

Quality of life in diabetes

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This article emphasises the need to assess quality of life (QoL) as a key outcome of diabetes management and introduces the linguistically validated and culturally adapted, Hindi and Punjabi versions of an individualised questionnaire (the ADDQoL) to assess the impact of diabetes on the QoL of Indian people with diabetes. ADDQoL findings in the UK indicated that approaches to diabetes management were needed that allowed for dietary freedom. Use of the ADDQoL in the subsequent DAFNE (Dose Adjustment For Normal Eating) trial showed significant benefits to quality of life from training in insulin dose adjustment to provide for dietary freedom without loss of diabetes control. ADDQoL findings from research in India have helped highlight the negative impact of diabetes on various life domains of Indian people with diabetes, especially their self-confidence, their family life and their freedom to eat as they wish. It is suggested that targets of diabetes management are more likely to be achieved if the importance of protecting and improving QoL is recognised and monitored alongside biomedical outcomes such as blood glucose levels.

KEY WORDS: Clinical trial, diabetes, diabetes-specific measures, dietary freedom, health care, linguistic validation, Patient Reported Outcomes (PRO), Quality of Life (QoL).

Health-care professionals are becoming increasingly aware of the need to assess and monitor the quality of life (QoL) as an important outcome of diabetes care. QoL is an important outcome in its own right, but also because it may influence the patient's self-care activities, which may consequently impact their diabetes control and

management. If the demands of a treatment regimen do not fit in with how the patients wish to live their lives, they may choose to compromise achieving tight blood glucose control in order to protect their QoL.^[1]

QoL is a multifaceted, dynamic concept and particular care is needed to define and assess this psychological outcome. Joyce stressed the highly subjective characteristic of QoL by defining it as "what the patient says it is".^[2] In other words, QoL is how good or bad a person feels their life to be. This view emphasizes the most essential feature of measuring QoL, which is to capture the individual's subjective evaluation of their QoL and not what others imagine it to be. Clinicians and nurses may feel that because of the enduring relationships they share with their patients they know them well and therefore have a good knowledge of their QoL. However; such impressions can be quite misleading. Walker and Bradley^[3] showed that when the diabetes-specialist nurse rated the QoL of her teenage patients, those ratings correlated more strongly with patient's HbA_{1c} levels ($\rho = -0.38$) than with the QoL ratings of the patients themselves ($\rho = 0.08$) which, in turn, showed a small, positive correlation with HbA_{1c} ($\rho = 0.29$). Thus, although the patients tended to associate better blood glucose control with worse QoL, the nurse tended to assume that better blood glucose control would be associated with better QoL. Health professionals, with their particular focus on biomedical outcomes, are likely to produce estimates that cannot be regarded as substitutes for measuring the patients' personal opinions on how diabetes affects their QoL.

The literature is full of reports, claiming to measure QoL using questionnaires, which in fact are actually measures of health status and measure quality of health rather than QoL. It is likely that health status will have some correlation with how good or bad a person feels their life

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to be, but quality of health and QoL are not the same thing. Efforts to achieve excellent health may damage QoL. Therefore, results can be highly misleading if we interpret health status measures as if they are measures of QoL. The UK Prospective Diabetes Study (UKPDS) investigated the effects of intensifying blood glucose control on complications of people with type 2 diabetes. Researchers involved in this study wanted to measure QoL but in late 1970s, when the study started, there were no diabetes-specific QoL measures available and they used the EuroQoL (also known as the EQ5D), which is a health status measure. However, when the results of this study were reported later in late 1990s, the health status measure had been misinterpreted as a QoL measure.^[4] The researchers incorrectly and overoptimistically claimed that intensifying treatment for people with type 2 diabetes had no impact on their QoL, whereas, in fact, what they had found was that intensifying treatment of type 2 diabetes had no impact on the perceived health of the participants.^[5] Results of such studies which fail to distinguish between QoL and health status measures need to be interpreted with particular care. We now have validated measures of QoL, including condition-specific, individualized instruments that allow the individual to respond only to those aspects of life that are relevant to them, rate the impact of their diabetes on the aspects of life and rate the importance of each aspect for their QoL.

The audit of diabetes-dependent QoL

The audit of diabetes-dependent QoL (ADDQoL) is an individualized questionnaire measure to assess the impact of diabetes on QoL.^[6,7] The design of the ADDQoL was influenced by the philosophy underlying the individualized SEIQoL interview method.^[8] The ADDQoL allows the respondent to indicate aspects of life which are not applicable to them, rate the amount of impact of diabetes, positive or negative, on the applicable aspects of life, and rate the perceived importance of each applicable aspect of life for their QoL. The impact rating is multiplied by the importance rating for each applicable aspect of life to provide weighted impact scores, which can be averaged across all applicable domains to form a single, average-weighted impact (AWI) score. The ADDQoL includes two overview items designed for audit purposes: the generic or “present QoL” and the diabetes-specific or “impact of diabetes on QoL.” There are 19 domain-specific items, designed for clinical and research use, which are concerned with the impact of diabetes on specific aspects of life such as “working life,” “family life,” “freedom to eat as I wish,” and “self-confidence.” This instrument has proven to be sensitive to changes in treatment,^[9] and unlike health status instruments

commonly used in diabetes; it is not affected by comorbidity unrelated to diabetes.^[10] The features that individualize the ADDQoL give the ADDQoL important advantages over other instruments used in diabetes research, which claim to measure QoL.

The ADDQoL was used as part of the DIABQoL+ study involving approximately 800 patients with diabetes from two hospital diabetes clinics in the United Kingdom.^[7] Considerable individual variability was observed within the AWI of various items. However, the greatest negative impact was reported for “freedom to eat as I wish,” indicating that dietary restrictions exerted considerable negative impact on the QoL of people with diabetes. This finding has been replicated in several centers and several other countries, suggesting that interventions that promote dietary freedom will do much to improve QoL. Unlike the EuroQoL health status measure which was unable to detect any effect of treatment intensification in the UKPDS, the ADDQoL in the DIABQoL+ showed significant differences between more and less intensively treated patients. Patients treated with insulin reported greater negative impact on their QoL than those who were treated with tablets or *diet alone*.^[7] This difference was significant on the overall AWI score and on many of the specific domains. “Freedom to eat as I wish” was the most negatively impacted aspect of life for both subgroups of people with diabetes, whether they were treated with insulin or not. These results suggest that if restrictions on dietary freedom could be reduced, the negative impact of diabetes on QoL for people with type 1 or type 2 diabetes might also be reduced.

Dose adjustment for normal eating: the DAFNE trial methods of protecting dietary freedom and also improving glycemic control at the same time have previously been developed by Berger and colleagues in Dusseldorf^[11] and Howorka in Vienna.^[12] The DAFNE trial in the United Kingdom evaluated the Dusseldorf training program in a flexible, intensive insulin regimen combining dietary freedom with insulin adjustment.^[9] Patients in this trial were trained to match their insulin doses to their food choices while keeping their blood glucose levels close to normal. Because “dietary freedom” was the most impacted aspect of life for people with diabetes, it was expected that the Dusseldorf approach would improve QoL as well as improving glycemic control in people with type 1 diabetes.

Results from the DAFNE trial demonstrated highly significant improvements in glycemic control, treatment satisfaction, well-being, and QoL scores of the

participants with no significant change in severe hypoglycemia, weight, blood pressure, or lipids.^[9] As expected, the negative impact of diabetes on dietary freedom as measured by the ADDQoL was markedly improved by DAFNE. Many other individual domains also showed significant improvements, as did the overall AWI score combining all domains and the overview item measuring QoL *per se*.

Diabetes-specific psychological measures for use in India

It will be useful to study whether approaches similar to DAFNE in the United Kingdom could be used in India to help improve the QoL and glycemic control of diabetes patients. First, however, it is important to develop reliable and valid psychological measures in native Indian languages, which can assess psychological outcomes of diabetes care in India and identify whether diabetes has a similarly negative impact on the QoL of people with diabetes in India.

We undertook the linguistic validation of five diabetes-specific measures in Hindi and Punjabi, including the ADDQoL.^[13] The questionnaires were translated using the procedures developed by the Mapi Research Institute (Lyon, France)^[14] and culturally adapted for use with people in India and Indians living in the United Kingdom. Figure 1 outlines the various components of the linguistic validation process which were undertaken for each questionnaire in each language. Each of the stages illustrated in this figure is an essential step toward ensuring not only that the version of the questionnaire being developed captures the intended meaning of the

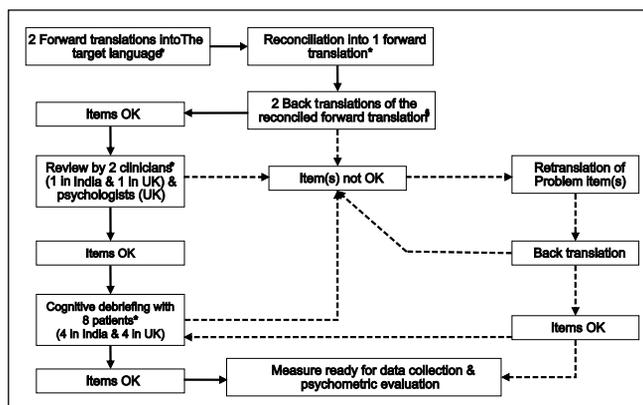


Figure 1: Linguistic validation methodology used to develop each questionnaire in each language.

*Forward translators, reconciler, clinicians and patients were native speakers of Punjabi or Hindi. Translators and clinicians were also fluent in English. One of the psychologists was native English and the other was a native speaker of both Hindi and Punjabi and fluent in English.

‡Back translators were native English speakers, fluent in Hindi or Punjabi

source questionnaire but also to ensure the appropriateness of the translation for the cultural group with whom it is to be used. The complexity of the process of translating questionnaires is commonly underestimated. It is a very time-consuming process and hence expensive. However, if shortcuts are taken, the validity of the measures being developed is compromised and the final results could be misleading.^[15]

QoL in people with diabetes in India

The ADDQoL-19 in Hindi and Punjabi has recently been used along with other measures in a study conducted at the Postgraduate Institute of Medical Education and Research (PGIMER) in Chandigarh, India. The questionnaires were completed by 108 patients in Hindi and 102 patients in Punjabi. In India, it seemed that self-confidence is more generally affected by diabetes and family life is more negatively impacted. These aspects are seen as rather more important in India than in the United Kingdom.

Figure 2 presents a comparison between the DIABQoL + study data from the United Kingdom and the data from India, including the 16 items that are very similar in the two versions of the ADDQoL used—the ADDQoL 18 (for the DIABQoL+ study) and the ADDQoL 19 (a more recent version used for the study in India). All aspects of life were reported to be more negatively impacted in India. Even though freedom to eat as I wish was not reported to be the most negatively impacted in India, it was still more negatively impacted than in the United Kingdom.

The DAFNE study showed significant improvements in the “confidence” domain of the ADDQoL with DAFNE training, together with most other aspects of life. The

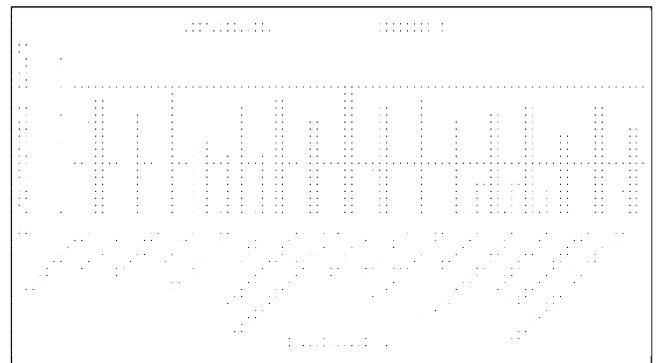


Figure 2: Showing the mean weighted impact scores on the ADDQoL from the UK DIABQoL+ study compared to the Indian data from the Hindi ADDQoL.

^{18/19}Minor variations in wording are shown with superscripts showing wording used in the latest ADDQoL 19 and that used in the ADDQoL 18 in the DIABQoL study.

*The results from the Punjabi ADDQoL (not shown in this figure) were very similar to the Hindi data.

present study highlights that there is plenty of scope for such improvements here in India not just with the intensive DAFNE approach for those using insulin but also by changing tablet treatment regimens to treatments that do not require regular meals at particular times and unwanted snacks.

The ADDQoL has led the way in the development of similar individualized QoL measures for other conditions such as renal failure (RDQoL), growth hormone deficiency (HDQoL), macular disease (MacDQoL), diabetic retinopathy (RetDQoL), underactive thyroid (ThyDQoL), and the ADDQoL Teen for teenagers with diabetes. These measures are now being increasingly widely used in the United Kingdom and worldwide and development of other versions is either planned or in progress.

Conclusion

Treatments for chronic disorders may damage QoL of patients even if they improve their health. In evaluating outcomes of diabetes care, it is essential to assess the impact of diabetes on QoL. It informs us not only about the patients' experience of living with the condition, but also shows us ways in which we could improve diabetes care. If QoL is made a target of clinical and research efforts and seen as at least as important as the target of improved health, we are more likely to achieve both.

For access to questionnaires

The ADDQoL and other measures including the DTSQs and c, the W-BQ, are available from Professor Clare Bradley, Health Psychology Research, Department of Psychology, Royal Holloway, University of London, Egham, Surrey TW20 0EX, United Kingdom. E-mail: c.bradley@rhul.ac.uk

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during the linguistic validation of the Hindi and Punjabi measures.

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