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Survey of fear and compliance of Insulin Degludec and Insulin Aspart injection in type 2 diabetes mellitus patients and analysis of influencing factors

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Abstract

This study aims to investigate the fear and compliance of Insulin Degludec and Insulin Aspart (IDegAsp) injection in type 2 diabetes mellitus (T2DM) patients and study the factors influencing patient compliance. A total of 120 patients with T2DM treated from February 2019 to March 2022 were investigated and analyzed for fear and compliance on the Diabetes Fear of Injecting and Self-testing Questionnaire of diabetic patients and were divided into compliance and noncompliance groups according to the results to analyze the factors affecting patient compliance. The study found a high level of fear of IDegAsp injection among the 120 T2DM patients, with an average Diabetes Fear of Injecting and Self-testing Questionnaire score of (39.19 ± 4.59) points. Scores for medication compliance, dietary compliance, blood sugar monitoring, and lifestyle changes were (10.48 ± 1.52) points, (12.18 ± 2.27) points, (0.84 ± 0.12) points, and (9.13 ± 2.21) points, respectively. There was no significant difference between the compliance and noncompliance groups in terms of gender, age, lifestyle, educational level, occupation, current treatment method, family monthly income per capita, and medical payment method ($P > .05$). However, there were significant differences influenced by disease duration, complications, cognitive level, self-efficacy level, comorbidity count, and living status ($P < .05$). Multifactorial analysis showed that educational level, disease duration, complications, cognitive level, self-efficacy level, comorbidity count, and living status all affected patient compliance ($P < .05$). Educational level, disease duration, complications, cognitive level, self-efficacy level, comorbidity count, and living status are important factors affecting the fear and treatment compliance of IDegAsp injection in T2DM patients. These findings have implications for improving patient compliance and alleviating treatment fear.

Abbreviations: D-FISQ = diabetes fear of injecting and self-testing questionnaire, FSI = fear self-injecting, FST = fear self-testing, IDegAsp = Insulin Degludec and Insulin Aspart, T2DM = type 2 diabetes mellitus.

Keywords: compliance, fear, influencing factors, Insulin Degludec and Insulin Aspart, type 2 diabetes mellitus

1. Introduction

As a globally prevalent chronic metabolic disease, type 2 diabetes mellitus (T2DM) poses a major challenge to public health.[1] The disease is usually caused by a combination of island β-cell dysfunction and insulin resistance and requires lifelong management and treatment.[2] For patients with T2DM with poor efficacy of glucose-lowering drugs, insulin therapy is a key to control blood glucose and reduce the risk of complications. In recent years, as a new premixed insulin analog, Insulin Degludec and Insulin Aspart (IDegAsp) has been favored in clinical treatment due to its unique pharmacological properties, such as long-term action time and stability of glycemic control.[3] However, despite the wide recognition of the clinical effect of IDegAsp, patient compliance to treatment remains a key factor influencing its efficacy. Previous studies have indicated that low adherence to treatment may result from multiple factors, including fear of injection, concern about side effects, and suspicion of treatment effects, which not only lead to poor glycemic control, but may also increase the risk of complications and negatively affect patient quality of life.[4,5] Therefore, recognizing and understanding patient psychological response to IDegAsp injection is crucial to clinically developing individualized treatment plans and improving patient compliance. In view of this, this study aims to explore the key factors affecting adherence in patients with T2DM during dual insulin therapy and to provide targeted intervention strategies to improve treatment compliance and improve their efficacy and quality of life.

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The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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2. Data and methods

2.1. General information

This study was approved by the Ethics Committee of the Affiliated People's Hospital of Hubei University of Medicine. This study included 120 patients with T2DM treated between February 2019 to March 2022. Inclusion criteria: ① Patients with the following indications for the exclusive use of IDegAsp, whose disease is relatively stable after treatment. (1) All the patients included in the study met the relevant criteria in *Guidelines for the Prevention and Treatment of Type 2 Diabetes Mellitus in China*,[6] with typical symptoms of diabetes and at least one of the following conditions: fasting glucose level ≥ 7.0 mmol/L, oral glucose tolerance test 2-hour glucose ≥ 11.1 mmol/L or glycated hemoglobin (HbA 1 c) level ≥ 6.5%; (2) aged ≥ 18 years old; (3) have oral hypoglycemic drug therapy for more than 3 months, with insignificant therapeutic effect, glycated hemoglobin (HbA 1 c) ≥ 7.0%; ② patients in relatively stable condition and received IDegAsp for at least 1 year; ③ patients who can complete follow-up and get inform consent for the study. Exclusion criteria:① with serious complications such as diabetic nephropathy, diabetic retinopathy, diabetic neuropathy and diabetic foot; ② type 1 diabetic mellitus patients; ③ with consciousness disorder or mental illness, unable to communicate patients; ④ patients with severe heart, brain, liver and kidney disorders; ⑤ showed resistance to this study and refused to cooperate with doctors.

2.2. Method

2.2.1. Intervention protocol. All patients were treated with IDegAsp. During the initial stage of treatment, each patient received a dose of IDegAsp (produced by Novo Nordisk [China] Manufacturing Co., S20227004, 3 mL, 300 units) of 0.6 U/(kg · day) everyday. Patients receive subcutaneous injections before breakfast and dinner. According to the blood glucose level of each patient, the drug dose was adjusted timely, and this course was continued for 3 months.

2.2.2. FISQ scale score. The instrument used to assess the level of fear regarding injection and self-monitoring in patients with diabetes is "the Diabetes Fear of Injecting and Self-testing Questionnaire[7]"(D-FISQ). This scale is supported by Celik et al[8] and divided into 2 subsections: fear self-injecting (FSI) and fear self-testing (FST). The FSI subscale contains 6 questions, and the FST subscale contains 9 questions. Each question was scored according to the Likert 4 rating criteria with a range from 1 (never) to 4 (always). Total FSI scores ranged from 6 to 24, while FST scores ranged from 9 to 36, and D-FISQ scores ranged between 15 and 60, with higher scores indicating higher fear. The overall Cronbach α coefficient of this scale was 0.96, while the FSI and FST were 0.93 and 0.96, respectively. In the retest 2 weeks later, the within-group correlation for FSI ranged between 0.75 and 0.85 and the within-group correlation for FST was between 0.72 and 0.86. Although there is no currently official Chinese version of this scale, its Cronbach α coefficient of 0.89 was verified in the pretrial of this study and had a test-retest reliability of 0.78 after 2 weeks, indicating that the scale is suitable for assessing injection fear status in diabetic patients.

2.2.3. Compliance. The self-designed Treatment Compliance questionnaire for patients with T2DM was used to assess treatment compliance. This questionnaire was modified based on the Medication Adherence Scale for Chronic Diseases, given by Xu Weihua et al[9] in 2008 to assess medication adherence among patients with chronic diseases in China with high credit validity. The questionnaire included 13 items, divided into 4 subscales: medication compliance (3 items), dietary adherence (4 items), regular glucose monitoring compliance (2 items), and lifestyle modification compliance (including 4 items: exercise, regular life, and smoking and alcohol cessation). In addition, 8 items were added to the questionnaire specifically to assess patient compliance with the IDegAsp, including factors such as drug discomfort, side effects, busy work, financial stress and medical inconvenience. The questionnaire was scored by 1 to 4 points, and the total score ranged from 11 to 42 points. The higher score means the better treatment compliance, and the worse the versa. Based on practices in previous studies, patients were divided into compliance group (score ≥ 30) and noncompliance group (score < 30). The present study examined the Cronbach'α coefficient of 0.883 to assess the reliability of the questionnaire, indicating good internal consistency of the questionnaire. Furthermore, KMO and Bartlett tests were performed to assess the validity of the questionnaire, and the results showed KMO values between 0.665 and 0.808, indicating a correlation between variables of the questionnaire and suitable for factor analysis. The factor loading coefficient ranged between 0.448 and 0.642, showing the good construct validity of the questionnaire.

2.2.4. Basic data collection. The basic data of patients with diabetes were collected by using self-made Questionnaire on General condition of Diabetes Patients, covering the following aspects: gender, age, education, lifestyle, the current treatment, course, complications, occupation, family per capita monthly income, medical payment, cognitive level, self-efficacy level, number of complications, living conditions.

2.2.5. Research quality management. (1) The preparatory stage. Firstly, the inclusion criteria of the research objects were defined, and the questionnaire was revised and optimized for many times; secondly, the relevant literature was extensively searched out to form the first draft, and the experts in the fields of medical, nursing and epidemiology were invited to review and revise; finally, a small-scale preliminary test to determine the final form, content and structure of the questionnaire items to ensure consistency. (2) Implementation stage. ① Actively establish contact with the relevant departments of the local hospital, and introduce the purpose, importance and steps of the research to the heads of department in detail to win support and collaboration; ② Select professional and responsible investigators to ensure that they fully understand the purpose and key points of the survey; ③ After the questionnaire is distributed, the investigators are responsible for face-to-face inquiry and auxiliary filling, including Questionnaire on General Situation of Diabetes Patients and Questionnaire on Diabetes Knowledge. The investigator is responsible for filling out, recovering and checking the questionnaires to ensure the completeness and accuracy of the information. (3) Data processing stage. Before data entry, the questionnaire is checked, then the database is established, and strict data entry rules are set, such as variable value range, required items, logical jump and automatic query, to reduce errors in the data entry process.

2.3. Observational indicators

① The D-FISQ evaluated the level of fear that patients may experience during self-injection and self-glucose monitoring, including the FSI scale and FST scale, and the total scale score was recorded.

② Patient compliance was assessed by a self-designed compliance questionnaire, including medication compliance, dietary compliance, blood glucose monitoring, and life behavior change, all of which were evaluated by a 1 to 4 score method, with the

score ranging from 11 to 42 points, the higher the score, the better the patient's treatment compliance, the worse the versa; they were divided into compliance group (30 ≥ points, 89 cases) and noncompliance group (<30 points, 31 cases) according to the results.

③ General data of patients in the compliance and noncompliance groups were collected, and univariate and multivariate analysis was conducted to explore the factors affecting patient compliance; In terms of medical history collection for the treatment of nondiabetic diseases, we have coded the presence of nondiabetic disease treatment as "1" and absence as "0" for univariate regression analysis to examine the relationship with IDegAsp compliance.

④ In this observational study, we utilized the Mini-Mental State Examination to assess the cognitive function of participants. The Mini-Mental State Examination is a standardized assessment tool widely used in both clinical and research settings for the rapid screening of cognitive impairments. It evaluates various aspects including memory, attention, calculation ability, language comprehension and expression, and visual-spatial skills. The scale has a maximum score of 30, with lower scores indicating more severe cognitive impairment. A score of 27 to 30 is defined as good cognitive function, while scores below 27 are categorized as average/poor cognitive function.

2.4. Statistical method

SPSS23.0 software was used for data processing, counting data including gender, age, duration of disease were expressed as (n/%), and Chi-square test was performed; measurement data were expressed by ($\bar{\chi} \pm s$); multivariate logistic regression analysis was used to explore the influencing factors affecting patient compliance. $\alpha = 0.05$ is the inspection level.

3. Results

3.1. Investigation of fear of IDegAsp injection in T2DM patients

After evaluation, 120 patients with T2DM had a high level of fear of IDegAsp injection, with an average D-FISQ score of (39.19 ± 4.59) points. See Table 1.

3.2. Compliance survey among people with T2DM

The scores of medication compliance, dietary compliance, blood glucose monitoring and lifestyle change in T2DM were (10.48 ± 1.52) points, (12.18 ± 2.27) points, (0.84 ± 0.12) points, and (9 ± 2.21) points, respectively. See Table 2.

Table 1

Patient D-FISQ scale scores.

Factor	Score (points)
FSI Scale Score	17.55 ± 2.65
Cognition	5.68 ± 1.26
Physiological	5.55 ± 1.78
Emotional	4.98 ± 1.89
Behavioral	1.34 ± 0.41
FST Scale Score	21.64 ± 3.59
Cognition	6.02 ± 1.65
Physiological	6.54 ± 2.45
Emotional	6.78 ± 1.45
Behavioral	2.30 ± 0.98
D-FISQ Score	39.19 ± 4.59

D-FISQ = diabetes fear of injecting and self-testing questionnaire, FST = fear self-testing.

3.3. Univariate analysis of factors influencing compliance in T2DM population

There was no difference in the compliance and noncompliance groups in gender, age, lifestyle, education, occupation, current treatment, family per capita monthly income, medical payment, treatment of nondiabetic diseases ($P > .05$), but there were statistical differences in the course of disease, complications, cognitive level, self-efficacy, number of comorbidities, and living conditions ($P < .05$) (Table 3).

3.4. Multivariate analysis affecting population compliance with T2DM

Multivariate analysis showed that the educational level, course of disease, complications, cognitive level, number of comorbidities, and residence status all affected the patients' compliance ($P < .05$) (Tables 4 and 5).

4. Discussion

As a global chronic metabolic disease, the incidence of T2DM is rising sharply in China with the lifestyle changes and the aging population.[10,11] Effective management and treatment of this condition is essential to reduce its burden on the public health system. Insulin therapy, especially novel premixed insulin analogues such as IDegAsp, are widely used in clinical practice due to their favorable glycemic control effects. However, patients' treatment compliance is essential to achieve these efficacy, and inadequate compliance may lead to multiple serious consequences. First, irregular or incorrect drug use leads to poor glycemic control and increases the risk of hyperglycemia and hypoglycemic events, thus affecting the patient's ability to daily live and work.[12] Second, long-term poor glycemic control also increases the risk of diabetic complications such as cardiovascular disease, nephropathy, retinopathy, and neuropathy, and may even lead to death in severe cases. Finally, patients may need more frequent medical interventions and treatments due to poor glycemic control and increased complications, including hospitalization, examination, and medication adjustment, which will not only increase the health care burden of medical costs for individual patients, but also put greater financial pressure on the public health system.[13] In view of these problems, it is particularly important to explore and improve the compliance of IDegAsp in patients with T2DM.

The results of this study showed that patients had a generally higher fear of IDegAsp injection, with a mean D-FISQ score of 39.19 ± 4.59 points, indicating that fear of injection is a common phenomenon that may affect patients' treatment compliance. And the fear may stem from concerns about needle pain, unfamiliarity with the injection technique, or

Table 2

Compliance of T2DM patients.

Factor	Score (points)
Medication compliance	10.48 ± 1.52
Taking medication as prescribed (frequency)	3.41 ± 0.56
Taking medication as prescribed (dosage)	3.56 ± 0.76
Taking medication as prescribed (timing)	3.51 ± 0.73
Dietary compliance	12.18 ± 2.27
Follow a dietary plan to control meals	3.21 ± 0.60
Regularly have meals on time	3.14 ± 0.64
Frequently measure food portions	3.11 ± 0.61
Regularly use a food exchange list to organize meals	2.72 ± 0.53
Blood sugar monitoring	0.84 ± 0.12
Lifestyle behavioral changes	9.13 ± 2.21

T2DM = type 2 diabetes mellitus.

Table 3

Univariate analysis of factors influencing compliance in T2DM population.

Item	Noncompliant group (n = 31)		Compliant group (n = 89)		χ^2	*P*
	Number	Percentage (%)	Number	Percentage (%)		
Gender						
Male	18	58.06	51	57.30	0.005	.941
Female	13	41.94	38	42.70		
Age (years)						
≥60	21	67.74	55	61.80	0.35	.554
<60	10	32.26	34	38.20		
Educational level						
Below high school	12	38.71	24	26.97	1.51	.219
High school and above	19	61.29	65	73.03		
Lifestyle						
Good	18	58.06	64	71.91	2.037	.154
Average/Poor	13	41.94	25	28.09		
Current treatment method						
Lifestyle intervention	16	51.61	38	42.70	0.739	.390
Medication	15	48.39	51	57.30		
Disease duration						
≥5 years	29	93.55	57	64.04	9.856	.002
<5 years	2	6.45	32	35.96		
Complications						
Yes	28	90.32	29	32.58	30.736	.000
No	3	9.68	60	67.42		
Treatment of nondiabetic diseases						
Yes	16	51.61	43	48.31	0.100	.752
No	15	48.39	46	51.69		
Occupation						
Employed	18	58.06	55	61.80	0.134	.714
Unemployed/retired	13	41.94	34	38.20		
Family monthly income per capita						
≥5000 RMB	18	58.06	43	48.31	0.874	.350
<5000 RMB	13	41.94	46	51.69		
Medical payment method						
Self-pay	14	45.16	34	38.20	0.464	.496
Health insurance	17	54.84	55	61.80		
Cognitive level						
Good	12	38.71	75	84.27	23.937	.000
Average/poor	19	61.29	14	15.73		
Self-efficacy level						
Good	13	41.94	85	95.51	44.069	.000
Average/poor	18	58.06	4	4.49		
Number of comorbidities						
≥3	17	54.84	28	54.84	5.361	.021
<3	14	45.16	61	45.16		
Living status						
Living alone	16	51.61	27	51.61	4.526	.033
Living with others	15	48.39	62	48.39		

T2DM = type 2 diabetes mellitus.

Table 4

Assignment of values.

Factor	Assigned value
Disease duration	≥5 years = 1, <5 years = 0
Complications	Present = 1, absent = 0
Cognitive level	Average/poor = 1, good = 0
Self-efficacy level	Average/poor = 1, good = 0
Number of comorbidities	≥3 = 1, <3 = 0
Living status	Living alone = 1, living with others = 0

concerns about potential side effects. Specifically, patients with more sensitive pain or acupuncture phobia will tend to be concerned about the acupuncture pain during the injection process. Second, for patients unfamiliar with the injection technique, suspicion of uncertainty and ability to self-operant can lead to anxiety and fear.[14] In addition, patients may be concerned about possible side effects of insulin injections, such as hypoglycemia, subcutaneous tissue changes or allergic reactions, that may be amplified in the absence of adequate medical information.[15] Finally, if patients do not receive adequate education and support before starting insulin therapy, they may feel less confident about self-management, causing increased fear of injection.[16]

For medication compliance, the mean score was 10.48 ± 1.52 points; dietary treatment compliance was 12.18 ± 2.27 points, blood glucose monitoring compliance was 0.84 ± 0.12 points, and lifestyle modification compliance was 9.13 ± 2.21 points. These data reflect the imbalance in compliance across treatments in T2DM, especially in glucose monitoring, where low compliance may pose a significant barrier to the effective management of diabetes, suggesting that medical providers need more education and support in blood glucose monitoring and lifestyle changes to improve patient compliance. Therefore, this study further analyzed the factors influencing patients' compliance, and the results showed that there were significant

Table 5

Multifactor analysis of factors influencing compliance in T2DM population.

Factor	B (coefficient)	SE (standard error)	Wald	*P* (probability)	OR (odds ratio)	95% CI (confidence interval)	
						Lower limit	Upper limit
Disease duration	2.097	0.764	7.538	.006	8.140	1.822	36.369
Complications	2.961	0.648	20.860	.000	19.310	5.420	68.796
Cognitive level	-2.138	0.470	20.708	.000	0.118	0.047	0.296
Self-efficacy level	-3.382	0.628	29.009	.000	0.034	0.010	0.116
Number of comorbidities	0.973	0.427	5.190	.023	2.645	1.146	6.109
Living status	0.896	0.427	4.401	.036	2.449	1.061	5.656

T2DM = type 2 diabetes mellitus.

differences between the compliance and noncompliance groups in terms of disease course, presence of complications, cognitive level, self-efficacy level, number of comorbidities and residential status. Moreover, through multivariate analysis, the study found that such factors as education level, disease course, presence of complications, cognitive level, self-efficacy level, number of comorbidities and residential status had a significant impact on patient compliance.

The reason for this is that patients with higher education usually have better health knowledge and disease understanding, which helps them to better understand and follow the treatment plan.[17] Patients with longer disease duration have a deeper awareness of their own disease, but long-term treatment may lead to treatment fatigue and affect compliance. The presence of complications usually implies more complex treatment needs, with greater psychological and physiological burden to patients. Meanwhile, patients with higher cognitive levels could more effectively understand the need for treatment and are more likely to follow medical orders.[18] Patients with higher self-efficacy have more confident in managing their health, which is essential for the management of long-term disease. Furthermore, the increasing number of comorbidities may aggravate the complexity and psychological burden of treatment. Residence status is also an important factor, as patients living alone may face more problems in accessing medical resources and social support.[19] In summary, treatment adherence in patients with T2DM is influenced by a combination of individual and social factors. This finding indicates that more attention and support are required for patients at risk of nonadherence, particularly those who have been living with the disease for more than 5 years, have complications, and live alone. Medical institutions need to reassess the effectiveness of treatment plans for patients with prolonged disease duration and collaborate with interdisciplinary teams to provide more comprehensive treatment approaches. This should be coordinated with community support, regular record-keeping, and follow-up to monitor patients' medication adherence timely, assisting in medication completion. In formulating treatment strategies, varying educational needs demand healthcare providers to adopt more understandable communication methods, ensuring all patients fully comprehend their condition and treatment plans. Enhancing self-efficacy and providing psychological support are key to patient self-management, which can be achieved through community-based psychological counseling activities and patient-friendly new media videos. The influence of factors such as the length of the disease course, complications and number of comorbidities suggests that personalized treatment regimen is essential to meet the specific needs of patients. At the same time, socioeconomic factors, such as family economic status and residence status, also significantly affect patients' treatment compliance, which requires medical institutions and policy makers to reduce the economic burden and provide more resources and support. Furthermore, the collaboration of interdisciplinary teams, including the joint efforts of physicians, nurses, dietitians, psychologists, and social workers, is essential to comprehensively address the challenges facing patients.[20]

In conclusion, educational level, duration of disease, presence of complications, cognitive level, number of comorbidities and residential status are important factors affecting the fear of IDegAsp injection and treatment compliance in patients with T2DM, and have guiding significance for improving patient compliance and reducing treatment fear.

Author contributions

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