

Measuring the impact of type 1 diabetes from the patient's perspective

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ARTICLE POINTS

1 Most health-related quality of life measuring tools have been developed by professionals for patients.

2 The aim of this study was to measure the impact of diabetes from the perspective of the patient.

3 Areas that are important to patients were identified by qualitative interviews.

4 The central identified theme was that diabetes demands 'constant attention'.

5 A questionnaire was developed to reflect the emerging and central themes.

KEY WORDS

- Type 1 diabetes
- Patient perspective
- Impact of diabetes
- Insulin analogue

Introduction

Methods for assessing health-related quality of life for people with diabetes have mostly been developed by health professionals for patients. The aim of this study was to develop an assessment tool that measures the impact of type 1 diabetes on lifestyle from the perspective of the individual. The impact of type 1 diabetes was identified from interviews with patients, which were analysed and categorised into emerging themes. The Bournemouth Impact of Diabetes Scale (BIDS) was developed from the emerging themes, piloted, and then tested for reliability and validity on 237 patients with type 1 diabetes. The usefulness of BIDS was determined by examining the influence of insulin formulation (an insulin analogue or regular soluble insulin) on the impact of the condition on patients with type 1 diabetes.

People with type 1 diabetes are often upset to learn and be frequently reminded that they have a serious, life-threatening disease that cannot be cured. To add to their daily burden, successful self-management of diabetes involves multiple injections, regular blood glucose monitoring and paying attention to content and timing of meals. Extra vigilance is also essential during physical exercise, illness and holidays (Glasgow et al, 1997).

Patient-assessed measures are particularly important in chronic diseases where the main objective of self-management is reversing and/or halting decline and measuring quality of life. In a review of diabetes-specific methods that assess health-related quality of life, some were picked out as having good evidence for reliability validity (Garratt et al, 2002). Although there are a number of validated psychological scales measuring quality of life and well-being for people with diabetes, the majority have been developed by health professionals for patients, and not from the perspective of the individuals with the condition, the individuals being consulted only after professional input.

Furthermore, there is controversy as to the actual meaning of the term 'quality of life' (Bradley et al, 1999). Quality of life assessments often contain multiple questions that can take considerable time to complete and, consequently, are used mainly for research rather than in clinical practice. Despite a plethora of assessment methods being available (see for example, Everett and Kerr, 2001), it is difficult to find one that is easy to use with meaning and relevance for people with type 1 diabetes.

The aim of this study was to develop a simple tool that measures the impact of type 1 diabetes from the perspective of patients who have the condition.

Methods and results

Four stages of questionnaire development and validation were conducted:

- Identifying areas that have an impact on people with type 1 diabetes.
- Developing a questionnaire from these identified areas.
- Revision and evaluation of the questionnaire using a clinic population of people with type 1 diabetes.
- Testing the questionnaire for reliability and validity.

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Identifying the impact of type 1 diabetes

Thirty-one patients (ten interviewed twice, before and 3 months after starting a rapid acting insulin analogue; the others were using traditional soluble insulin) participated in qualitative, semi-structured interviews by one of the investigators, a diabetes specialist nurse (examples of question areas covered include 'tell me about yourself', 'what symptoms did you experience?' and 'has diabetes made any difference to your lifestyle?'; see Everett, 1999). Interviews were taped, transcribed and analysed by coding, which involved designating specific scores to words and scoring for recurrence, and then by categorising the responses into emerging themes. Further analysis revealed core constructs and a central theme. The three major constructs were:

- physical control of diabetes ('balancing act')
- personal control of diabetes ('doing what's right for me')
- control of lifestyle ('being normal').

The central theme was the constant attention that diabetes demands. A questionnaire was designed to reflect the emerging themes and core constructs.

To ensure both researcher and participant viewed the data in the same and consistent manner, participants were sent a transcript of their interview and asked to confirm accuracy of this and the emerging themes that had been identified by the researcher; response rate for confirmation was 69%.

BIDS questionnaire development

The Bournemouth Impact of Diabetes Scale (BIDS) questionnaire consists of 25 questions using a visual analogue response scale of 0–10 and takes approximately 5 minutes to complete. A reverse scoring system was designed for positive statements so that the lower the total score, the less negative impact that diabetes had upon the individual. Conversely, the higher the score, the more negative the impact diabetes was considered to have (see *Figure 1* for the first page of the questionnaire).

Revision of BIDS

To allow for an unbiased evaluation of assessed items, clinic attendees with type 1 diabetes were asked to complete and comment about the ease of use, relevance and items missing from the questionnaire.

The questionnaire had several rewrites, although changes were often minor (for example, question three in the BIDS questionnaire started out as 'eating out at restaurants is difficult'). After each change, patients attending the diabetes clinic completed the new version. Altogether, 55 patients attending the clinic were involved in the configuration of the questionnaire.

Reliability and validity testing of BIDS

Clinical practice demonstrated that people talked about improved quality of life after starting an insulin analogue (insulin lispro, the only available analogue at the time) because some of the restrictions of diabetes had been lifted. The hypothesis to be tested was: the negative impact of diabetes, when measured by the BIDS, will differ according to the type of insulin (analogue or soluble) used.

To test for reliability and validation of BIDS, the study participants were grouped into two categories of probability and non-probability samples, with the former involving a random sample of participants being used, and the latter being hand-selected.

Probability sampling involved random selection of the study participants using specific inclusion criteria:

- type 1 diabetes
- diagnosed longer than 6 months
- aged between 18 and 65 years
- on multiple daily injections
- attended Bournemouth diabetes clinic within the previous year.

A probability sample of 100 people, with a 60% response rate, was obtained by simple random sampling from the diabetes centre's central database.

In addition, a non-probability sample of 177 patients with type 1 diabetes attending the diabetes clinic for a routine

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1 The central theme derived from the BIDS questionnaire was the constant demand that type 1 diabetes demands.

2 BIDS contained 25 questions which used a visual analogue from 0 to 10.

3 The study participant's views on the questions asked were used to refine the questionnaire.

Figure 1. Page 1 of the approved BIDS questionnaire.

Name	
Date	

Bournemouth Diabetes and Endocrine Centre 'The Impact of Diabetes'

Please circle around the number that reflects your experience

Example: I have headaches																					
0	1	2	3	4	5	6	7	8	9	10	
never																					often

Question 1

I have to eat at regular times because of my diabetes

0	1	2	3	4	5	6	7	8	9	10	
not at all																					often

For scoring use only

Total overall score:

Question 2

I am always thinking about food

0	1	2	3	4	5	6	7	8	9	10	
never																					all the time

Question 3

Eating away from home is difficult

0	1	2	3	4	5	6	7	8	9	10	
not at all																					often

Question 4

I eat what I want to

0	1	2	3	4	5	6	7	8	9	10	
never																					all the time

For scoring use only

1			
2			
3			
4			
5			
6			
7			
Total for page:			
<table border="1" style="width: 100%; height: 30px;"> <tr> <td></td> </tr> </table>			

Question 5

I eat when I want to

0	1	2	3	4	5	6	7	8	9	10	
never																					all the time

Question 6

I feel guilty when eating sweet foods

0	1	2	3	4	5	6	7	8	9	10	
not at all																					often

Question 7

I am happy with my present weight

0	1	2	3	4	5	6	7	8	9	10	
never																					all the time

Table 1. Descriptive statistics of BIDS questionnaire respondents.

	Minimum	Maximum	Mean	Standard deviation
Age (years)	17	66	36.5	11.87
Duration of diabetes (years)	1	55	16.1	10.41
HbA _{1c} (%)	4.6	15.7	8.7	1.69
Body mass index (kg/m ²)	17.6	40.9	24.9	3.50

appointment was also included. Therefore, in total, BIDS was tested on a sample of 237 individuals with type 1 diabetes (see Table 1 for respondent characteristics).

The Cronbach's alpha equation measures the reliability of a questionnaire; if a questionnaire achieves a value greater than 0.7 it is considered to be of enough value to be used. BIDS achieved a score of 0.72.

The questions had been developed from the information gained from participants in qualitative interviews and in many cases their own words were used.

BIDS detected a significant difference in the impact of type 1 diabetes on patients using an insulin analogue compared with regular soluble insulin (Table 2). The BIDS score was lower (i.e. had less negative impact) in those patients using an analogue (Table 2).

There was no significant difference in age, duration of type 1 diabetes or HbA_{1c} levels between individuals using an analogue or soluble insulin (Table 3).

Limitations

Expert consultation and shared decision making with professional team members may have enhanced the study although they were not included as the assumption was made that the experts were the participants with type 1 diabetes.

Two-thirds of individuals involved in the validation of BIDS were an opportunistic sample of those attending the hospital-based diabetes clinic. Generally, more motivated and self-managing patients attend clinic appointments, perhaps biasing the sample. The demographic and clinical data were not collected for the non-responders or the non-attendees and there may have been a significant difference between these groups.

BIDS was not compared to an alternative 'gold standard' measuring the impact of diabetes and therefore concurrent validity could not be assessed.

Co-morbidity and complications arising from diabetes were not recorded

Table 2. Comparison of mean total score of BIDS with type of insulin (analogue or soluble).

Type of insulin	Number of participants	BIDS mean score	Maximum possible score	Standard deviation	p value
Analogue	113	81	250	27.1	<0.0001
Soluble	124	107	250	25.4	

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1 The impact of diabetes on quality of life is likely to depend considerably on the extent and severity of associated medical complications.

2 This study placed the perspective of the patient at the centre of the research process.

3 The BIDS questionnaire is currently being used, post-validation, at the investigators' diabetes centre to assess the quality of life of people with type 1 diabetes.

Table 3. Comparison of age variables, diabetes duration and HbA_{1c} with type of insulin.

Insulin	Number	Age, years (standard error [SE])	HbA _{1c} , % (SE)	Duration, years (SE)
Analogue	113	34 (1.18)	8.3 (0.26)	12 (1.08)
Soluble	124	35 (1.15)	8.7 (0.24)	15 (1.01)

in this study. It is known that depression and anxiety are commonly associated with diabetes and can affect quality of life (Nyhlin, 1990). There is also evidence that diabetes-related complications are associated with a poorer quality of life and the presence of two or more such complications are associated with clinically meaningful symptoms of depression or anxiety (Peyrot and Rubin, 1997). The impact of diabetes on quality of life is likely to depend considerably on the extent and severity of associated medical complications, (Rodin, 1990), therefore, results of this study may have been biased by not including co-morbidity or complications of diabetes.

Conclusions

This study placed the perspective of the patient at the centre of the research process by using qualitative information to develop a simple tool that can measure the impact of type 1 diabetes.

The hypothesis that the BIDS would be able to differentiate between a quick acting insulin analogue and slower acting soluble insulin used by people with type 1 diabetes was supported after testing on 237 people with the condition. There was a significant reduction in the impact of diabetes in patients using an analogue compared to individuals using soluble insulin.

The validation of any questionnaire is the crucial final stage in its development to ensure its effectiveness. As the BIDS questionnaire has been validated using accepted methods, it has been deemed to be a useful tool in assessing the quality of life of people with type 1 diabetes and is currently being used at the diabetes centre, Royal Bournemouth Hospital. ■

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