Development and validation of a tool to identify barriers to starting insulin treatment in patients with type-2 diabetes mellitus

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KEY MESSAGES

1. The 13-item Chinese version of the Attitudes to Starting Insulin Questionnaire has reliable psychometric properties and an interpretable and relevant structure. It can be used by clinicians to assess psychological barriers to insulin treatment in Chinese patients with type-2 diabetes mellitus in primary care settings.

2. The most significant barriers to starting insulin treatment in Chinese patients with poorly controlled type-2 diabetes mellitus appear to be fear of pain and needles and perceived insufficient social support. Women are more negative towards starting insulin treatment.

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Introduction

In Hong Kong, type-2 diabetes mellitus (T2DM) is commonly managed in general out-patient clinics. Insulin treatment is eventually indicated once the maximal dose of oral medication is no longer sufficient to control the blood sugar level ('failed oral therapy'). Most patients with T2DM resist insulin treatment,[1] particularly Chinese patients (>70%),[2] women, and patients with lower education levels,[3] probably owing to cognitive appraisals or emotional reactions affected by culture, degree of self-efficacy, and health literacy.[1]

None of the existing questionnaires[4,5] have been validated for use in predominantly elderly or socially deprived primary care patients who have not yet started insulin treatment ('insulin naïve' patients). This study aimed (1) to develop a Chinese questionnaire and to assess its psychometric properties, acceptability, and feasibility in elderly patients with T2DM in primary care settings; and (2) to determine the association between attitude toward starting insulin treatment and biomedical and socio-demographic factors in patients with poorly controlled T2DM who were receiving the maximum tolerable dose of oral drugs.

Methods

This study was approved by the Research Ethics Committee of the Kowloon West Cluster, Hospital Authority of Hong Kong.

A total of 27 potential items were identified from a literature review.[1,2,4,5] An expert panel rated the items for content, breadth, validity, and relevancy. Each item that scored ≥80% on the content validity index was retained. The resulting structured English questionnaire used a four-point Likert scale for each item (from strongly agree to strongly disagree). The questionnaire was translated into Chinese and back-translated into English. The resulting Chinese version of the Attitudes to Starting Insulin Questionnaire (Ch-ASIQ) was field tested in 10 patients with different age, sex, and previous insulin use status.

Consecutive eligible patients were identified through the Hospital Authority system and invited to complete the questionnaire by self-administration or face-to-face interview from June 2012 to March 2013. There were 27 potential items; therefore, a sample size of 270 was required for a patient-to-item ratio of 10:1. The inclusion criteria were (1) Chinese-speaking adults aged ≥18 and ≤80 years, (2) receiving the maximum recommended or tolerable doses of oral diabetic medications (gliclazide 320 mg, modified release gliclazide 120 mg, or glibenclamide 15 mg and metformin ≥2 g daily), and (3) haemoglobin A1c level of ≥7.5% within the past 12 months. Exclusion criteria were pregnancy, inability to answer the questionnaire, and already receiving insulin treatment.

Under the Risk Factor Assessment and Management Programme, patients with T2DM underwent laboratory tests, retinal photo or ophthalmologist assessment, and nurse-led diabetes

complication screening once every 1 to 2 years. Our nurses collected the patients' records for data analysis.

Negative items were reverse coded. Scores ranged from one to four, with higher scores indicating more positive attitudes. Exploratory factor analysis was used to explore the instrument's underlying structure and to sort the items into subscales. The Kaiser-Meyer-Olkin measure of sampling adequacy (using a cut-off of 0.5) and Bartlett's Test of Sphericity (using a cut-off $P<0.001$) were used to ensure the appropriateness of the dataset for exploratory factor analysis. A Cronbach's alpha coefficient of ≥ 0.6 was used as the cut-off to indicate

TABLE 1. Sociodemographic and clinical characteristics of patients with type-2 diabetes mellitus

Characteristics	Mean (range) or No. (%) of patients (n=303)
Age, y	63 (54-70)
Male	136 (44.9)
Female	167 (55.1)
Education	
No formal education	44 (15.4)
Primary	117 (41.1)
Secondary	107 (37.5)
Tertiary	17 (6.0)
Occupation	
Full-time	90 (32.8)
Unemployed/retired	82 (29.9)
Homemaker	99 (36.1)
Part-time	3 (1.1)
Mode of questionnaire administration	
Self	104 (34.4)
Interviewer	199 (65.7)
Duration of diabetes mellitus, y	11 (7-16)
Diabetes drug	
Glibenclamide	37 (12.2)
Gliclazide	259 (85.5)
Metformin	7 (2.3)
Body mass index, kg/m^2	25.2 (22.6-27.7)
Body mass index cut-off, kg/m^2	
<18.50 (underweight)	3 (1.0)
≥18.50 to <24 (normal)	109 (36.5)
≥24 to <27 (overweight)	91 (30.4)
≥27 (obese)	96 (32.1)
Haemoglobin A1c level, %	8.3 (7.9-9.1)
Low-density lipoprotein, mmol/L	2.5 (2.0-3.0)
Estimated glomerular filtration rate, mL/min/1.73m^2	88.0 (70.5-108.0)
Hypertension	246 (81.2)
Nephropathy	49 (16.8)
Foot ulcer	4 (1.4)
Neuropathy	6 (2.0)
Peripheral vascular disease	0 (0.0)
Retinopathy	165 (57.5)
Ischaemic heart disease	5 (1.7)
Stroke	14 (4.8)

sufficient internal reliability. Linear regression was performed to explore the associations of Ch-ASIQ with socio-demographic and clinical characteristics. SPSS (version 20.0; IBM Corp., Armonk [NY], US) was used for statistical analyses.

Results

All 27 items yielded >80% on the content validity index and cognitive debriefing. Of the 306 patients invited, 303 completed the questionnaire (response rate, 99%). The median haemoglobin A1c level was 8.3% (interquartile range, 7.9%-9.1%) indicating very poor glycaemic control (Table 1).

Ten factors with eigenvalues of ≥1 were extracted using exploratory factor analysis with varimax rotation. The Kaiser-Meyer-Olkin measure was 0.725, indicating sampling adequacy. Sufficient variability of data was confirmed by Bartlett's Test of Sphericity (P<0.001).

After collapsing and combining factors, the internal consistency of four out of the seven subscales had Cronbach's alpha values of >0.6, indicating sufficient internal consistency (Table 2). The remaining subscales had poor internal consistency were removed.

The final instrument yielded 13 items in four subscales: (1) self-image and stigmatisation, (2) factors promoting self-efficacy, (3) fear of pain or needles, and (4) time and family support.

The mean scores of the 13 items of the Ch-ASIQ were calculated. The mean overall Ch-ASIQ score was 2.50 (standard deviation, 0.38), which was the mid-point. The item yielding the most negative attitude toward starting insulin treatment was "I am afraid of needle injection" (70.6%), whereas the item yielding the most positive attitude towards starting insulin treatment was "I can manage the skill of injecting insulin" (67.5%) in the factors promoting self-efficacy subscale.

The linear regression analysis showed that women had more negative attitudes toward starting insulin treatment (P=0.022, Table 3). Patients who could not self-administer the questionnaire had lower scores on the factors promoting self-efficacy subscale. Age, education level, working status, haemoglobin A1c, coexisting hypertension, and complications related to retinopathy were not associated with the Ch-ASIQ scores.

Discussion

Two subscales of the Ch-ASIQ measure two common psychological barriers to starting insulin treatment: stigma of insulin use and fear of injection. Clinicians should consider patients' negative emotions and concerns when counselling them to start insulin treatment. Similarly, two subscales of the Ch-ASIQ

measure patients' perceived needs in terms of personal resources required to take on the added responsibility of insulin therapy. It is important to identify ways to empower patients, especially those with lower education levels and health literacy, and to assess their needs in terms of knowledge, skills, and social support. Time should be factored in an evaluation of a patient's readiness to adhere to any change in drug regimen.

Time appears to be an important factor, although less than one-third of the patients were employed full-time. This may reflect long working hours and limited free time.

The deleted items 'Misunderstanding of insulin therapy', 'Worry about complications of insulin therapy', and 'Trust in health care professionals' appear to be relatively unimportant in our study population, possibly owing to their lower levels of education, age, and ethnicity. Elderly Chinese patients appear to be less likely to question the doctor's expertise or advice.

The items related to fear of hypoglycaemia, weight gain, and complications of insulin, which have been reported to be important,[4,5] were not consistently weighted in the exploratory factor analysis on our patients. Similar findings were also found in another study that interviewed Chinese subjects.[2] One explanation is that the anxiety evoked by injection exceeds that evoked by any other factor.

One reason for insulin refusal is that Chinese patients might not trust Western medicine.[1] Nonetheless, in our patients, the items related to distrust of Western medicine were deleted, indicating that these were not barriers to starting insulin treatment in our patients.

The mean overall score for attitudes toward insulin treatment was at the mid-point (2.5), indicating ambivalence. Fear of pain and needles has been reported to be an important barrier to starting insulin treatment.[1-3] Primary healthcare professionals should be trained to manage patients' anxiety about needles, counsel patients on the use of less-painful insulin pens, instruct patients on proper injection techniques, and provide support to help patients starting insulin treatment.

There are limitations to the study. The questionnaire was interviewer-administered in most patients owing to poor literacy levels. The psychometric properties of the Ch-ASIQ may have differed if self-administered. Test-retest reliability measurements were not performed; further studies to examine the responsiveness of the instrument (ability to detect change) following intervention or over time are warranted. Our patients were generally older; younger patients with higher education levels might have responded differently. Further studies with age subgroups are needed.

TABLE 2. Mean scores of individual items and internal consistency of each subscale

Subscale/item	Mean±standard deviation score	No. (%) of patients agree/totally agree	Cronbach's alpha if item deleted
Self-image and stigmatisation (Cronbach's alpha=0.802)			
Item 22: I worry that people will know I have diabetes if I am on insulin treatment	2.36±0.85	121 (40.33)	0.702
Item 23: Injecting insulin is embarrassing; I worry about being seen when I inject insulin	2.49±0.81	147 (49.16)	0.663
Item 24: If I have to inject insulin, it makes me feel like a drug addict	2.45±0.80	133 (44.93)	0.812
Factors promoting self-efficacy (Cronbach's alpha=0.675)			
Item 1: I have up-to-date knowledge about diabetes management	2.60±0.83	189 (63.21)	0.670
Item 8: Insulin can help control blood glucose and prevent complications	2.65±0.68	181 (63.73)	0.618
Item 14: I can manage the skill of injecting insulin	2.72±0.75	201 (67.45)	0.592
Item 26: There is social support available if I have to inject insulin	2.37±0.68	131 (44.41)	0.601
Item 27: I can pay as close attention to my diet as insulin treatment requires. For example, I may need to eat snacks or reduce my amount of eating accordingly.	2.67±0.66	196 (66.67)	0.640
Fear of pain or needles (Cronbach's alpha=0.653)			
Item 13: Injecting insulin is painful	2.79±0.73	200 (66.89)	0.620
Item 16: I am afraid of needle injections	2.91±0.86	211 (70.57)	0.340
Item 17: I worry about needing to perform home blood sugar monitoring	2.59±0.82	158 (53.02)	0.656
Time and family support (Cronbach's alpha=0.620)			
Item 20: I can spare enough time to perform insulin injection	2.58±0.71	176 (59.46)	-
Item 25: My family will support me in injecting insulin	2.45±0.73	133 (45.70)	-
Misunderstanding of insulin therapy (Cronbach's alpha=0.573)			
Item 6: Insulin can cause permanent damage to or worsening of my health	2.50±0.71	133 (45.86)	0.512
Item 9: Diabetes tablets work better than insulin	2.82±0.70	205 (69.26)	0.460
Item 10: Insulin injection means failure of oral diabetes treatment	2.73±0.64	197 (66.55)	0.560
Item 15: Injecting insulin is inconvenient	3.05±0.72	242 (80.40)	0.463
Worry about complications of insulin therapy (Cronbach's alpha=0.488)			
Item 5: Insulin treatment for diabetes causes feelings of drug dependence	2.63±0.69	172 (58.70)	0.550
Item 11: An insulin overdose can lead to extremely low blood sugar levels (hypoglycaemia). I am afraid of experiencing the symptoms of low blood sugar levels.	2.61±0.68	168 (57.53)	0.337
Item 12: I worry about weight gain associated with insulin injections	2.40±0.65	117 (39.80)	0.374
Item 18: I worry about skin marks or skin complications associated with injecting insulin	2.56±0.72	152 (51.18)	0.383
Item 21: Insulin treatment will make life less flexible or affect my social life and hobbies (eg, performing exercise, dining out)	2.67±0.73	174 (58.78)	0.485
Trust in health care professionals (Cronbach's alpha=0.203)			
Item 2: I trust that my doctor is providing me with the most appropriate diabetes management for me	3.22±0.60	278 (92.67)	-
Item 3: I wish to or I am now trying traditional Chinese medicine to control blood sugar	2.35±0.79	130 (43.05)	-
Item 4: I wish to or am now trying lifestyle (diet control and exercise) or other alternative medicine (eg, complementary medicine, Qi Kung, etc) to control blood sugar	3.15±0.58	280 (92.72)	-

TABLE 3. Factors associated with the Chinese version of the Attitudes to Starting Insulin Questionnaire

Factors	Self-image and stigmatisation*		Factors promoting self-efficacy†	
	Coefficient (95% CI)	P value	Coefficient (95% CI)	P value
Age	−0.006 (−0.018 to 0.006)	0.359	−0.007 (−0.015 to 0.002)	0.114
Female	0.158 (−0.058 to 0.374)	0.152	−0.083 (−0.238 to 0.073)	0.297
Education				
No formal education		0.568		0.277
Secondary or above	0.127 (−0.154 to 0.408)	0.376	0.164 (−0.039 to 0.367)	0.112
Primary	0.037 (−0.227 to 0.301)	0.783	0.102 (−0.087 to 0.291)	0.290
Working status				
Working		0.427		0.993
Homemaker	−0.130 (−0.389 to 0.128)	0.324	−0.009 (−0.193 to 0.175)	0.924
Unemployed/retired	−0.152 (−0.397 to 0.093)	0.223	−0.009 (−0.184 to 0.165)	0.919
Interviewer administration	0.063 (−0.117 to 0.244)	0.491	−0.176 (−0.303 to −0.049)	0.007
Duration of diabetes	−0.012 (−0.027 to 0.004)	0.140	0.007 (−0.004 to 0.017)	0.225
Diabetes drug				
Metformin only		0.152		0.187
Gliclazide and metformin	−0.482 (−0.983 to 0.018)	0.059	0.330 (−0.036 to 0.696)	0.078
Glibenclamide and metformin	−0.527 (−1.078 to 0.024)	0.061	0.271 (−0.128 to 0.671)	0.183
Body mass index				
Underweight/normal		0.195		0.359
Overweight	−0.088 (−0.299 to 0.123)	0.414	−0.108 (−0.258 to 0.043)	0.160
Obese	−0.199 (−0.415 to 0.017)	0.071	−0.038 (−0.191 to 0.115)	0.624
Haemoglobin A1c	−0.028 (−0.103 to 0.048)	0.473	0.046 (−0.008 to 0.099)	0.095
Low-density lipoprotein	−0.073 (−0.186 to 0.040)	0.204	0.023 (−0.054 to 0.101)	0.552
Estimated glomerular filtration rate	0.001 (−0.003 to 0.005)	0.501	0.002 (−0.001 to 0.005)	0.195
Hypertension	0.142 (−0.076 to 0.360)	0.203	0.093 (−0.064 to 0.250)	0.248
Nephropathy	0.247 (−0.025 to 0.519)	0.075	0.034 (−0.154 to 0.223)	0.721
Retinopathy	0.079 (−0.094 to 0.252)	0.370	0.048 (−0.074 to 0.171)	0.439

* Higher scores indicate greater barriers to insulin treatment
† Higher scores indicate lower barriers to insulin treatment

Conclusions

The 13-item Chinese version of Ch-ASIQ has reliable psychometric properties and an interpretable and relevant structure. The most significant barriers to starting insulin treatment appear to be fear of pain and needles and perceived insufficient social support. Nonetheless, most patients are aware of the effectiveness of insulin and have confidence to learn the skill of insulin injection. Women are more negative towards starting insulin treatment and have more fear of pain and needles. Support and education for patients may increase their acceptance of insulin treatment.

Acknowledgements

References
1. Wang HF, Yeh MC. Psychological resistance to insulin therapy in adults with type 2 diabetes: mixed-method systematic review. J Adv Nurs 2012;68:743-57.
2. Wong S, Lee J, Ko Y, Chong MF, Lam CK, Tang WE.

Fear of pain or needles*		Time and family support†		Overall*	
Coefficient (95% CI)	P value	Coefficient (95% CI)	P value	Coefficient (95% CI)	P value
−0.003 (−0.014 to 0.008)	0.550	−0.001 (−0.013 to 0.011)	0.868	0.002 (−0.005 to 0.009)	0.633
0.266 (0.068 to 0.465)	0.008	−0.054 (−0.261 to 0.154)	0.611	0.154 (0.022 to 0.285)	0.022
	0.909		0.398		0.827
0.046 (−0.209 to 0.300)	0.725	0.167 (−0.101 to 0.435)	0.221	−0.050 (−0.221 to 0.122)	0.569
0.053 (−0.185 to 0.290)	0.664	0.166 (−0.084 to 0.416)	0.192	−0.048 (−0.208 to 0.112)	0.558
	0.428		0.227		0.799
0.124 (−0.114 to 0.362)	0.307	0.150 (−0.101 to 0.401)	0.241	−0.024 (−0.181 to 0.134)	0.769
0.136 (−0.086 to 0.359)	0.230	0.204 (−0.035 to 0.443)	0.094	−0.050 (−0.198 to 0.097)	0.503
0.125 (−0.042 to 0.291)	0.141	0.057 (−0.116 to 0.230)	0.518	0.103 (−0.004 to 0.210)	0.060
0.002 (−0.012 to 0.016)	0.756	0.004 (−0.011 to 0.019)	0.592	−0.006 (−0.015 to 0.003)	0.178
	0.087		0.960		0.063
−0.365 (−0.818 to 0.089)	0.115	−0.065 (−0.536 to 0.406)	0.786	−0.360 (−0.663 to −0.057)	0.020
−0.162 (−0.662 to 0.337)	0.524	−0.074 (−0.596 to 0.447)	0.780	−0.320 (−0.651 to 0.012)	0.059
	0.459		0.073		0.628
−0.112 (−0.306 to 0.082)	0.256	0.235 (0.032 to 0.437)	0.023	−0.022 (−0.148 to 0.104)	0.733
−0.105 (−0.303 to 0.094)	0.301	0.102 (−0.105 to 0.309)	0.336	−0.063 (−0.193 to 0.067)	0.342
−0.039 (−0.110 to 0.031)	0.275	0.038 (−0.036 to 0.111)	0.316	−0.042 (−0.086 to 0.003)	0.070
−0.043 (−0.147 to 0.061)	0.414	0.050 (−0.056 to 0.156)	0.351	−0.059 (−0.124 to 0.007)	0.082
0.001 (−0.003 to 0.004)	0.762	0.001 (−0.002 to 0.005)	0.503	−0.001 (−0.003 to 0.002)	0.671
−0.012 (−0.215 to 0.191)	0.909	−0.016 (−0.227 to 0.194)	0.879	−0.026 (−0.160 to 0.108)	0.701
0.307 (0.062 to 0.552)	0.014	−0.070 (−0.327 to 0.186)	0.590	0.120 (−0.036 to 0.277)	0.132
0.093 (−0.065 to 0.251)	0.251	0.043 (−0.123 to 0.208)	0.611	0.023 (−0.079 to 0.126)	0.655

Perceptions of insulin therapy amongst Asian patients with diabetes in Singapore. Diabet Med 2011;28:206-11.

3. Nam S, Chesla C, Stotts NA, Kroon L, Janson SL. Factors associated with psychological insulin resistance in individuals with type 2 diabetes. Diabetes Care 2010;33:1747-9.

4. Petrak F, Stridde E, Leverkus F, Crispin AA, Forst T, Pfutzner A. Development and validation of a new measure to evaluate psychological resistance to insulin treatment. Diabetes Care 2007;30:2199-204.

5. Snoek FJ, Skovlund SE, Pouwer F. Development and validation of the insulin treatment appraisal scale (ITAS) in patients with type 2 diabetes. Health Qual Life Outcomes 2007;5:69.