

Clinical Study on Jiangtangning Capsules Combined with Insulin Aspart in the Treatment of Gestational Diabetes Mellitus

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Abstract: Objective To study the clinical efficacy of Jiangtangning Capsules combined with Insulin Aspart Injection in the treatment of gestational diabetes mellitus **Methods** A total of 120 gestational diabetes mellitus patients who were treated in Shaanxi Provincial People's Hospital and Northwest Women and Children Hospital from August 2018 to August 2019 were selected and randomly divided into the Control Group and Treatment Group, with 60 cases in each group. Patients in the Control Group were given Insulin Aspart Injection, with the recommended dose of 0.5-1.0 U/kg, of which 2/3 dosage was given at meal time, and the remaining 1/3 dosage was basic insulin. Patients in the Treatment Group were orally administered with Jiangtangning Capsules based on the therapy for the Control Group, 4 capsules/time, 3 times/day. Patients in the two groups were treated for 4 consecutive weeks. After treatment, the clinical efficacy in both groups was observed, and the blood glucose level, the levels of C-reactive protein (CRP), serum magnesium (Mg^{2+}) and adiponectin, the incidence of hypoglycemia, daily insulin dosage, and the time of blood glucose reaching the standard, were compared between the two groups. **Results** After treatment, the overall effective rates of the Control Group and Treatment Group were 83.33% and 95.00%, respectively, and the difference between the two groups was statistically significant ($P < 0.05$). After treatment, the levels of HbA1c, 2 h PG and FPG in the two groups were significantly decreased, and the difference before and after treatment in the same group was statistically significant ($P < 0.05$). In addition, HbA1c, 2h PG and FPG of the Treatment Group were significantly lower than those in the Control Group, and the difference between the two groups was statistically significant ($P < 0.05$). After treatment, the level of CRP in both groups were significantly decreased, but the levels of Mg^{2+} and adiponectin in both groups were significantly increased, and the difference was statistically significant in the same group ($P < 0.05$). CRP, Mg^{2+} and adiponectin levels in the Treatment Group were significantly superior to those in the Control Group, with significant difference between two groups ($P < 0.05$). After treatment, the incidence of hypoglycemia, the daily insulin dosage, and the time of blood glucose reaching the standard in the Treatment Group were significantly lower than those in the Control Group, and the difference between the two groups was statistically significant ($P < 0.05$). **Conclusion** Jiangtangning Capsules combined with Insulin Aspart Injection have achieved a good therapeutic effect in the treatment of gestational diabetes mellitus, which can reduce the level of blood glucose, regulate the levels of CRP, Mg^{2+} , and adiponectin, and reduce the use of

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insulin. The safety is high, which has a certain clinical application value.

Keywords: Jiangtangning Capsules; Insulin Aspart Injection; gestational diabetes mellitus; Blood Glucose; CRP; Daily Insulin Dosage

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Gestational diabetes mellitus is a common clinical obstetrics and gynecology disease. There is no or abnormal blood sugar level or diabetes before pregnancy, Type 2 diabetes occurs after pregnancy.[1]gestational diabetes mellitus can cause various maternal and child hazards, such as excessive amniotic fluid and fetal distress. In severe cases, it may cause stillbirth or miscarriage [2]. At present, insulin aspart combined with exercise control and diet therapy are often used clinically to treat gestational diabetes. Insulin aspart is a fast-acting insulin analogue, which can bind to the insulin receptors on fat and muscle cells to promote the absorption of glucose and lower blood sugar [3-4]. Jiangtangning capsule is composed of yam, ginseng, etc. It has the effects of nourishing qi, nourishing body fluid and nourishing yin [5]. In this study, 120 patients with gestational diabetes mellitus treated in Shaanxi Provincial People's Hospital and Northwest Women and Children Hospital were selected as the research subjects to explore the clinical efficacy of Jiangtangning Capsules combined with insulin aspart injection in the treatment of gestational diabetes.

1 Subjects and Methods

1.1 Research Subjects

A total of 120 patients with gestational diabetes mellitus who were treated at Shaanxi Provincial People's Hospital and Northwest Women and Children Hospital from August 2018 to August 2019 were selected as the research subjects. Among them, the age ranged from 24 to 33 years old, with an average age of (28.16 ± 3.74) years old. Weeks range from 20 to 36 weeks, and the average gestational week is (28.75 ± 4.17) weeks. All patients met the diagnostic criteria for gestational diabetes mellitus[6] and were diagnosed by fasting blood glucose measurement, urine glucose, glucose tolerance test, and glucose screening test. Exclusion criteria: patients are allergic to the drugs used in this study; patients have diabetic complications such as retinopathy, nephropathy, and peripheral neuropathy; patients with autoimmune diseases, severe cardiovascular and cerebrovascular diseases.

1.2 Drugs

Insulin Aspart Injection is produced by Novo Nordisk (China) Pharmaceutical Co., Ltd., specifications 3mL: 300U, product batch numbers 180119, 190325; Jiangtangning Capsules are produced by Henan Furentang Pharmaceutical Co., Ltd., specifications 0.4g/capsule, product batch numbers 180225, 180523 .

1.3 Grouping and Treatment Methods

All patients were randomly divided into a control group and a treatment group, with 60 cases in each group. The patients in the control group were 24 to 32 years old, with an average age of (28.12 ± 3.71) years, a gestational age of 20 to 36 weeks, and an average gestational age of (28.78 ± 4.19) weeks. The treatment group was 24 to 33 years old, with an average age of (28.20 ± 3.77) years, a gestational age of 20 to 36 weeks, and an average gestational age of (28.72 ± 4.15) weeks. There was no significant difference in general information between the two

groups, and they were clinically comparable.

After admission, both groups of patients were given lifestyle adjustments such as diet adjustment, eating less and more meals, and moderate exercise. Patients in the control group were given Insulin Aspart Injection, the recommended dose was 0.5-1.0 U/kg, 2/3 of the dose was given during meals, and the remaining 1/3 was basal insulin; the treatment group was given Jiangtangning Capsules on the basis of the control group. 4 capsules/time, 3 times/d. Patients in the two groups continued treatment for 4 weeks.

1.4 Clinical Efficacy Criteria^[7]

Cure: Blood glucose is within the satisfactory range of the treatment target, pregnancy is normal, fetal development is normal, and symptoms and signs are significantly improved; improvement: blood sugar reaches the control target, fetal development and pregnancy are normal, symptoms and signs are improved; invalid: those who do not meet the above standards.

Total Effective Rate = (Cure + Improvement)/Total Number of Cases

1.5 Observation Indicators

1.5.1 Blood Sugar Level

The serum glycosylated hemoglobin (HbA1c) level was measured by high performance liquid chromatography before and after treatment, and the 2h postprandial blood glucose (2hPG) and fasting blood glucose (FBG) were measured by hexokinase method.

1.5.2 The incidence of hypoglycemia, daily insulin dosage, and blood glucose reaching standards between the two groups were compared.

1.5.3 C-reactive protein (CRP)、serum magnesium (Mg²⁺) and adiponectin levels were determined by enzyme-linked immunosorbent assay CRP and adiponectin levels, and biochemical detectors were used to determine Mg²⁺ levels.

1.6 Adverse Reaction Observation

Observe the occurrence of adverse reactions in the two groups of patients.

1.7 Statistical Method

Use SPSS19.0 software for data processing. The χ^2 test was used for comparison of count data, and the t test was used for comparison of measurement data.

2 Results

2.1 Comparison of Clinical Efficacy between the Two Groups

After treatment, 18 cases in the control group were cured, 32 cases improved, 10 cases were ineffective, and the total effective rate was 83.33%; in the treatment group, 22 cases were cured, 35 cases improved, and 3 cases were ineffective. The total effective rate was 95.00%. The effective rate is statistically significant ($P < 0.05$), see Table 1.

Table 1 Comparison of Clinical Efficacy between the Two Groups

| Groups | n/cases | Cured/cases | Improvement/cases | Invalid/cases | Total Effective Rate/% |
|-----------|---------|-------------|-------------------|---------------|------------------------|
| Control | 60 | 18 | 32 | 10 | 83.33 |
| Treatment | 60 | 22 | 35 | 3 | 95.00* |

* $P < 0.05$ vs control group

2.2 Comparison of Blood Glucose Levels between the Two Groups

After treatment, the levels of HbA1c, 2hPG and FPG in the two groups were significantly reduced, and the difference in the same group before and after treatment was statistically significant ($P < 0.05$); and the levels of HbA1c, 2hPG and FPG in the treatment group were

significantly lower than those in the control group. The difference is statistically significant ($P < 0.05$), see Table 2.

Table 2 Comparison of Blood Glucose Levels between the Two Groups ($\bar{x} \pm s, n=60$)

| Group | HbA1c/% | | 2h PG (mmol·L ⁻¹) | | FPG/(mmol·L ⁻¹) | |
|-----------|-----------|------------|-------------------------------|-------------|-----------------------------|-------------|
| | Before | After | Before | After | Before | After |
| | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment |
| Control | 8.79±0.89 | 7.19±0.78* | 11.69±1.36 | 9.47±1.15* | 9.47±0.62 | 7.46±0.49* |
| Treatment | 8.82±0.91 | 6.29±0.71* | 11.61±1.39 | 8.35±0.92*▲ | 9.48±0.64 | 6.35±0.42*▲ |

* $P < 0.05$ vs same group before treatment; ▲ $P < 0.05$ vs control group after treatment

2.3 Comparison of CRP, Mg²⁺ and Adiponectin Levels between the Two Groups

After treatment, the levels of CRP in the two groups were significantly reduced, and the levels of Mg²⁺ and adiponectin were significantly increased. The difference between before and after treatment in the same group was statistically significant ($P < 0.05$); and the levels of CRP, Mg²⁺ and adiponin in the treatment group were significantly better than those in the control group. The difference between the two groups was statistically significant ($P < 0.05$), see Table 3.

Table 3 Comparison of CRP, Mg²⁺ and Adiponectin Levels between the Two Groups ($\bar{x} \pm s, n=60$)

| Groups | CRP/(mg·L ⁻¹) | | 2h PG (mmol·L ⁻¹) | | adiponectin/(μg·L ⁻¹) | |
|-----------|---------------------------|-------------|-------------------------------|-------------|-----------------------------------|-----------------|
| | Before | After | Before | After | Before | After Treatment |
| | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment |
| Control | 3.53±0.43 | 2.16±0.32* | 0.67±0.08 | 0.94±0.12* | 20.31±2.65 | 30.41±3.59* |
| Treatment | 3.58±0.42 | 1.57±0.21*▲ | 0.65±0.09 | 1.45±0.18*▲ | 20.26±2.59 | 38.59±4.63*▲ |

Compared with the same group before treatment: * $P < 0.05$; compared with the control group after treatment: ▲ $P < 0.05$

2.4 Comparison of the incidence of hypoglycemia, daily insulin dosage, and the time of blood glucose reaching the standard between the two groups

After treatment, the incidence of hypoglycemia, daily insulin dosage, and blood glucose compliance time in the treatment group were significantly lower than those in the control group. The difference between the two groups was statistically significant ($P < 0.05$), as shown in Table 4.

Table 4 Comparison of the incidence of hypoglycemia, daily insulin dosage, and the time of blood glucose reaching the standard between the two groups ($\bar{x} \pm s, n=60$)

| Group | The incidence of hypoglycemia/% | Daily Insulin Dosage/U | The Time of Blood Glucose Reaching the Standard/d |
|-----------|---------------------------------|------------------------|---|
| Control | 21.67 | 36.58±4.28 | 14.25±2.62 |
| Treatment | 11.67* | 31.22±3.75* | 10.95±1.75* |

2.5 Comparison of Adverse Reactions between the Two Groups

During the treatment, the control group had 2 cases of lipoatrophy at the injection site, 1 case of rash, and the incidence of adverse reactions was 5.00%; the treatment group had 1 case of lipoatrophy at the injection site, 1 case of blood pressure drop, 2 cases of rash, and the incidence

of adverse reactions. It is 6.67%. There was no difference in the incidence of adverse reactions between the two groups.

3 Discussion

The etiology of gestational diabetes mellitus is more complex and is closely related to factors such as increased insulin resistance, genetic susceptibility, dysfunction of islet D cells, oxidative stress, metabolic disorders, and chronic inflammation [8]. gestational diabetes mellitus can significantly increase the occurrence of complications in infants and pregnant women, and controlling blood sugar levels can reduce the occurrence of complications [9].

Insulin aspart is a recombinant human insulin analogue, which is mainly composed of protein. Its physiological properties and immunogenicity are closer to human insulin. It can bind to insulin receptors on fat and muscle cells to promote glucose absorption and reduce the role of blood sugar [10-11]. After insulin aspart enters the body, it can be quickly absorbed by the body, and has a faster onset of action without side effects. Jiangtangning Capsules has the effects of nourishing qi, nourishing body fluid and nourishing yin [12]. In this study, after treatment, the total effective rate of the treatment group was significantly higher ($P<0.05$); the levels of FPG, 2hPG and HbA1c in the two groups were significantly reduced ($P<0.05$), and the indicators of the treatment group decreased more ($P<0.05$); the blood glucose standard time, daily insulin dosage and the incidence of hypoglycemia in the treatment group were significantly lower than those in the control group ($P<0.05$).

The serum CRP level of patients with gestational diabetes mellitus is significantly increased, and CRP can aggravate insulin resistance, which is closely related to the occurrence of gestational diabetes mellitus [13]. The ability of patients with gestational diabetes mellitus to take up Mg^{2+} decreases, and the symptoms of hyperglycemia can increase the secretion of Mg^{2+} in the renal tubules, which leads to an increase in the amount of Mg^{2+} excreted in the urine [14]. Serum adiponectin is a plasma hormone protein specific to human fat, which can improve insulin sensitivity [14]. In this study, the levels of CRP, Mg^{2+} , and adiponectin in the two groups were significantly improved after treatment ($P<0.05$), and the treatment group improved more ($P<0.05$).

In summary, Jiangtangning Capsules combined with Insulin Aspart Injection has a good therapeutic effect in the treatment of gestational diabetes mellitus. It can reduce blood sugar levels, regulate CRP, Mg^{2+} and adiponectin levels, and reduce insulin usage. It has high safety and has a certain degree of safety. The value of clinical application.

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