Open Access Original

Journal of Renal Endocrinology

J Renal Endocrinol 2020;6:e02.

http://www.jrenendo.com

Nickan Research Institute

Persian version of insulin treatment satisfaction measurement; an original study

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Abstract

Introduction: Diabetes mellitus (DM) is a common non-communicable disease with increasing rate of incidence. All of type 1 DM and some type 2 DM patients are treated with insulin which causes an economic and social burden. Treatment satisfaction influences patient compliance and adherence.

Objectives: To have an accurate and valid scale for assessment of satisfaction, we needed a valid questionnaire in Persian version.

Patients and Methods: It was a cross-sectional analytic study performed in Yazd diabetes research center and a private diabetes' clinic in Tehran in the years of 2014 to 2016. Totally 304 patients were included during the study period.

Results: Cronbach's alpha coefficients were >0.69 for all domains and acceptable. Cronbach's alpha and intra-class correlation coefficient (ICC) for overall questionnaire were 0.88 and 0.81. Therefore the Persian version of questionnaire is valid and reliable.

Conclusion: The Persian version of insulin treatment satisfaction questionnaire is a valid and reliable instrument to assess patients' satisfaction with insulin therapy in type 2 DM. Results showed the tool is clinically and psychometrically valid instrument for insulin treatment satisfaction measurement.

Keywords: Diabetes mellitus, Insulin therapy, Treatment satisfaction, Questionnaire, Validity, Reliability

Citation: Ghadiri-Anari A, Jam-Ashkezari S, Namiranian N, Biglari Abhari M. Persian version of insulin treatment satisfaction measurement; an original study. J Renal Endocrinol. 2020;6:e02.

Introduction

Diabetes mellitus (DM) is a common non-communicable disease followed by several complications, causes disabilities and imposes a great burden on countries' health systems. In 2016, 2.63% of total death around the world was attributed to DM. In Middle-East and North-African regions and Iran this percent was 3.82% and 3.85 % (1). The condition forces health system to develop more efficient interventions to prevent and control the disease. Many patients tend to give up treatments and necessary follow up because of rigid form of treatment and annoying complications in DM. An important efficient approach may be asking about their comfort with treatment and quality of life to help them to improve (2).

Among different anti-hyperglycemic agents, insulin is one of most effective treatment modalities. All of type 1 DM and many type 2 DM patients are treated with insulin, since optimal control of blood glucose needs insulin in some cases (3). Treatment satisfaction directly influenced patient compliance (4,5), cost of care (6,7) and self-management behaviors (8).

Weaver and colleagues defined treatment satisfaction as the patient's view of the treatment process and its associated outcomes based on predefined criteria (9). Assessment of treatment satisfaction in diabetes is including three issues; 1) drugs' side effects 2) trouble or burden and 3) effective control of blood glucose levels (10). Evaluation of side effects of drugs may consist of factors such as weight gain or incidence of hypoglycemic events. Assessment of trouble or burden of treatment may be including number of injections or problems with devices and difficulty in access. Hemoglobin A1C (HbA1c) is the best factor for evaluations of efficacy. Also patient and disease features such as age, gender and duration of diabetes may influence insulin treatment satisfaction (11).

The questionnaire contains 22 questions in 5 subscales with the same weights and answers would be from 1 (extremely satisfied) to 7 (extremely dissatisfied). The final score of each item is reported from 0 to 100, whole higher scores indicating better treatment satisfaction (10). Anderson et al estimated internal consistency (using Cronbach α coefficient) between 0.79 to 0.91 and test-retest reliability ranged from 0.63 to 0.94. Insulin treatment satisfaction questionnaire is a valid scale to

Received: 10 May 2019, Accepted: 19 July 2019, ePublished: 5 November 2019

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Implication for health policy/practice/research/ medical education

The Persian version of insulin treatment satisfaction questionnaire is a valid and reliable instrument to assess patients' satisfaction with insulin therapy in type 2 DM. Results showed the tool is clinically and psychometrically valid instrument for insulin treatment satisfaction measurement.

measure patient's satisfaction with insulin treatment (11).

Objectives

To have an accurate and valid scale for assessment of satisfaction, which is a subjective and latent variable, we needed a valid questionnaire in Persian version. We conducted the study to obtain two main objectives; 1- translation and validation of a scale to assess satisfaction of patients and 2- investigation of factors affected cure or failure of treatment and controlling complications.

By understanding these relationships, physicians will be able to identify barriers to treatment satisfaction and organized programs to maximize treatment satisfaction

Patients and Methods

Study design

It was a cross-sectional analytic study performed in Yazd diabetes research center and private diabetes' clinic in Tehran (2014 to 2016).

Study sample

We used convenience sampling method through the following inclusion criteria; type 2 diabetic patients treated with insulin, insulin therapy for more than 4 weeks and age ≥18 years. Physical examination of all patients was performed by an endocrinologist. Patients with apparent cognitive impairment, severe comorbidities such as congestive heart failure, renal failure (GFR ≤60 cc/min), severe retinopathy or severe neuropathy were excluded. However these patients came to Yazd diabetes research center regularly and had medical record. At the end of study duration, 304 patients were included the study and their data were analyzed thereafter. A common method for sample size calculation in questionnaire validation studies, based on factor analysis recommends that a sample size of 100 is poor, 200 is fair, and 300 is good for the validation of a scale. Hence, the sample size of the current study is claimed as a fair sample size (12).

Measures

As mentioned, Insulin Treatment Satisfaction Questionnaire (ITSQ) provided by Anderson et al, contains 22 questions in 5 subscales (domains) as; 1) inconvenience of regimen; IR-5 comprising questions number 1, 4, 5, 15 and 16. 2) Lifestyle flexibility; LF-3 in questions 2, 3 and 6. 3) Glycemic control; GC-3 through questions number 12, 13and 14. 4) Hypoglycemic control: HC-5 through questions 7, 8, 9, 10 and 11. 5) Insulin delivery device satisfaction; DD-6 in questions number 17 to 22 (10). All items are scored on a seven-point Likert scale ranging 1 to 7; "not at all" to "extremely". "ITSQ is scored 0-100 in each item and higher scores show better satisfaction. For each subscale, the sum score is divided by number of items" (9).

Translation

Translation procedure of original questionnaire was performed by two independent researchers (N.N and A.GH), expert in both English and Persian languages with much experience in prevention, diagnosis and treatment of DM. Their original speaking language was Persian. We asked them to pay attention to cultural context and various educational levels of patients. Thus, they avoided ambiguous words or scientific idioms in translating process. The initial translated text was corrected by two linguistic experts in Persian language and wrong words were extracted. Backward translation of default Persian text was done by two experts fluent in both English and Persian language with no knowledge about original version of questionnaire. An expert panel was performed by three experts to compare original text and backward translated one to revise and correct the initial Persian version. A draft of questionnaire was prepared to pilot, then. We offered questionnaire to 20 patients with various levels of education and jobs. They completed them and mentioned any ambiguous or equivocal word or scientific idioms if they had seen.

Fifteen people filled the final questionnaire form containing questions about demographic information and some comorbidity. After two weeks the questionnaires were recompleted by them for evaluation of test-retest reliability. We revised the translation considering people's idea in pilot phase and confirm the final version to start the study.

This questionnaire was backward translated into English by two professional translators. After review and adaptation, some changes have been made and the Persian version of questionnaire was provided. Cronbach α was measured for evaluation of internal consistency of questionnaire. To determine the content validity, translated questionnaire was given to two experts for expressing opinions about the content of questionnaire (unrelated, low correlation, relevant, very relevant). If there were disagreement between two experts, the third expert would help us. Factor analysis was performed for assessment of various aspects of questionnaire. Final questionnaire with demographic information is filled by 10 patients. After two weeks the questionnaire completed by the same patients and the results compared with the first time for evaluation of test-retest reliability.

After completing questionnaires, this cross-sectional study was carried out on 304 type2 diabetic patients referred to Yazd diabetes research center and a private

diabetes clinic in Tehran from 2015 to 2017. The convenience sampling method was performed.

Data collection

Through three years of study, up to 304 patients were included (those with exclusion criteria were excluded at the first step of assessments). The questionnaire is patient-reported based through a comprehensive interview, (11) thus all included patients had almost complete data. At the beginning of questionnaire form there were questions asked about comorbidities like coronary artery disease (CAD), complications of DM containing retinopathy, nephropathy, neuropathy and some risk factors like high BMI and smoking. Insulin application characteristics were asked too, like numbers of injections per day, kind of insulin vial and device of applying. To know about economic burden we asked only the costs of insulin and medical cares per month.

Ethical issues

The research followed the Tenets of the Declaration of Helsinki. To keeping ethical principles, names of the patients were not pointed in the checklists. Ethics approval was also obtained from Iran University of Medical Sciences and ethics committee (# IR.IUMS.REC.1394.9311223005).

Statistical analysis

The data analysis was performed using SPSS, version 20.0 (SPSS Inc., Chicago, Ill., USA). In order to evaluate internal consistency, Cronbach's alpha was used. Test–retest analysis with intra-class correlation coefficient (ICC) was provided to show the reliability of the scale (12).

Results

Totally 304 patients were included at the end of study period. The mean age (± standard deviation) of participants was 60.05 ± 9.35 years (range 36-83 years), 51.6 % were male. Most of the patients were educated (72.69%). Around 67.6% of participants had mild to moderate retinopathy, 25.48 % mild nephropathy, 89.1% neuropathy and 34.6% had cardiovascular disease. Participant characteristics are summarized in Tables 1, 2 and 3. Mean scores of domains and alpha-Cronbach and ICC of them are provided in Table 4. We controlled adequacy of sample size through KMO and Bartlett's test with P value <0.001. Overall

Table 2. Descriptive characteristics of participants (Part 2)

Variable			No. (%)
Insulin availability	Difficult	Male	44 (15)
		Female	30 (10)
		All	70 (25)
	Easy	Male	110 (37.6)
		Female	102 (34.9)
		All	212 (72.5)
Health insurance	Yes	Male	149 (51)
		Female	128 (43)
		All	277 (94.8)
	No	Male	8 (2.3)
		Female	7 (2)
		All	15 (4.3)
Retinopathy	Yes	Male	103 (35.6)
		Female	94 (32)
		All	197 (67.6)
	No	Male	51 (17.6)
		Female	41 (14.1)
		All	92 (31.7)
Nephropathy	Yes	Male	42 (13.9)
		Female	35 (11.58)
		All	77 (25.48)
	No	Male	115 (38.07)
		Female	100 (33.11)
		All	125 (71.18)
Neuropathy	Yes	Male	140 (47.6)
		Female	122 (41.5)
		All	162 (89.1)
	No	Male	19 (6.4)
		Female	13 (4.4)
		All	32 (10.8)
Coronary artery disease	Yes	Male	62 (20.8)
		Female	41 (13.8)
		All	103 (34.6)
	No	Male	100 (33.67)
		Female	94 (31.6)
		All	194 (65.27)
Smoking (now/past)	Yes	Male	10 (3.4)
		Female	13 (4.4)
		All	23 (7.8)
	No	Male	122 (41.7)
		Female	147 (50.3)
		All	269 (92)

Table 1. Descriptive characteristics of participants (part 1)

	Descriptive characteristics of participants							
	Age (y)	DM duration (y)	Insulin payment in (month)	Medication payment in (month)	Insulin duration (month)	Weight (kg)	BMI (kg/m²)	HbA1c (%)
Mean	60.05	15.20	43138.18	134410.48	56.93	74.57	28.4766	8.66
SD	9.335	8.710	46239.331	129266.578	57.903	13.512	5.31907	1.806
Minimum	36	1	0	0	1	50	20.08	5
Maximum	83	46	400000	600000	360	135	52.73	14

Table 3. Descriptive characteristics of participants (part 3)

Numbers of hypoglycemic event in week	No. (%)	Numbers of insulin injection per day	No. (%)	Insulin injection device	No. (%)	Insulin type	No. (%)
0	159 (52.5)	**0**	3 (1)	**Syringe**	75 ()	**Nph**	5 (1.6)
1	79 (26)	**1**	44 (14.5)	**Pen**	221 ()	**Lantus**	45 (14.8)
2	38 (12.5)	**2**	127 (41.8)	**Syringe+pen**	6 ()	**Nph+R**	68 (22.4)
3	20 (6.8)	**3**	96 (31.6)	**Total**	302 ()	**Novomix**	112 (36.8)
Several times	6 (2)	**4**	12 (3.9)			**Novomix+ Novorapid**	6 (2)
						Novorapid	19 (6.3)
						Lantus+ Novorapid	37 (12.2)
						Novorapid+R	6 (2)
						Total	298 (98)

Table 4. Questionnaire validity and scores

Sub-scale of questionnaire	Cronbach alpha	ICC	*P* value	Mean score(SD)	Scores Range
IR-5	0.79	0.73	0.000	75.58(20.31)	14.3-100
LF-3	0.698	0.76	0.000	83.33(16.99)	33.33-100
GC-3	0.7	0.736	0.000	156.26(45.16)	38.10-233.33
HG-5	0.73	0.698	0.000	314.04(101.10)	14.29-420
DD-6	0.735	0.71	0.000	398.64(114.34)	7.14-516.67
Overall score	0.88	0.81	0.000	823.27(164.41)	283.3-1090

Cronbach's alpha and intra-class correlation coefficient for all questions were 0.88 and 0.80, which were acceptable for questionnaire internal consistency and reliability (13). Other analytic results of validity are presented in online Supplementary file 1.

There were significant differences between mean of age, monthly payment for insulin and medications, duration of insulin-therapy and scores of IR, LF, HG and DD in different groups of insulin type. The age mean was the least in NPH group with a significant difference with all other groups through ANOVA post hoc. The IR subscale score mean was the least in NPH+R group with a significant difference with each other groups through ANOVA post hoc score mean was the highest in Lantus group (Table 5 and online Supplementary file 2).

There were significant differences between means of age, duration of insulin therapy and scores of HG, GC, DD and overall satisfaction in groups of education. Although there were no significant differences between HbA1C levels and body mass index (BMI) groups (Table 5). Mean differences of overall satisfaction, DD, GC and HG scores were significant between uneducated and educated patients (Table 6).

Devices of insulin usage (pen or syringe) showed a significant difference in all subscales and overall satisfaction score. All aspects of satisfaction were better in patients who used pen insulin. However, the monthly payment for insulin and medications was higher in pen insulin users (Table 5).

Based on BMI, a significant difference in glycemic control subgroup and hypoglycemic control sub-group score was seen. The mean glycemic control score in persons with normal BMI was 62.07 ± 13.12 kg/m^2 and in the overweight and obese patients was 51.94 ± 16.13 kg/m^2 ($P = 0.004$). Additionally, hypoglycemic control score in patients with normal BMI was 54.72 ± 18.13 kg/m^2 and in the other group was 44.07 ± 20.54 kg/m^2 ($P = 0.014$). Normal BMI had a positive effect on serum levels of glucose (BMI <30 kg/m^2, OR = 0.453, 95% CI: 0.229-0.694).

There were significant associations between retinopathy, smoking, nephropathy, neuropathy and age and monthly payment for insulin and medications, respectively. Other findings are presented in Table 8.

There were significant correlations between duration of DM from one side and duration of insulin-therapy (r: 0.401, $P < 0.001$) and monthly payment for insulin (r: 0.454, $P < 0.001$) from other side (Table 7).

Age and numbers of injection in day (r:-0.158, p=0.008) and serum levels of $HbA1_C$ (r: 0.152, P=0.009), inconvenience of regimen score (r: 0.160, P=0.006), lifestyle flexibility (r: 0.169, P=0.006) and hypoglycemic control (r: -0.269, $P < 0.001$) were correlated significantly (Table 8).

Discussion

The ITSQ has been translated and validated in 22 languages and is now available for use in 18 countries (including 8 Eastern European nations) (14). The expanded use of this instrument could imply its accuracy and being friendly for users. Therefore, we think it is the best current questionnaire for assessment of patients' satisfaction and

Table 5. ANOVA by insulin types, job, education and insulin usage device

		Sum of squares	df	Mean square	F	*P*
ANOVA (by insulin types)						
Age	Between Groups	2629.684	7	375.669	4.824	.000
Insulin payment in month	Between Groups	45778283438.863	7	6539754776.980	3.244	.003
Duration of insulin-therapy	Between Groups	114483.203	7	16354.743	5.317	.000
IR5	Between Groups	16662.164	7	2380.309	6.506	.000
LF3	Between Groups	131142.420	7	18734.631	6.738	.000
HC5	Between Groups	205655.678	7	29379.383	3.053	.004
DD6	Between Groups	828829.775	7	118404.254	11.499	.000
ANOVA (by job)						
Age	Between Groups	2804.902	5	560.980	7.175	.000
Medication payment in Month	Between Groups	330951813754.093	4	82737953438.523	5.276	.000
Weight	Between Groups	2497.266	5	499.453	2.796	.017
IR5	Between Groups	14241.392	5	2848.278	7.708	.000
GC3	Between Groups	28865.692	5	5773.138	2.896	.014
ANOVA (by education)						
age	Between Groups	3184.515	4	796.129	10.391	.000
Duration of insulin-therapy	Between Groups	42276.999	4	10569.250	3.257	.012
HC5	Between Groups	481510.824	4	120377.706	14.560	.000
GC3	Between Groups	51277.588	4	12819.397	6.709	.000
DD6	Between Groups	268132.443	4	67033.111	5.394	.000
Overall satisfaction	Between Groups	765538.832	4	191384.708	7.890	.000
ANOVA (by devices of insulin usage)						
Insulin payment in month	Between Groups	37639073790.943	2	18819536895.472	9.333	.000
Medication payment in month	Between Groups	114350923847.471	2	57175461923.735	3.500	.032
Insulin duration in month	Between Groups	66084.677	2	33042.338	10.489	.000
IR5	Between Groups	11733.383	2	5866.692	15.480	.000
LF3	Between Groups	58731.019	2	29365.509	9.882	.000
HC5	Between Groups	204059.262	2	102029.631	10.639	.000
GC3	Between Groups	25740.811	2	12870.406	6.630	.002
DD6	Between Groups	787040.728	2	393520.364	37.578	.000
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GC3		25740.811	2	12870.406	6.630	.002
DD6		787040.728	2	393520.364	37.578	.000

Table 6. Mean differences of questionnaire's scores in educated and uneducated groups and patients with good and poor control of glucose

Variables	Mean in educated patients	Mean in uneducated patients	P value
Overall satisfaction	850.8006	739.7698	<0.001
DD6	409.9003	369.4779	0.006
GC3	160.1164	146.0126	0.015
HC5	337.8644	249.4325	0.001
IR5	76.2767	73.7349	0.332
HbA1c	8.55	8.94	0.104
	Mean in patient with good glucose control	**Mean in patient with poor glucose control**	
Overall satisfaction	908.57	795.77	<0.001
DD6	426.52	390.86	0.014
GC3	173.55	151.56	0.000
HC5	344.35	306.23	0.006
IR5	85.36	72.92	<0.001

Table 7. Significant correlations between scores and other variables

Sub-scale of questionnaire	IR-5	LF-3	GC-3	HG-5	DD-6	Overall score
Correlated variable	Pearson's r (*P* value)	Pearson's r (*P* value)	Pearson's r (*P* value)	Pearson's r (*P* value)	Pearson's r (*P* value)	Pearson's r (*P* value)
Duration of dis.					0.157 (0.009)	
Monthly medical payment		-0.212(0.002)	-0.198(0.003)		0.157(0.000)	-0.212(0.002)
Age	0.158(0.006)	-0.166 (0.006		-0.3(0.000)		
Duration of insulin-therapy					-0.166(0.000)	
No. of hypoglycemic attacks in week				-0.3(0.000)	-0.247(0.000)	-0.275(0.000)
BMI						-0.193(0.004)
Hb A_1C			-0.187(0.004)			-0.166(0.004)

Table 8. The significant associations between variables

Variables	Insulin availability		Comorbidities		Smoking		Insurance +	
	χ^2	*P* value	χ^2	*P* value	χ^2	*P* value	χ^2	*P* value
Insulin type	22.7	0.002	297.446	0.000			100.05	<0.001
Comorbidities	315	0.003			24.63	0.026	58.18	<0.001
Retinopathy +	11.81	0.001			12.96	0.000*		
Nephropathy +					11.51	0.003		
Neuropathy +	10.807	0.001**						
Cardiovascular dis.+					5.95	0.015***		

*OR=1.140(CI 95%: 1.1-1.2); **OR=3.383(CI 95%: 1.58-7.22); ***OR=2.717(CI 95%:1.86-6.224)

quality of life. The purpose of study was translation and validation of ITSQ to Persian language and extrapolation of this questionnaire to T2DM in the province of Yazd and Tehran. Yazd is a city in the center of Iran with high prevalence of diabetes (15). Tehran, the capital of Iran is an overcrowded metropolis with increasing rates of non-communicable diseases such as DM (14).

As the goal of study, our findings showed acceptable validity and reliability of Persian version of ITSQ. The overall Cronbach's alpha in our study was 0.88 and ranged from 0.698 to 0.88 which was consistently comparable with the origin questionnaire (11).

In our study, persons who used pen injection had better glycemic satisfaction and low hypoglycemic score compared with NPH group. Bradley et al showed treatment satisfaction would be greater in the insulin glargine group than the NPH group (16).

Given the nature of insulin glargine, with its longer action and constant release of insulin without a pronounced peak, achieved with only one daily injection

of basal insulin, it was expected that treatment satisfaction would be greater in the insulin glargine group than the NPH group (16).

In some studies insulin glargine is associated with similar glycemic control with fewer hypoglycemic episodes than NPH insulin in type 1 diabetes (17,18). Additionally, another reason for better satisfaction may be related to easier and comfortable injection with pen than syringe method. In some studies, the most satisfaction was scored in patients with insulin pomp (19).

In our study nobody was using insulin pomp during the research. Hence, we couldn't assess the scores of this method of insulin usage.

In a study by Farmer et al (20), patients with suboptimal gyrated hemoglobin levels were randomized to biphasic insulin aspart twice-daily, prandial insulin aspart three times daily or basal insulin detemir once-daily, ITSQ scores were significantly different between groups for each of the ITSQ domains, with lower scores for prandial insulin compared with the basal or biphasic groups. Median ITSQ scores were lower in patients with a gain in body mass index (BMI) >1.23 kg/m^2 over one year compared to those with a lesser or no gain in BMI and in those with occurrence of hypoglycemia compared to those with no hypoglycemia (18). We have identified over-weight and obese persons have low glycemic control and much hypoglycemic satisfaction than normal BMI persons, because of insulin resistance in the former groups.

In addition, patients taking more complicated regimens for example cardiovascular drugs, anti-hypertensive drugs may have experienced less satisfaction with their insulin regimen. Randomized controlled trials need to overcome these confounding factors. Additionally, future studies with large sample size are needed to compare different insulin regimens.

Conclusion

The Persian version of insulin treatment satisfaction questionnaire is a valid and reliable instrument to assess patients' satisfaction with insulin therapy in type 2 DM. Results show the tool is clinically and psychometrically valid instrument for insulin treatment satisfaction measurement. This instrument opens the way for studies on the subject in the future.

Limitations of the study

ITSQ was developed specifically for insulin users and no address satisfaction with other medications. It may be one limitation of this study.

Other limitation is the nature of this study that is cross sectional and was not capable of examining cause and effect of influences of low treatment satisfaction on clinically relevant outcomes. Likewise, patients taking more complicated regimens for example cardiovascular drugs, anti-hypertensive drugs may have experienced less satisfied with their insulin regimen. Randomized controlled trials need to overcome these confounding factors. Future studies with large sample size are needed to compare different insulin regimens.

A final limitation is that despite the strong construct validity and sensitivity to clinical indices, responsiveness to change (changes in $HbA1_C$ values) of the ITSQ was not examined in this cross-sectional study. Prospective studies should be planned to address this issue.

Acknowledgments

Great thanks to the Yazd Diabetes Research Center, Shahid Sadoughi University of Medical Science for the support and providing the facilities for this work. The authors declare that there is no conflict of interest.

Authors' contribution

All authors had serious engagement in all steps of the study.

Conflicts of interest

The authors declate thst they have no conflicts of interest.

Ethical considerations

Ethical issues (including plagiarism, data fabrication, double publication) have been completely observed by the authors.

Funding/Support

Yazd Diabetes Research Center, Shahid Sadoughi University of Medical Science provided the support and facilities for this work.

Supplementary Materials

See online supplementary files 1 and 2 for more details.

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