Clinical Observation of Miglitol Combined with Insulin in Newly Diagnosed Type 2 Diabetes Mellitus

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Abstract: Objective — To study the clinical efficacy of miglitol combined with insulin in the treatment of newly diagnosed type 2 diabetes mellitus. Methods — 96 newly diagnosed type 2 diabetes patients admitted to our hospital from January 2021 to September 2021 were selected as the subjects of this study. They were randomly divided into two groups by drawing lots. The control group was treated with acarbose combined with insulin glargine, and the observation group was treated with miglitol combined with insulin glargine. Fasting blood glucose, 2h postprandial blood glucose, glycosylated hemoglobin (HbA1c), blood glucose compliance time, occurrence of adverse reactions and quality of life score of 2 groups were measured before and after treatment. Results — After treatment, fasting blood glucose, 2h postprandial blood glucose and HbA1c in both groups were lower than before ($P < 0.05$), and there was no statistical significance in the difference between the two groups and the time of blood glucose reaching the standard ($P > 0.05$). The incidence of adverse reactions in observation group was lower than that in control group, and the quality of life score in observation group was better than that in control group ($P < 0.05$). Conclusions — Miglitol or acarbose combined with insulin glargine can effectively control blood glucose in patients with newly diagnosed type 2 diabetes, but miglitol combined with insulin glargine has fewer adverse reactions, which can be used as the first choice for clinical treatment of newly diagnosed type 2 diabetes.
***Keywords*:** miglitol, insulin glargine, type 2 diabetes mellitus, clinical curative effect

In recent years, with the rapid development of social economy, people's living standard has been greatly improved, and the incidence of diabetes has increased significantly, among which type 2 diabetes is the most common, which is mainly characterized by progressive decline of pancreaticβcell function and insulin resistance. The main treatment for diabetes is blood sugar control, which is a key basis for preventing other complications. Insulin glargine is a novel human insulin analogue produced by recombinant DNA technology. It is a long-acting insulin that lasts for 24 hours. Miglitol is a new type ofα-glucosidase inhibitor, which has a very similar structure to glucose and is very beneficial for lowering blood glucose [1]. This study conducted an in-depth study on the efficacy of miglitol combined with insulin in the treatment of newly diagnosed type 2 diabetes mellitus. The details are as follows.

1. Data and methods

1.1 General information

A total of 96 newly diagnosed type 2 diabetes patients admitted to our hospital from January 2021 to September 2021 were selected as the subjects of this study. They were randomly divided into 2 groups by drawing lots, which were observation group and control group respectively. All patients met the diagnostic criteria related to type 2 diabetes, including 28 males and 20 females in the control group. The average age was (63.05±8.15) years. The mean course of disease was (7.85±5.05) years. In observation group, there were 25 males and 23 females. The average age was (63.25±9.25) years. The mean course of disease was (8.09±6.15) years. 2 There was no statistical significance in the general data of the patients ($P > 0.05$).

Patient inclusion criteria: (1) patient age > 18 years; (2) After repeated monitoring of fasting blood glucose (FBG) ≥8.0mmol/L, 2h postprandial blood glucose (2hPG) ≥14.0mmol/L, and HbA1c ≥8.0%; (3) None of the patients had received insulin treatment before participating in this study.

Exclusion criteria: (1) medical records of all patients were consulted, and those with insulin allergy were excluded; (2) after admission, a comprehensive physical examination was conducted to exclude serious liver and kidney function damage (alanine aminotransferase > 2.5 times the upper limit of normal value, myoenzyme > 133ummol/L); (3) Patients with severe pancreatitis or pancreatectomy were excluded; (4) Patients with thyroid disease and serious cardiovascular and cerebrovascular diseases; (5) Patients still had systolic blood pressure ≥180mmHg and/or diastolic blood pressure

≥110mmHg after hypotensive therapy; (6) The patients had acute complications such as diabetic ketoacidosis and non-ketotic hyperosmolar coma; (7) The patient underwent other operations within six months; (8) The patient is a woman in pregnancy or lactation.

1.2 Methods

All patients received routine treatment, such as diet control, appropriate exercise, and health education. Both groups were treated with insulin glargine, the first dose was 0.2U/KG, injected subcutaneously before bed every day, and the dosage was adjusted according to fasting blood glucose, 2h postprandial blood glucose level and hypoglycemic response. Observation group was given miglitol 50-100mg orally, 3 times a day; The control group received acarbose 50-100mg orally, 3 times a day. Both groups were treated for a course of 6 weeks.

1.3 Evaluation indicators

(1) Fasting blood glucose, 2h postprandial blood glucose, HbA1c and blood glucose standard time before and after treatment.

(2) The blood glucose standard time and the occurrence of adverse reactions in the two groups, including abdominal distension, exhaust and diarrhea.

1.4 Statistical Software

SPSS21.0 statistical software was used for data analysis. The measurement data conforming to normal distribution were expressed as mean ± standard deviation ($\bar{x}$±s). T-test or repeated measurement analysis of variance was used for comparison between groups. The rate table of counting data indicated that the chi-square test or Fisher's exact test was used for comparison between groups. The measurement data that did not conform to the normal distribution were represented by median (quartile spacing) and Wilcoxon rank sum test. $P < 0.05$ indicated statistically significant differences.

2. Results

2.1 Fasting blood glucose, 2h postprandial blood glucose, (HbA1c) before and after treatment

After treatment, fasting blood glucose, 2h postprandial blood glucose and HbA1c in both groups were lower than before ($P < 0.05$), and there was no statistical significance between the two groups ($P > 0.05$). See Table 1 below.

Table 1. Fasting blood glucose, 2h postprandial blood glucose, (HbA1c) before and after treatment

Group	The number of cases	Fasting plasma glucose (mmol/L)		2h postprandial blood glucose (mmol/L)		HbA1c (%)	
		Before the treatment	After treatment	Before the treatment	After treatment	Before the treatment	After treatment
The control group	48	12.85±2.15	5.60±0.85	18.25±5.65	7.35±1.09	7.80±1.50	5.35±0.30
Observation group	48	12.45±2.55	5.50±1.70	16.90±4.90	7.20±0.95	7.85±1.60	5.20±0.30
t		0.552	0.067	0.481	0.399	0.566	0.060
P		＞0.05	＞0.05	＞0.05	＞0.05	＞0.05	＞0.05

2.2 Time of blood glucose reaching standard and incidence of adverse reactions in the two groups

There was no statistical significance in the time of blood glucose reaching standard between 2 groups ($P > 0.05$). The complication rate of observation group was lower than control group ($P < 0.05$). See Table 2 below.

Table 2. Blood glucose standard time and incidence of adverse reactions in the two groups

Group	The number of cases	Time of blood glucose reaching standard	Adverse reactions		Incidence of adverse reactions
			Abdominal distension	Diarrhea	
The control group	48	5.35±0.65	3（6.25%）	6（12.5%）	18.75%
Observation group	48	5.15±0.60	0（0.00%））	1（2.08%）	2.08%
t		0.019	6.104		
P		＞0.05	＜0.05		

2.3 Quality of life scores of patients in both groups

Before treatment, there was no statistical significance in quality of life score between 2 groups (P > 0.05). After treatment, quality of life scores in 2 groups were improved, and the observation group was better than the control group (P < 0.05). See Table 3 below.

Table 3. Life quality scores of patients in the two groups

Group	The number of cases	PF		SF		BP		MH	
Time		Before the treatment	After treatment	Before the treatment	After treatment	Before the treatment	After treatment	Before the treatment	After treatment
Observation group	48	51.29±5.01	73.02±3.93	52.98±4.58	76.05±3.87	53.11±4.62	75.10±4.03	53.86±5.09	75.95±4.90
The control group	48	52.00±4.65	66.95±2.95	53.15±4.15	67.35±3.65	53.75±4.75	66.70±3.82	54.15±4.90	68.45±5.35
t		0.022	9.089	0.061	10.004	0.052	9.776	0.041	11.066
P		＞0.05	＜0.05	＞0.05	＜0.05	＞0.05	＜0.05	＞0.05	＜0.05

3. Discussion

In recent years, with the rapid development of social economy, people's living standards have been greatly improved, and with the increasingly serious aging of the population, the incidence of diabetes is on the rise. According to the latest figures, 425 million adults worldwide had diabetes in 2017, and experts estimate the figure will rise to 629 million by 2045. Studies have shown that compared with the general population, patients with diabetes are more likely to suffer from other diseases and the prognosis is worse. Diabetes combined with other complications brings great pressure and economic burden to patients' families. Therefore, how to better control patients' blood glucose level and reduce the occurrence of diabetes complications has become the focus of clinical treatment. At present, insulin is one of the important treatment methods for diabetes in clinic. However, there are many types of insulin in clinical use and its mechanism is complex, so how to select effective and safe treatment is the focus of diabetes treatment at present.

Type 2 diabetes mellitus (T2DM) is a chronic and low-grade inflammatory metabolic disease, which is mainly characterized by deficiency of insulin secretion. Experts [2] believe that T2DM is a complex disease under the joint action of multiple genes and multiple environmental factors, and insulin resistance and pancreatic beta cell dysfunction (insufficient insulin secretion) are the basic characteristics of T2DM. [3] in recent years, the scholars think that T2DM is a chronic inflammation disease, and obesity is one of the independent high risk factors of T2DM, obese patients because the number of insulin receptors on the cell membrane to reduce or flaws, make insulin can't play his normal physiological functions, in addition, obesity can also lead to abnormal lipid composition of cell membrane, Blocking the normal movement of glucose across the membrane, reducing the ability to clear glucose, and eventually causing insulin resistance. Therefore, it is a key measure to prevent and reduce complications of diabetes to control blood glucose in diabetic patients at a stable and ideal level safely and efficiently. The goal of blood glucose control in diabetic patients is to maintain a normal value of FBG, 2hPG and HbA1c as far as possible without hypoglycemia, which requires the joint action of drugs and good living habits.

Insulin glargine is a novel human insulin analogue produced by recombinant DNA technology. It is a long-acting insulin that can be sustained for 24 hours. At present, many clinical studies [4-6] have confirmed that insulin glargine can effectively control blood glucose level, which is a basic insulin with good efficacy. Moreover, insulin glargine can effectively control fasting blood glucose and improve insulin sensitivity of the body, and has high safety in clinical application. Alpha glycosidase inhibitor acarbose, FuGe wave mig and sugar alcohol, alcohol mig column is the new drugs in the treatment of T2DM, the chemical structure of the drug are glucose analogue structure, so it can be competitive inhibition with alpha glucose, liver enzymes, and since the structure of mig columns and glucose more similar, so it is easier to close to the enzyme active center, It has a strong inhibitory effect on various α -glucose liver enzymes, so it is considered as the first choice for the treatment of T2DM in China. Moreover, it can effectively inhibit a variety of enzymes on the brush edge of small intestinal chorionic membrane, thus reducing the postprandial blood glucose level of patients, and has been widely used in clinical practice.

In addition to drug therapy in the treatment of diabetes, the rest of the treatment is more important, first of all, the treatment of T2DM, diabetes education work should be through the whole process of diabetes treatment, which is mainly basic knowledge of diabetes, mental health, diet therapy, exercise therapy, and self blood glucose monitoring and self health care, etc. Effective clinical research data have confirmed that regular lifestyle interventions have a significant effect on the prevention and treatment of T2DM, because the effectiveness of these interventions largely depends on lifestyle changes,

indicating that regular healthy lifestyle is very beneficial for the prevention and treatment of T2DM [7-9].

The results of this study showed that the blood glucose levels in both groups were better after treatment than before, suggesting that miglitol or acarbose combined with insulin glargine has a significant effect on the treatment of type 2 diabetes and can effectively reduce fasting and postprandial blood glucose. However, there were no statistically significant differences in fasting blood glucose, 2h postprandial blood glucose, HbA1c and the time of blood glucose reaching standard between the two groups after treatment, but there was a significant trend of decrease, indicating that follow-up studies are needed to obtain more accurate results. In addition, the incidence of adverse reactions in the observation group was significantly lower than that in the control group, which may be because acarbose has a certain inhibitory effect on α -amylase, but miglitol can only delay the absorption of monosaccharides in the intestinal tract, but has no inhibitory effect on α -amylase [10].

In conclusion, miglitol or acarbose combined with insulin glygine in the treatment of type 2 diabetes can effectively control the blood glucose level of patients, but miglitol has fewer adverse reactions and relatively good clinical efficacy, which is worthy of active clinical application.

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