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Original Article

Development and psychometric properties of "Iranian diabetic adolescent girl's quality of life" questionnaire

Masomeh Hemmati Maslakpak[1], Fazlollah Ahmadi[2*], Monireh Anoosheh[2], Ebrahim Hajizadeh[3]

[1] Department of Nursing, School of Nursing and Midwifery, Urmia University of Medical Sciences, Urmia, Iran
[2] Department of Nursing, School of Medical Sciences, Tarbiat Modares University, Tehran, Iran
[3] Department of Biostatistics, School of Medical Sciences, Tarbiat Modares University, Tehran, Iran

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ABSTRACT

Background & Aim: Diabetes with permanent changes in a person's lifestyle may influence diabetic adolescent quality of life (QOL) negatively. Studies conducted on diabetic patients are increasingly measuring patient-centered outcomes such as functional status and health-related QOL (HRQOL). The development of a HRQOL questionnaire with an optimal measuring performance provides nurses with a standardized assessment tool in order to determine the impact of the disease on diabetic adolescent girl's activity daily living. This study aimed to develop and assess psychometric properties of "Iranian Diabetic Adolescent Girl's QOL (IRDAGQOL)" questionnaire.

Methods & Materials: The items and content of "IRDAGQOL" questionnaire were generated from themes and items extracted from a qualitative study using content analysis approach with the participation of 20 adolescent girls with diabetes. Face validity of questionnaire with the participation of 10 adolescent girls and content validity by 15 experts, was approved. Convergent and discriminant validity of questionnaire confirmed. Exploratory factor analyses using principal component extraction method was performed to determine the questionnaire domains. The Cronbach's coefficient alpha was calculated to determine the instrument internal consistency in 250 samples. In 30 samples, using SPSS statistical package, test re-tests after 2 weeks confirmed questionnaire reliability.

Results: The patient interviews allowed for the identification of 50 items in the final questionnaire. Principal components analysis revealed the presence of five components that jointly accounted for 79.945% of the variance. The face and content validity processes resulted in an approved and valid questionnaire. Reliability analysis showed satisfactory result (Cronbach's $\alpha = 0.870$).

Conclusion: The findings showed that the "IRDAGQOL" questionnaire presented in this study is a valid and reliable instrument that can be used for measuring adolescent girl's QOL.

Introduction

Diabetes is a chronic condition with several implications in activity daily life of people diagnosed with this disease (1). Researches have shown that adolescent patients with diabetes are susceptible to a number of issues that make management of diseases troublesome. Adolescence with diabetes misses more school than their healthy siblings and are more likely to have behavioral problems (2, 3). Delamater noted that some investigations have found a high-degree of emotional difficulty in adolescents with diabetes, including depression, suicide and latent anxiety (4). Other psychological problems of juvenile are as dependence-independence balance, self-perception, sexual identification, and body

* Corresponding Author: Fazlollah Ahmadi, Postal Address: Postal Address: Department of Nursing, School of Medical Sciences, Tarbiat Modares University, Nasr Bridge, Tehran, Iran. Email: ahmadif@modares.ac.ir

image changes (5). Management problems in adolescents with diabetes cited by clinicians include frequent food sprees, falsified urine test reports, forgetting to take insulin, and numerous missed appointments (6).

Gender differences between female and male adolescents with diabetes require additional considerations in approaches to diabetes care delivery. Adolescent girls have a higher tendency to mismanage their diabetes than boys (7); her growth as well as her emotional and intellectual functioning may be impaired (8). It is estimated that poor diabetic control may increase menstrual irregularity rate up to 50% (9). Prevalence of overweight in adolescent girls with type 1 diabetes resulted in an increased need to insulin (10). Risk of sexually transmitted disease infections in girls with diabetes is more than healthy adolescents (11).

Health-care professionals have the duty to monitor diabetic control to ensure prescribed treatment is effective to its full potential (1). Quality of life (QOL) is now recognized as an important outcome for people with diabetes. In general, diabetes has been shown to negatively affect QOL (12).

Theofilou defines QOL as an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns (13). Other experts suggest that QOL is a multidimensional, subjective, and dynamic concept (14, 15). In medical sciences, QOL is used in two ways: general QOL or the general feeling of well-being and health-related QOL (HRQOL), involving health-related problems for different diseases (16). The past few decades have witnessed considerable research about HRQOL, leading to the development and refinement of a number of generic and disease-specific HRQOL measures (17-19). A finding underscoring the importance of HRQOL is that clinical variables alone do not comprehensively capture patients' perceptions of their health (20).

Research findings suggest that in the context of pediatric diabetes care, the use of self-report questionnaires could facilitate communication between patients and their care providers and help guide clinical decision-making (21). Valid and reliable questionnaires are therefore, needed to capture changes in and relevant domains of HRQOL in young people with diabetes (22). In 2007, De Wit and colleagues reviewed generic and disease specific "HRQOL" questionnaires for adolescents with diabetes. In total, nine questionnaires were identified: four generic questionnaires and five diabetes specific questionnaires. The five diabetes specific questionnaires that were identified are the diabetes QOL-youth questionnaire (DQOL-Youth), the PedsQL-diabetes module (PedsQL-DM), the KINDL-R-diabetes module (KINDL-R-DM), the audit of diabetes dependent QOL-teen version (ADDQOL-Teen), and the recently developed DISABKIDS-diabetes module (DISABKIDS-DM) (21). Generic and diabetes specific questionnaires have both strengths and weaknesses. Ideally, a combination of a generic and diabetes specific questionnaire is used to provide a comprehensive assessment of the teenagers' HRQOL. The responsiveness of most instruments warrants further research should be sought to facilitate comparisons across centers and countries (23). Beside it is important to note that fees have to be paid for the use of these questionnaires in clinical practice (21).

According to the WHO definition of HRQOL, cultural perceptions and values play an important role in understanding the concept and the content of QOL by an individual (24). By definition, HRQOL is a method for uniform measurement of a subjective condition, thus expressing the teenager's experiences, beliefs, expectations, and perceptions (25). It is, therefore, crucial to culturally validate the existing instruments and to test their reliability or to design some specific reliable and valid instruments bearing in mind the cultural beliefs and understandings of each target group (24).

Iran has a very young population; Iranian population is near 75,149,669 that more than 3,000,000 of them are adolescents (26). It is estimated that 1 out of 400-500 adolescents has type 1 diabetes (27). Improving QOL in this age group becomes very important task. Valid and reliable questionnaire is therefore needed that can capture relevant domains of HRQOL in Iranian adolescents girls with diabetes. Taking this into consideration, this

study aimed to develop and assess psychometric properties of "Iranian Diabetic Adolescent Girl's QOL (IRDAGQOL)" questionnaire.

Methods

The items of the questionnaire were drawn up based on a qualitative study using a content analysis approach. The participants consisted of 20 adolescent girls with type 1 diabetes, aged 13-18, who had the disease for more than 1 year. All the participants were members of the Iranian Diabetes Society (IDS), a nongovernmental educational organization for diabetes in Urmia, a big urban city in the Northwest of Iran. Adolescents' girls with other chronic diseases or psychology problems were excluded from the study. Data were collected using semi-structured interviews. Each interview session lasted between 30 and 80 min. Probing questions were used to follow the participants' thoughts and increase the depth of the interviews. Then, two additional focus groups were held with five participants in each to complete data. The study participants were selected purposively. The process continued until data saturation was achieved that is, no new concept emerged from the data.

Common statements and concepts were recorded, and the relevant/appropriate items for a questionnaire were designed based on them. For example, most patients declared that they preferred to hide their disease, and this had caused them unnecessary stress. Based on this statement, an item was devised "I prefer to hide my disease" with 5-point Likert scale as possible answers: never = 0, almost never = 1, sometimes = 2, often = 3, and almost always = 4. Reverse scoring were used for negative items. Other items such as "I worry about marriage and married life" and "My menstrual cycle is regular" were composed in the same way. The complete questionnaire was drawn up in Persian and comprised 50 items. The possible score was 0-100, higher scores indicating better QOL.

Face and content validity were addressed through the manner in which items were generated from statements and themes from qualitative interviews. The instrument face validity was evaluated with the help of 10 adolescent girls with diabetes from the Urmia Diabetes Society. The content validity of the questionnaire was reviewed by 15 experts who had published one or more than one published an article on QOL area. Construct validity was performed using convergent validity to demonstrate the extent to which the "IRDAGQOL" correlates with "PedsQL" (Diabetes Module Version 3.0 Teenage report 13-18). It was expected that the "IRDAGQOL" would correlate with "PedsQL". This was assessed by the Pearson product moment statistic (Pearson's correlation coefficient = r) and r equal to 0.40 or above was considered satisfactory. Furthermore, discriminant validity used to evaluate discriminatory power that is, ability of the questionnaire to detect differences between patients' subgroups, namely between adolescent girls in frequency of insulin injection 1-2 times/day and adolescent girls in frequency of insulin injection more than 2 times/day.

In order to determine the psychometric properties of the 50-item "IRDAGQOL", at least 250 completed questionnaires were needed as factor analyses ideally require five or more respondents per item (28). Over the 4-month period of the study, 250 adolescent girls with type 1 diabetes mellitus members of the Tehran and Urmia Diabetes Society, aged 13-18, agreed to participate in the study and provided consent form and completed the questionnaire. Exploratory factor analyses (EFAs) using principal component extraction method with Varimax rotation and Eigenvalue >1 were used to examine the items in each of the domains. The purpose was to select items that best represent the facets and to and to reduce items that did not fit in well with other items in any facets under the domain. The suitability of the data for factor analysis was confirmed by using Bartlett's test of sphericity and the Kaiser–Meyer–Oklin (KMO) measure of sampling adequacy. The recommended KMO value was 0.6 (29).

To test the instrument reliability, the internal consistency of the questionnaire was assessed using Cronbach's alpha coefficient and $\alpha \geq 0.70$ was considered satisfactory (30). The basic reliability of the questionnaire was evaluated by conducting a pilot study. The questionnaire was filled in by 30 adolescent volunteers, diabetic

patients from the IDS. The pilot test was re-tested on the same sample after 2 weeks.

The research proposal was approved by the Research Committee of Tarbiat Modares University. All the participants were informed about the purpose of the study by the first author. It was explained that the participation was voluntary, and they were assured regarding the confidentiality and anonymity of data gathering and were assured that they could withdraw from the study in every time.

Results

The questionnaire

A final 50-item Likert scale "IRDAGQOL", questionnaire was developed. Items were adjusted in five sub-scale, physical (8 items), psychological-emotional (21 items), social (14 items), beliefs (4 items), and economic structure (3 items). In this study, beliefs and economic were of the dimensions adolescent girl's QOL that this is a unique feature of the "IRDAGQOL" questioners. The questionnaire was developed to be self-administrated and appropriate for ages 13-18 years old. Administration of the "IRDAGQOL" lasted 15-20 min.

Scoring of "IRDAGQOL" is simple. For positive items "Almost Always" received a score of 4, "Often" received a score of 3, "Sometimes" received a score of 2, "Almost Never" received a score of 1 and "Never" received a score of 0. Of course in negative items were received reverse scoring. The minimum score is theoretically 0, and the maximum is 100. A higher score indicates better QOL.

Descriptive findings

The descriptive findings are presented in table 1. The mean age of respondents was 16 years (SD = 1.83). Mean duration of diabetes was 6.93 years (SD 3.88). Most of the participants (56.80%) injected insulin 3 times/day.

Validity

In the evaluation of the face validity, reviewers were in agreement that the instrument appeared sound and relevant with a logical between the purpose and items. Questions were considered grammatically correct, clear in meaning, conveying a single thought, appropriate for the response choice, and free of excess wording. Content validity was evaluated by 15 experts. The questionnaire was then revised based on the experts' suggestions for minor changes. It is worth noting that no item was deleted. The revised questionnaire was then sent back to the experts for approval. Furthermore, validity of the instrument was performed using convergent validity. When the correlation between the "IRDAGQOL" and "PedsQL" (Diabetes Module Version 3.0 Teen report age 13-18) scores was investigated, as expected a significant correlation emerged ($r = 0.6730$, $P < 0.0001$). Furthermore, the questionnaire was able to detect differences between patients' subgroups. t-test showed a greater negative impact on the QOL adolescent girls injecting insulin more than 2 times/day ($t = 5.740$, $df = 192$, $P < 0.001$).

Table 1. The demographic characteristics of the study respondents (n = 250)

Variable	mean ± SD or percent
Age (years)	16.00 ± 1.83
Duration of diabetes (years)	6.93 ± 3.88
Onset age (years)	13.00 ± 4.53
Insulin injection	
Two times/day (%)	23.7
Three times/day (%)	56.8
Four times/day (%)	19.5
Complication of diabetes	
Without (%)	94
With (%)	6
Educational level	
Primary (%)	8.1
Secondary (%)	29.1
High school (%)	62.8

Factor analysis

The data obtained were subjected to EFA. The results showed that the KMO value was 0.79; this exceeding the recommended value of 0.6 indicated the sampling adequacy. EFA using principal components analysis revealed the presence of five components with Eigen values exceeding 1 and an inspection of the screen plot revealed a clear break after the second component. Therefore, it was decided to retain five components for further investigation. To aid in the interpretation of these five components, orthogonal rotation was then performed through the Varimax procedure

(Table 2). The five factors explained nearly 79.945% of the variance of the questionnaire. These five factors labeled physical, psychological-emotional, social, and economic.

Table 2. Factor structure of the Iranian Diabetic Adolescent Girl's Quality of Life using principal component analysis

IRDAGQOL item	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5
I have good appetite	0.66	-	-	-	-
I have trouble sleeping	0.93	-	-	-	-
I am cheerful and wholesome	0.62	-	-	-	-
My menstrual cycle is regular	0.50	-	-	-	-
I to do sports activity or exercise regularly	0.93	-	-	-	-
I preserve proportion between my weight and height	0.41	-	-	-	-
I can be the fun leisure time	0.67	-	-	-	-
I protect my skin from insulin injection hurts	0.74	-	-	-	-
I control myself when I am angry	-	0.69	-	-	-
I am one anxious person	-	0.46	-	-	-
I am confident	-	0.40	-	-	-
I am able to cope well with my illness	-	0.76	-	-	-
I feel sad or blue	-	0.63	-	-	-
Blood sugar control to prevent myself from being ill	-	0.53	-	-	-
I try to get new information and skills for control of my illness	-	0.52	-	-	-
I am a regular person	-	0.53	-	-	-
I try to achieve my goals	-	0.45	-	-	-
Future is vague for me	-	0.88	-	-	-
I worry about marriage and married life	-	0.69	-	-	-
I worry about pregnancy and possibility of transmission diabetes to child	-	0.72	-	-	-
I worry about employment and career opportunities	-	0.90	-	-	-
I am satisfied with my life	-	0.93	-	-	-
I feel alone	-	0.58	-	-	-
I enjoy of the food I would eat	-	0.94	-	-	-
It is hard for me to take insulin shots	-	0.59	-	-	-
It is easy for me to do medical care	-	0.88	-	-	-
I am afraid of hospitalization	-	0.42	-	-	-
I am satisfied with my being a girl	-	0.86	-	-	-
I have popularity among the people	-	0.87	-	-	-
My parents support me	-	-	0.86	-	-
I have freedom at home	-	-	0.78	-	-
My parents are worry about me and control my status	-	-	0.74	-	-
My family relationships is good	-	-	0.87	-	-
I find school interesting	-	-	0.86	-	-
I miss school to go to the doctor or hospital	-	-	0.92	-	-
Teachers and school officials can help me	-	-	0.91	-	-
Diabetes leads to impaired concentration and my educational shortage	-	-	0.90	-	-
Other people feel pity for me	-	-	0.64	-	-
I do accept any responsibility in social relationships	-	-	0.90	-	-
Some people are meddler about my illness	-	-	0.48	-	-
My social relationships is good	-	-	0.73	-	-
I prefer to hide my disease	-	-	0.49	-	-
It is easy for me to go travel	-	-	0.86	-	-
God aid me	-	-	-	0.61	-
Appeal to help me Imams and is effective	-	-	-	0.92	-
I avow prayer and comfortable draw	-	-	-	0.94	-
My belief to some superstition calm down me	-	-	-	0.93	-
My illness burden to my family financial pressure	-	-	-	-	0.91
I have enough money	-	-	-	-	0.65
Governmental organizations to control and treatment to help me			-	-	0.76

IRDAGQOL: Iranian Diabetic Adolescent Girl's Quality of Life

Table 3. Determine the internal consistency: Cronbach's alpha of "Iranian Diabetic Adolescent Girl's Quality of Life" questionnaire

Sub-scale	Item number	Cronbach's alpha, N = 245
Physical	8 (1-8)	=α = 0.746
Psychological-emotional	21 (9-29)	=α = 0.736
Social	14 (30-43)	=α = 0.845
Beliefs	4 (44-47)	=α = 0.831
Economic	3 (48-50)	=α = 0.905
Total scale	50	=α = 0.875

Reliability

To test the reliability the internal consistency of the questionnaire was measured using Cronbach's alpha coefficient. The alpha for the whole sample was found to be 0.87 which showed the high reliability of this scale (Table 3). The exclusion of any single item did not change Cronbach's alpha more than 0.01, which showed strong internal consistency. The test–retest was calculated using Pearson's correlation to determine the strength of the relationship between responses (n = 30) to the "IRDAGQOL" over time, with 2 weeks between administrations. The test-retest reliability resulted in a coefficient of 0.940 (P < 0.001) for the "IRDAGQOL". The "IRDAGQOL" was deemed to be a stable over the 2-week testing period.

Discussion

The study aimed at developing the "IRDAGQOL" for using in clinical settings and testing psychometric properties of questionnaire. Items of questionnaire created based on the result of content analysis. The psychometric properties of the "IRDAGQOL" have been empirically tested. The results revealed adequate validity and reliability.

Face and content validity of questionnaire confirmed. Construct validity of "IRDAGQOL" confirmed using convergent validity and discriminant validity. Discriminant validity of the "IRDAGQOL" was supported by the differences between adolescent girls in frequency of insulin injection 1-2 times/day and adolescent girls in frequency of insulin injection more than 2 times/day. Adolescent girls in frequency of insulin injection more than 2 times/day reported significantly more negative impact of diabetes on QOL. In Bradley and colleagues study conducted to design and develop a questionnaire to measure individuals' perceptions of the impact of diabetes on their QOL, it was reported that construct validity of the "ADDQOL" was supported by the differences between patients treated with insulin versus those on tablets or diet (31).

EFA is most frequently used as a part of the instrument development process. It can be used to reduce the number of items on a scale by eliminating items with low factor loadings or items that load at approximately equal level on two or more factors (32). EFAs adjusted 50-item in five sub-scales, physical, psychological-emotional, social, beliefs, and economic structure. In this study, beliefs and economic were of the dimensions adolescent girl's QOL, that this is a unique feature of the "IRDAGQOL" questioners. Beliefs in adolescent girls with diabetes are an important factor that affects them QOL. It is essential as an aspect of diabetes care needs to be taken into consideration (33, 34). Results showed that the internal consistency of the new form was high under different conditions. These results indicated a reliability of 0.87, which is acceptable for the instrument to be used in research.

The teenagers participated in interviews during work to develop the questionnaire lived in and around Urmia. However, in the psychometric properties of questionnaire, the respondents in the questionnaire study were from Urmia and Tehran, and there were clear indications of acceptability to all, and that neutral, non-regional vocabulary had been chosen.

Conclusion

The "IRDAGQOL" is a new measure of perceived impact of diabetes and its treatment on QOL of Iranian diabetic adolescent girls. It will help healthcare professionals when caring for adolescent girls with diabetes. It may be used in clinical trials and for routine clinical monitoring in a

context of continuing evaluation. The instrument is also expected to be useful in evaluating new treatments and educational interventions for diabetes in clinical trials. In order to further facilitate the use of questionnaires, other research is recommended to provide a short form "IRDAGQOL" questionnaire. Also to develop this questionnaire is recommended psychometric instruments mentioned in other Iranian culture. The scale might be able to predict QOL as an important outcome in the follow-up of diabetic adolescent girls, although the predictive criterion validity of the questionnaire needed more assessment.

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