Validity and reliability of the Chinese version of the Insulin Treatment Appraisal Scale among primary care patients in Hong Kong

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ABSTRACT

Introduction: Patients with diabetes mellitus often delay insulin initiation and titration due to psychological factors. This phenomenon is known as 'psychological insulin resistance'. Tools that identify psychological insulin resistance are valuable for detecting its causes and can lead to appropriate counselling. The Insulin Treatment Appraisal Scale was initially developed for western populations and has been translated and validated to measure psychological insulin resistance in Taiwan (Chinese version of the Insulin Treatment Appraisal Scale, C-ITAS). The current study examined the prevalence of psychological insulin resistance and the validity of the C-ITAS in a local population.

Methods: This cross-sectional study involved 360 patients with diabetes mellitus from a government-funded general out-patient clinic who completed the C-ITAS questionnaire. The total C-ITAS score was compared for patients with psychological insulin resistance and those without, and the internal consistency and test-retest reliability of the C-ITAS were calculated. An exploratory factor analysis was used to identify factors within the C-ITAS.

Results: The prevalence of psychological insulin resistance was 44.9%. The internal consistency of the scale was high (Cronbach's alpha=0.78). The test-retest reliability was positive with all C-ITAS questions (0.294-0.725). The mean C-ITAS score was significantly higher among patients with psychological insulin resistance than those without (42.42 vs 35.78; P<0.001). The exploratory factor analysis, however, failed to identify the two clear factors identified in the original validation study.

Conclusions: The C-ITAS appears to be a feasible and potentially useful tool for identifying psychological insulin resistance, but additional validation or translation is required before it can be widely used clinically.

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New knowledge added by this study

- The Chinese version of the Insulin Treatment Appraisal Scale (C-ITAS) is a potentially useful and reliable tool to understand patients' underlying reasons for psychological insulin resistance (PIR).
- Further validation of C-ITAS is needed.

Implications for clinical practice or policy

- Understanding patients' PIR can lead to appropriate and patient-centred counselling.
- Validation of C-ITAS can facilitate a comparison of local PIR studies with those in other countries.

Introduction

Type 2 diabetes mellitus (DM) is a prevalent and increasingly common disease worldwide.[1] It is estimated to affect 10% of the Hong Kong (HK) population (approximately 700 000 people).[2] Achieving satisfactory DM control during the early disease course can reduce DM-induced microvascular and macrovascular complications (ie the 'legacy effect').[3,4] These benefits were maintained in patients in a tight DM-control group even though their glycosylated haemoglobin (HbA1c) level became similar to those in the control group after the end of the United Kingdom Prospective Diabetes Study.[4] It was proposed that a 'reverse legacy effect' also persists: "intensive glycaemic intervention started late in the natural course of diabetes seems disappointingly ineffective in limiting cardiovascular events".[5,6] Very tight control may even result in mortality.[7,8] Therefore, achieving tight HbA1c control early via lifestyle changes and the use of medications including insulin is important.

Because of the progressive nature of DM, most patients eventually require insulin.[9] Despite robust evidence of the benefits of early strict HbA1c control, patients often delay insulin initiation and titration. In a UK study, 50% of patients with DM delayed

胰島素治療評估量表（中文版）在基層醫療層面上的效度和信度

李錦培

引言：糖尿病患者往往因心理因素而抗拒啟動或延遲胰島素治療，這種現象被稱為「心理性胰島素抵抗」。能有效評估糖尿病患者的心理性胰島素抵抗的工具有助偵測抵抗原因，為患者提供適當的輔導。胰島素治療評估量表（ITAS）最初為西方國家的糖尿病患者而設，後來於台灣被翻譯加以驗證得出ITAS中文版。本研究探討心理性胰島素抵抗的比率，以及ITAS中文版的有效性。

方法：在這橫斷面研究中，於一所獲政府資助的普通科門診診所求診的360名糖尿病患者填寫了ITAS中文版問卷。按填寫好的問卷，我們比較具心理性胰島素抵抗的組別與沒有的組別的ITAS得分，並計算ITAS中文版問卷的內部一致性和重測可靠性。利用探索性因素分析找出ITAS中文版問卷的因素結構。

結果：心理性胰島素抵抗的比率為44.9%。ITAS中文版問卷的內部一致性信度高（Cronbach's alpha信度系數為0.78）。這問卷中所有問題的重測信度為正值（信度系數為0.294至0.725）。具心理性胰島素抵抗的組別的問卷平均得分比沒有的組別明顯較高（信度系數為42.42比35.78；P<0.001）。然而，探索性因素分析未能確定在原來驗證研究中兩個確定的因素結構。

結論：ITAS中文版問卷似乎是識別心理性胰島素抵抗的一個可行和有效的工具，但在臨床上廣泛應用前須進行額外的驗證或翻譯。

insulin initiation despite suboptimal control for 5 years, regardless of the presence of complications.[10] Their reluctance to initiate insulin use[10-12] and its subsequent titration[13] is known as 'psychological insulin resistance' (PIR). The prevalence of PIR has been estimated to be higher in Singapore (70.6%)[11] than in western countries (approximately 20%-40%).[12] A HK survey of 97 participants found a similarly high prevalence of PIR (72.1%).[14] Previous studies conducted in western countries have identified several factors that can lead to PIR.[11-13] These reasons might differ in Asian countries, however.[15,16] Recently, a local primary care research group developed a scale, Chinese Attitudes to Starting Insulin questionnaire, to identify barriers to insulin initiation in insulin-naïve patients with DM.[16] These investigators found that Asian patients might be more affected by the availability of social support and that cultural differences might also play a role. For example, Chinese patients are more likely to combine western medical treatments with traditional Chinese medicine[17] and might believe that hypoglycaemic agents cause renal toxicity.[18]

Doctors, particularly primary care physicians, can be insensitive to patients' psychological needs; physicians often fail to recognise psychological needs[19] and might incorrectly identify the reasons for a patient's PIR.[20,21] Identifying one's psychological needs might be hindered in HK due to short consultation times (lasting an average of 5-7 minutes per consultation). A limited number of longer sessions may be offered to DM patients with difficult glycaemic control, but the time limit would be 10 to 14 minutes. Therefore, a quick tool to help identify PIR and its underlying causes might help general practice physicians optimise care for their patients with DM.[12] The Insulin Treatment Appraisal Scale (ITAS) was developed for this purpose.[22] The Chinese version of the ITAS (C-ITAS) was validated in Taiwan,[23] and has been used in Taiwan[15] to investigate the underlying causes of PIR. Validating C-ITAS scores might enable direct comparisons of data between local and international studies. The C-ITAS might also be used to help local primary care clinicians identify PIR and offer appropriate counselling. The ITAS is sensitive to changes in PIR throughout the course of DM.[24]

This study is the first to be conducted in HK to examine the prevalence of PIR and the validity and reliability of the C-ITAS in our local population.

Methods

This research has been approved by the Research Ethics Committee at Kowloon West Cluster, Hospital Authority.

Participants

Participants were recruited from a government-funded primary care general out-patient clinic in HK from July to September 2013. Written consent was obtained when the participants were approached by the research assistant. The investigator's contact information was given to each participant if they had concerns after the administration of the questionnaire. Patients who fulfilled the following criteria were recruited: (1) diagnosed with type 2 DM as defined by the World Health Organization[25] for ≥6 months; (2) aged 30 years or above; (3) of Chinese ethnicity; (4) able to communicate effectively in Cantonese or Mandarin; and (5) had the mental capacity to provide informed written consent. The exclusion criteria were severe sensory deficits, severe mental illness (eg dementia, psychosis, or mental retardation), or any other health condition that compromised the ability to comprehend and complete the questionnaire. The required sample size was calculated from the estimated prevalence rate of PIR in the primary care setting. To achieve a 95% confidence interval with a margin of error of 5% and an estimated 70% prevalence of PIR among patients with DM in public primary care,[11,14] the required sample size was estimated to be 312 patients. To compensate for the predicted 20% refusal rate, at least 390 patients were recruited.

A list of DM patients who would attend the clinic the next day was obtained daily. From that list,

40 patients were randomly selected by computer (25 in the morning and 15 in the afternoon). A reminder was set in the clinical computer system such that clinic staff were alerted once the patient attended his or her appointment. The procedure was repeated until the number of patients recruited exceeded 390, which was checked at clinic closing time.

Patients were encouraged to complete the questionnaire unaided because the C-ITAS is self-administered. Because the majority of patients who attend public primary care clinics are of lower socio-economic status and education level, those who had difficulty completing the questionnaire were assisted by research assistants who were trained by the principal investigator.

Each patient was asked whether he or she was willing to have insulin started or titrated upon his or her case doctor's suggestion. The response options included "strongly unwilling", "unwilling", "might consider it", "willing", and "very willing". Demographic data were collected, and clinical data (eg the presence of DM complications, insulin use, and control of DM and lipid levels) were retrieved from a computer database.

Insulin Treatment Appraisal Scale

The ITAS is a 20-item instrument that contains 16 negative and four positive statements that appraise insulin treatment. Each statement is ranked using a 5-point Likert-type scale from 1 to 5. Positive scores are reversed to allow for summation. The total possible score ranges from 0 to 80. A higher score signifies a more negative appraisal of insulin. The ITAS was developed for clinical use to measure PIR.[22] No cut-off score is used to diagnose PIR. Of those who completed the clinical interview, 26 were selected for phone interview 2 to 4 weeks later to examine test-retest reliability. Because of the lack of a written language difference between Taiwan and HK, the validated C-ITAS was used with the permission of the Taiwan research group.

Statistical analyses

The C-ITAS was examined for its internal reliability using Cronbach's alpha, the test-retest reliability was assessed using Pearson's correlation of test scores and retest scores, and construct validity was assessed using an exploratory factor analysis (EFA) [using Oblimin rotation as this was used in the original development study of ITAS[22]]. Patients who answered "strongly unwilling" or "unwilling" to the question "Would you agree to start or titrate insulin treatment if advised by your case doctor?" were classified as having PIR. Descriptive statistics were used to describe the prevalence of PIR. Each C-ITAS item was dichotomised as "unwilling"

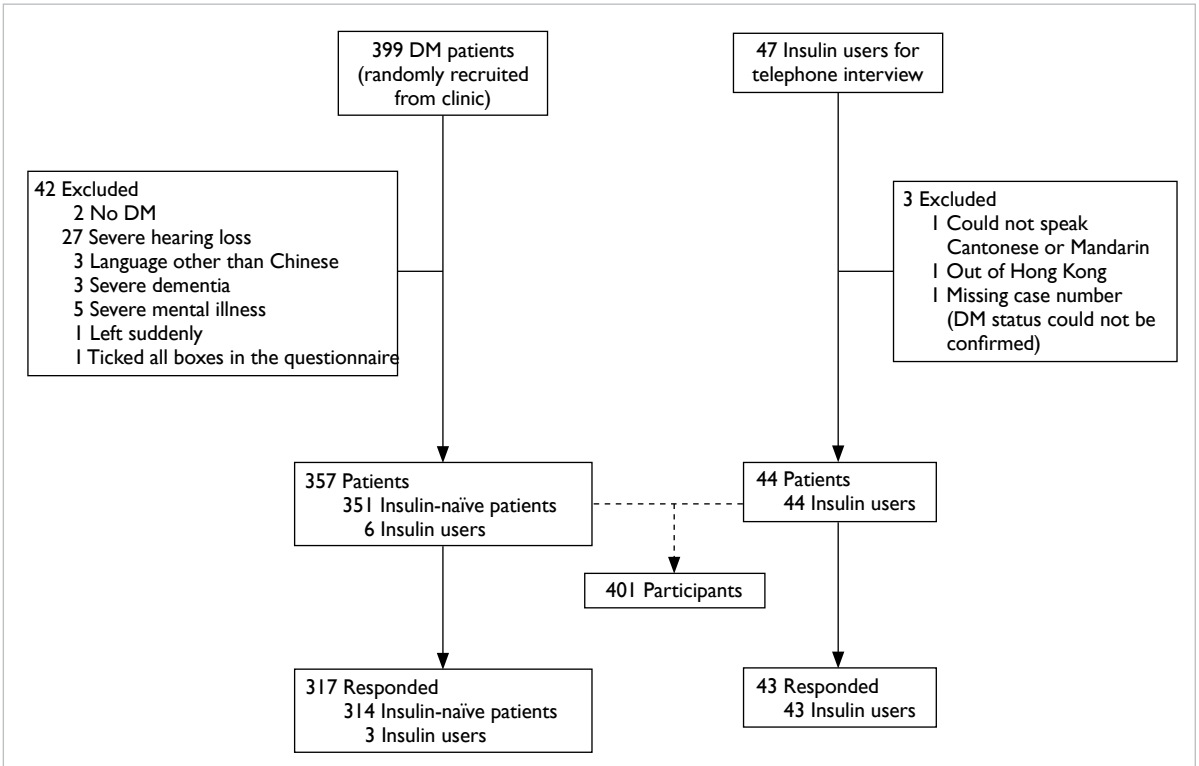

FIG 1. Enrolment and outcomes of the study
Abbreviation: DM = diabetes mellitus

(scores of 1 and 2) or "neutral/willing" (scores of 3 to 5); this dichotomy was created to assess the difference between patients with and without PIR. The responses of the patients with or without PIR were compared using a Chi squared test.

Results

Participants

A total of 399 patients with DM were randomly selected from the clinical database and approached by the research team (Fig 1). Of them, 42 patients were excluded due to the following circumstances: two patients were incorrectly diagnosed with DM; 27 had severely impaired hearing not compensated for with the use of hearing aids; three spoke languages other than Cantonese or Mandarin; eight had severe psychiatric illness such as dementia, psychosis, or mental retardation; one left at the beginning of the interview when called into a consultation room; and one was excluded for checking all boxes of the questionnaire.

In addition to the insulin-naïve patients with DM who were recruited as outlined above, all of the current insulin users who were not interviewed during the above period (47 patients) were invited to participate in this study and were interviewed over the phone; of whom three were excluded for the following reasons: one could not speak Cantonese or Mandarin, one was out of HK during the interview period, and one questionnaire was invalid due to a missing subject case number.

The overall response rate was 89.8% (n=360): 89.5% (n=314) for the insulin-naïve patients and 92.0% (n=46) for the insulin users. Other demographic data are shown in Table 1.

A total of 12.8% (n=46/360) of participants were insulin users. Patients with HbA1c ≥7% (≥53 mmol/mol; 21.6%) were more likely to be on insulin than those with HbA1c <7% (<53 mmol/mol; 2.9%; P<0.001). The HbA1c level was not significantly associated with the presence of DM complications in the current study. Of all participants, 96.3% received DM complication screening within 2 years, which was a nurse-led clinical service to screen for DM complications and provide counselling.

Non-respondents were significantly older (mean age=72.32 vs 67.17 years, *t* test: P<0.001), less likely to agree to titrate insulin (for current insulin users), and less educated (91.7% educated up to primary level vs 68.9%; Chi squared test; P=0.004). The differences with regard to the other demographics, including DM complication rate, insulin use status, marriage, work, family income, and gender were not significant.

The prevalence of PIR was 44.9% (141/314; 95% confidence interval [CI], 39.4% to 50.4%) in insulin-naïve patients; in contrast, the PIR rate was 6.8% (3/44; 95% CI, -0.64% to 14.24%) in current insulin users.

The questionnaire

The internal consistency of the C-ITAS questionnaire was high, with Cronbach's alpha of 0.78. The original ITAS was designed to have 16 negative and four positive statements. Cronbach's alpha was calculated separately for the negative and positive statements, yielding values of 0.812 and 0.738, respectively. Within the negative statement scale, removing two negatively stated questions individually, including Q1, "Insulin signifies failure with pre-insulin therapy", and Q18, "Taking insulin causes family/friends to be more concerned" improved the overall Cronbach's alpha to 0.819 and 0.825, respectively.

Of the 20 individual questions within the C-ITAS, answers to 17 questions were significantly

TABLE 1. Demographic information of patients

	No. of patients	%
Response rate		
Overall	360/401	89.8
Insulin users	46/50	92.0
Insulin-naïve patients	314/351	89.5
Demographics		
DM for >10 years	161/356	45.2
Family income (HK$)		
≤$10 000	238/352	67.6
<$5000	132/352	37.5
Female	216/360	60.0
Education		
No formal education	76/350	21.7
Primary school level	165/350	47.1
Tertiary level or above	19/350	5.5
Married	241/358	67.3
Retired	271/359	75.5
Control		
HbA1c ≤7%	195/360	54.2
LDL ≤2.6 mmol/L	218/360	60.6
LDL ≥3.5 mmol/L	41/360	11.4
Complications		
Presence of microalbuminuria/proteinuria	58/360	16.1
eGFR by MDRD <60 mL/min/1.73 m^2	72/360	20.0
Diabetic foot with impaired VPT	14/360	3.9
Retinopathy requiring referral to specialist	51/360	14.2
Insulin status		
On insulin	46/360	12.8

Abbreviations: DM = diabetes mellitus; eGFR = estimated glomerular filtration rate; HbA1c = glycosylated haemoglobin; LDL = low-density lipoprotein; MDRD = Modification of Diet in Renal Disease; VPT = vibration perception threshold

different in the expected direction between patients with PIR and those without. Importantly, Q18, "Taking insulin causes family/friends to be more concerned" was originally designed to detect a negative view towards insulin use; however, more insulin-accepting patients agreed with the statement (Table 2).

The total C-ITAS scores, as described above, were higher among participants who refused insulin initiation (42.42 vs 35.78; *t* test, P<0.001). The test-retest reliability for each question ranged from 0.294 to 0.725, and 13 questions were significant (P<0.05). The test-retest reliability of the overall scores as defined above was 0.571 (P=0.002).

The EFA identified five factors with an eigenvalue of >1. Nonetheless, the scree plot correctly identified two factors within the questionnaire. When two factors were extracted using an Oblimin rotation, a few negative statements including Q18 were significantly associated with the other positive statements (Table 3). The three-, four-, and five-factor solutions were calculated as suggested by the eigenvalue, which did not provide better representation of the latent structure of ITAS.

In the EFA, the Kaiser-Meyer-Olkin measure of sampling adequacy was 0.834 and Bartlett's test of sphericity was significant (P<0.001), and signified adequate sample size for the test.

Discussion

Because the participants were old and not well educated, difficulties in answering the C-ITAS were expected. This assumption was further supported by the fact that the non-respondents were less educated and were older than the respondents. Nevertheless a high proportion of participants (89.8%) were able to complete the entire questionnaire. Additional research might be necessary to assess the response rate if the questionnaire is self-administered because the staffing at our public out-patient clinics was limited. The use of ITAS might be limited if it cannot be self-administered because it was developed as a self-administered tool.

Prevalence of psychological insulin resistance

It is surprising that the prevalence of PIR was not as high as reported by previous studies.[11,14] More than 50% of patients were willing to consider or accept insulin if suggested by their primary doctor. This finding might be because of differences in the patient cohorts or the improvements made to the PIR over the years due to patient education. Only 53 patients with DM out of the thousands of patients followed up in our clinic were started on insulin. Alternative reasons might explain the low rates of insulin use (eg

TABLE 2. The Chinese version of the Insulin Treatment Appraisal Scale (C-ITAS) score differences between patients with and without psychological insulin resistance (only statistically significant results are shown; n=314)

	Willing to start insulin if advised?*		
	Yes / will consider	No	P value
Total C-ITAS score	35.78	42.42	<0.001
Q3. Taking insulin prevents diabetes complications	91.9% (159/173)	83.7% (118/141)	0.025
Q4. Others will see me as a sicker person	67.1% (114/170)	78.6% (110/140)	0.024
Q5. Taking insulin makes life less flexible	64.7% (112/173)	83.0% (117/141)	<0.001
Q6. I am afraid of injecting myself with a needle	69.6% (119/171)	87.2% (123/141)	<0.001
Q7. Taking insulin increases hypoglycaemia	70.8% (121/171)	80.9% (114/141)	0.04
Q8. Taking insulin improves health	88.4% (153/173)	80.0% (112/140)	0.039
Q9. Insulin causes weight gain	66.7% (114/171)	77.1% (108/140)	0.042
Q10. Insulin injections take a lot of time/energy	52.0% (89/171)	79.4% (112/141)	<0.001
Q11. Taking insulin means giving up activities I enjoy	40.1% (69/172)	62.9% (88/140)	<0.001
Q12. Taking insulin will worsen health	60.6% (103/170)	75.0% (105/140)	0.007
Q13. Injecting is embarrassing	41.3% (71/172)	61.9% (86/139)	<0.001
Q14. Injecting insulin is painful	62.8% (108/172)	81.6% (115/141)	<0.001
Q15. It is difficult to inject correctly every day	67.1% (116/173)	83.7% (118/141)	0.001
Q16. Taking insulin hinders fulfilling my responsibilities	49.7% (86/173)	73.8% (104/141)	<0.001
Q17. Taking insulin means better glucose control	95.3% (164/172)	84.4% (119/141)	0.001
Q18. Taking insulin causes family/friends to be more concerned	84.9% (146/172)	65.2% (92/141)	<0.001
Q19. Taking insulin improves energy level	87.3% (151/173)	70.9% (100/141)	<0.001

* Percentages of respondents who answered 'agree' or 'neutral' to these questions; denominators within the same group vary because missing data were excluded from calculation

TABLE 3. Results of the exploratory factor analysis for Insulin Treatment Appraisal Scale using two factors (only factor loading >0.3 are shown)

	Component	
	1	2
Use of insulin means control of diabetes failed		0.450
Use of insulin means my diabetes is worsened		0.408
Insulin can prevent diabetes complications		0.441
Use of insulin will make others view me as having more severe illness	0.302	
Use of insulin makes life inflexible	0.553	
I am afraid of injecting myself	0.508	
Use of insulin will increase hypoglycaemia	0.402	
Insulin can improve my health		0.627
Insulin will increase weight	0.401	
Insulin use will consume time and energy	0.720	
Insulin use means I have to give up my hobbies	0.613	
Use of insulin means my health will deteriorate	0.513	
Use of insulin is embarrassing	0.585	
Insulin injection is painful	0.516	
It is difficult to inject insulin correctly	0.717	
Use of insulin means difficulty in fulfilling my responsibilities	0.743	
Insulin can improve diabetes control		0.687
Insulin will make my family and friends more concerned		0.416
Use of insulin will increase my energy		0.534
Use of insulin will make me more dependent on my doctor	Not available*	

* Values not available because loading factor <0.3

physician beliefs and competencies regarding the use of insulin), and might merit additional research.

Validity and reliability of the questionnaire

The C-ITAS was reliable because it yielded high Cronbach's alpha scores (0.738-0.812) and correctly provided a higher score for patients who resisted insulin use. It identified many different attitudes towards insulin use; in the current study, answers to 17 out of 20 of the C-ITAS items significantly differed between patients who resisted insulin and those who did not, whereas a previous study showed that only four questions were able to make this distinction.[12] This may be because individual patients had multiple concerns and many different attitudes towards insulin use.

Although the test-retest reliability value of all ITAS items was positive, the values were low, ranging from 0.294 to 0.725 for individual C-ITAS questions. In the present study, the C-ITAS was completed either via a personal interview with a research assistant or by self-administration. Retests were administered via telephone interviews by either the research assistant or the principal investigator. Therefore, the low test-retest reliability scores might be because of the different means of administration or due to the different interviewers. Conversely, this difference might reflect the actual low test-retest reliability of the current C-ITAS that requires additional validation.

Question 18, "Taking insulin causes family/friends to be more concerned", merits additional discussion. Originally designed as a negative statement, it is expected that patient resistance to insulin would positively predict the score. The reverse was true, however, in the current study (Table 2). When the statement was reviewed by six family physicians and one psychiatrist, the word "concerned" (關心) was translated into a word in Chinese that can also mean "caring" (使用胰島素使家人和朋友對我更關心). It is likely that patients understood the question as, "Taking insulin causes my family and friends to be more caring toward me". Because Q18 was meant to be a negative statement, it is more appropriate to translate its meaning to "worry". This supposition is supported by both the Cronbach's alpha analysis, in which exclusion of Q18 improved the value of Cronbach's alpha, and the factor analysis, where Q18 was regarded as a factor with the other positive statements. The factor

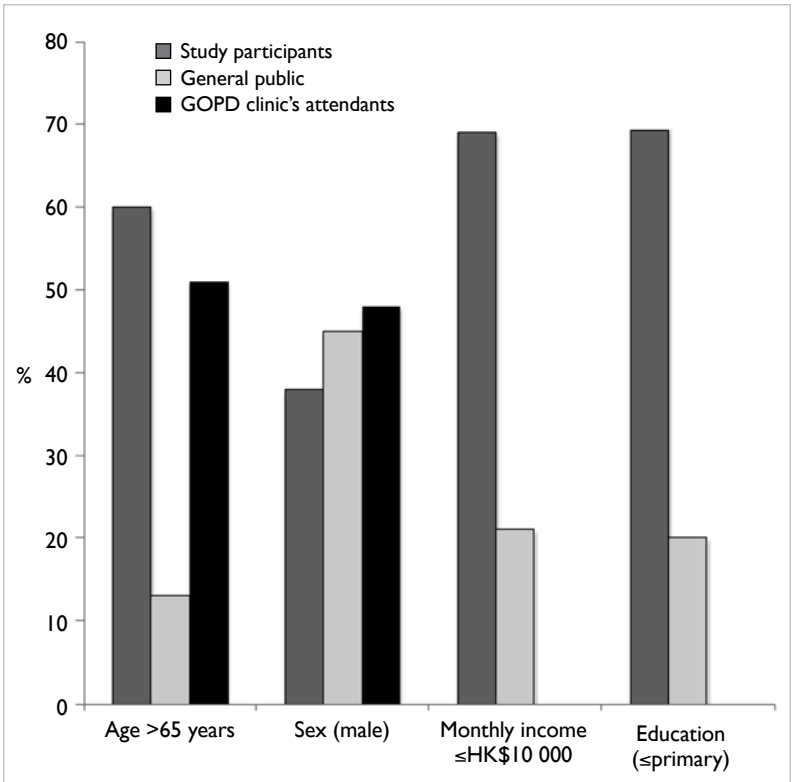

FIG 2. Comparison of demographic data in 2013
Abbreviation: GOPD = general out-patient department

analysis did not show a two-factor structure within the ITAS, as in the previous study.[22] As the factor analysis table notes (Table 3), when set as a two-factor construct, no trend can be drawn for these two groups. The factor analyses of the first study on the development of the ITAS[22] and the validation study in Taiwan[23] both showed a two-factor construct, with the two factors being positive statements and negative statements. This finding might reflect the previously noted translation problem; alternatively, our local community might have had a different set of causes for PIR. This finding suggests that a dialectic or cultural difference remains between HK and Taiwan, despite a shared written language.[26,27] Additional validation of the C-ITAS in our local population is likely necessary.

Strengths and weaknesses

The strengths of our study include its large sample size, the use of random sampling, and the high response rate. The use of an internationally validated questionnaire might aid comparison with results from other countries. The C-ITAS, however, might require additional validation as noted above.

The statement proposing the use of insulin to patients was hypothetical. For example, estimated PIR rates might be lower when patients perceive their disease as having deteriorated so that additional intervention is necessary.

This study was conducted in a major government-funded clinic in Hong Kong, and the demographics of the participants were more similar to those of other government clinics than to the general population (Fig 2). The extent to which the results can be generalised to other countries and to other social classes (eg wealthy patients attending private primary clinics) is not known.

A majority of the patients in the current study were insulin-naïve. Despite including all available insulin users in the clinic, the number of insulin users was small, and limits the potential applicability of this study's results to secondary or tertiary care where many patients may be on insulin.

The study also did not distinguish between questionnaires that were completed with the help of research staff and those that were self-administered. The influence of different administration methods on the outcome has not been previously described. For example, when participants did not understand a statement, the trained research assistant may use her own words to elaborate and explain it to the participant and thus may alter the statement's original sentence structure or intended meaning.

Another weakness was that data on macrovascular complications were not collected. Microvascular complications were well documented during the DM complication screening and were easily traceable. The tracing of macrovascular complications, however, was difficult because diagnostic coding needed to be entered or the complication needed to be mentioned in the latest case record by the respective doctors, and missed coding for macrovascular complications was not uncommon.

Conclusions

The prevalence of PIR was 44.9% in our population, which is less than that previously estimated. Tools such as the C-ITAS can improve physician's understanding of patient views on insulin and might help physicians to appropriately counsel their patients. The C-ITAS may provide clues to patients' knowledge about insulin use, eg the risk of hypoglycaemia or the side-effects of obesity. Despite good psychometric properties such as high internal consistency, there is a translation issue in at least one of the 20 statements. Health care professionals who wish to use the C-ITAS clinically should be aware of the instrument's limitations.

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Declaration

The author has disclosed no conflicts of interest.

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