement, good communication skills, skills in the interpretation of scores, and the willingness to apply such an important outcome parameter, are prerequisites to successfully implement HRQoL assessment in clinical practice. 30,31 What we need are dedicated outcomes researchers, methodologists, and psychometricians who continue working on this important patient-centered outcome in research, as well as clinicians willing to apply PROMs in clinical practice.

**REFERENCES**

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