ISSN 2307-8960 (online)

World Journal of *Clinical Cases*

World J Clin Cases 2024 August 26; 12(24): 5448-5635

Published by Baishideng Publishing Group Inc

World Journal of Clinical Cases

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ABOUT COVER

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RESPONSIBLE EDITORS FOR THIS ISSUE

NAME OF JOURNAL
World Journal of Clinical Cases

ISSN
ISSN 2307-8960 (online)

LAUNCH DATE
April 16, 2013

FREQUENCY
Thrice Monthly

PUBLICATION DATE
August 26, 2024

World Journal of Clinical Cases

Submit a Manuscript: https://www.f6publishing.com

World J Clin Cases 2024 August 26; 12(24): 5534-5541

DOI: 10.12998/wjcc.v12.i24.5534

ISSN 2307-8960 (online)

ORIGINAL ARTICLE

Clinical Trials Study

Effect of dietary with Zhibai dihuang pills and gonadotropin-releasing-hormone-analogue on girls with precocious and rapidly progressive puberty

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Specialty type: Medicine, research and experimental

Provenance and peer review: Unsolicited article; Externally peer reviewed.

Peer-review model: Single blind

Peer-review report's classification

Scientific Quality: Grade C

Novelty: Grade C

Creativity or Innovation: Grade B

Scientific Significance: Grade B

P-Reviewer: Enani G

Received: May 31, 2024

Revised: June 24, 2024

Accepted: July 1, 2024

Published online: August 26, 2024

Processing time: 40 Days and 20.3 Hours

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Abstract

BACKGROUND

At present, the clinical mechanisms underlying precocious puberty remain unclear, making effective intervention for children experiencing this condition and rapidly progressive puberty essential.

AIM

To explore the effects of Zhibai dihuang pills and gonadotropin-releasing hormone analogue (GnRHa) on growth and ovarian function in girls with precocious puberty.

METHODS

The clinical data of 84 adolescent girls with precocious puberty and rapidly progressive puberty from February 2017 to August 2023 were retrospectively analyzed. Girls were divided into a control group and an observation group, with 42 cases in each group. The control group received diet intervention combined with GnRHa treatment, while the observation group received diet intervention combined with Zhibai dihuang pills + GnRHa treatment. Outcomes such as clinical efficacy, growth indicators, ovarian function, and adverse reactions were compared between the two groups.

RESULTS

The observation group showed superior clinical efficacy compared to the control group ($P < 0.05$). Prior to the intervention, no significant differences were found in growth or ovarian function between the groups ($P > 0.05$). Post-intervention, the observation group exhibited significantly lower rates in growth, height, and bone age, along with reduced levels of progesterone, testosterone, estradiol, prolactin, luteinizing hormone, and follicle-stimulating hormone compared to the control group ($P < 0.05$). The incidence of adverse reactions was similar across both

groups ($P > 0.05$).

CONCLUSION

Combining Zhibai dihuang pills with GnRHa and dietary intervention effectively improves growth, enhances ovarian function, and minimizes adverse reactions in adolescent girls with precocious and rapidly progressive puberty.

Key Words: Zhibai dihuang pills; Gonadotropin-releasing hormone analogue; Dietary intervention; Precocious puberty; Rapidly progressive puberty; Ovarian function

Core Tip: Combining Zhibai dihuang pills with gonadotropin-releasing hormone analogue (GnRHa) and dietary intervention significantly improves growth outcomes and ovarian function in girls with precocious and rapidly progressive puberty. In this study, girls treated with this combination showed lower rates of growth and bone age advancement, along with reduced levels of key hormones, compared to a control group receiving only GnRHa and diet intervention. This study highlighted the enhanced efficacy and safety of the combined treatment and provides a promising intervention for managing precocious puberty.

Citation: Wang XM, Li W, Yang LQ, Luo R, Zhang CC. Effect of dietary with Zhibai dihuang pills and gonadotropin-releasing-hormone-analogue on girls with precocious and rapidly progressive puberty. *World J Clin Cases* 2024; 12(24): 5534-5541
URL: https://www.wjgnet.com/2307-8960/full/v12/i24/5534.htm
DOI: https://dx.doi.org/10.12998/wjcc.v12.i24.5534

INTRODUCTION

Precocious puberty is characterized by the early onset of puberty, occurring in girls before the age of 8 and in boys before the age of 9, typically resulting from abnormalities in the endocrine system. Rapidly progressive puberty describes a condition where the hypothalamic-pituitary-gonadal axis advances from the defined age of precocious puberty to the typical age of puberty onset, exhibiting an accelerated progression of sexual development and bone maturation[1]. Epidemiological studies have indicated that precocious puberty is relatively common in children, with an incidence rate of approximately 10%, making it the second most prevalent endocrine disorder[2]. The primary goals in treating precocious puberty and rapidly progressive puberty are to delay the onset and progression of secondary sexual characteristics and to improve adult height outcomes in affected children[3].

Compared to boys, girls exhibit a clearer gender identity concerning precocious puberty and rapidly progressive puberty, with a significantly higher incidence rate. The primary clinical manifestations in girls include premature breast development, early uterine and ovarian development, and early onset of menstruation[4,5]. Previous studies have shown that the presentation of precocious puberty depends on the degree of precocity, which may result in excessive skeletal growth and premature epiphyseal fusion, ultimately affecting normal development and leading to short stature. Additionally, precocious puberty and rapidly progressive puberty can have serious negative impacts on the psychological and psychosocial behaviors of affected children[6,7]. Given that the clinical mechanisms underlying precocious puberty are not fully understood, effective intervention for children experiencing these conditions is crucial.

Gonadotropin-releasing hormone antagonists, such as leuprorelin, are commonly used to treat children with precocious puberty. These drugs inhibit the release of sex hormones, thereby delaying the process of sexual development and preventing the premature closure of epiphyses, which can impact height development. Additionally, they can effectively reduce psychological issues, such as social withdrawal and feelings of inferiority, that affected children may experience[7,8]. Since treatment with leuprorelin requires a long duration, typically at least 2 years, to achieve the goal of improving adult height, some patients may experience slowed growth rates, necessitating additional growth hormone therapy. This not only increases the cost of treatment but also complicates the treatment process. Therefore, there remains a need for clinical exploration of alternative intervention methods[9]. Therefore, there remains a need for clinical exploration of alternative intervention methods. In addition, Meng *et al*[10] reported that a high-fat, high-calorie diet is a confirmed risk factor for precocious puberty. Dietary components can influence hormone levels in the body, and poor dietary habits may contribute to idiopathic central precocious puberty (CPP)[11]. This suggests that dietary intervention may have therapeutic effects on children with precocious puberty and rapidly progressive puberty. However, some patients may not achieve the desired therapeutic effect with dietary intervention alone. Moreover, gonadotropin-releasing hormone analogue (GnRHa) is expensive, and some patients experience adverse reactions such as redness and swelling, which can affect compliance. Clinically, it is believed that the incidence of precocious puberty is related to kidney abnormalities, with kidney deficiency and excessive fire being common causes. Treatment should focus on tonifying the kidney and reducing fire, with Zhibai dihuang pills being a representative drug. Zhibai dihuang pills have proven effective in treating precocious puberty, showing superior improvements in sex hormone levels and follicular diameter

compared to triptorelin. They have been increasingly used in the treatment of precocious puberty and related conditions in recent years. This study aims to observe the effects of combining Zhibai dihuang pills with GnRHa and rational dietary intervention on growth rate and ovarian function in girls with precocious puberty and rapidly progressive puberty, providing a reference for the treatment of children with these conditions.

MATERIALS AND METHODS

General information

This retrospective study included 84 girls with precocious puberty and rapidly progressive puberty admitted to our hospital between February 2017 and August 2023. The subjects were divided into two groups: A control group and an observation group, with 42 cases in each group. This study was approved by the Hospital Ethics Committee, and all procedures followed the ethical guidelines of the Helsinki Declaration regarding clinical research. Before enrollment, all subjects were informed of the research content and signed informed consent forms.

Inclusion and exclusion criteria

Inclusion criteria: Precocious puberty: (1) Diagnosis of precocious puberty according to the "Diagnosis and Treatment Consensus of CPP"[12], based on symptoms and signs; (2) The girl developed secondary sexual characteristics before the age of 8 and progressed according to the normal developmental procedure; (3) GnRH stimulated luteinizing hormone (LH) peak > 3.3-5.0 U/L, and LH peak/follicle-stimulating hormone (FSH) peak ratio > 0.6; and (4) The uterus is 3.4-4.0 cm, the volume of the unilateral ovary is ≥ 1-3 mL, and multiple follicles with diameter ≥ 4 mm can be seen. Rapidly progressive puberty: (1) Onset of the hypothalamic-pituitary-gonadal axis in girls aged 8-10 years, accompanied by accelerated sexual maturation (the interval from one Tanner stage to the next is shorter than 3-6 months); and (2) Accelerated bone age maturation (bone age exceeds actual age by more than 1 year).

Exclusion criteria: (1) Girls with secondary CPP after excluding other causes (such as adrenal disease, central nervous system disease); (2) Girls with organic diseases (such as uterine and ovarian dysplasia); (3) Girls with familial genetic diseases, metabolic diseases, and chromosomal abnormalities; and (4) Girls with incomplete clinical data.

Methods

Dietary intervention during the treatment period required patients to avoid consuming nutritional tonics, foods with high estrogen content, out-of-season vegetables, foods high in trace element zinc, and foods with high levels of preservatives and additives. In addition to dietary intervention, the control group was given leuprolide acetate microspheres for subcutaneous injection (manufacturer: Shanghai Lisheng Pharmaceutical Co., Ltd.; approval number: National Drug Approval No. 220826; specification: 3.75 mg), 3.75 mg per dose, administered once every 28 days. The initial dose of leuprorelin microspheres was 80 to 100 μg/kg, administered once every 4 weeks[13]. The treatment regimen was adjusted based on the child's response, with follow-up examinations conducted every 6 months. Observation group was treated with Zhibai dihuang pills (Jiuzhitang Co., Ltd., National Drug Approval No. Z20023069; specification: 1.7 g per 10 pills) in addition to the control group regimen. Zhibai dihuang pills were administered at a dose of 8 pills per time, 3 times a day, for a course of 4 weeks, with continuous treatment for 6 months.

Observation indicators

Clinical efficacy: The effectiveness of treatment was determined by the degree of reduction in breast nodules and the development of the uterus and ovaries in children after intervention. The criteria for evaluation were as follows: (1) Cure: Breast nodules almost disappeared, and the development of the uterus and ovaries stagnated; (2) Marked effect: Breast nodules decreased by more than 50%, and the development of the uterus and ovaries stagnated; (3) Effective: Breast nodules decreased by 30% to 50%, and the development of the uterus and ovaries stagnated; and (4) Ineffective: No significant reduction or continued enlargement of breast nodules, and no significant improvement or continued development of the uterus and ovaries. Total effective rate = cure rate + marked effect rate + effective rate.

Growth indicators: Comparison of growth indicators such as growth rate, height, and bone age between the two groups of children. Formula for calculating growth rate is: Growth rate (cm/year) = {[difference in height between two measurements (cm)]/[difference in time between two measurements (months)]} × 12 (months/year).The Greulich and Pyle method was used to analyze the bone age of the patients.

Ovarian function: Blood samples (5 mL) were collected from the subjects before and after the intervention. The levels of progesterone (P), testosterone (T), estradiol (E2), prolactin (PRL), LH, and FSH in both groups were measured using radioimmunoassay.

Adverse reactions: The occurrence of adverse reactions during the intervention period in both groups of children, such as sweating, back pain, dizziness, and dry mouth, was recorded.

Statistical analysis

SPSS 22.0 software was used for data analysis. Measurement data were expressed as mean ± SD, and the independent sample *t*-test was used to compare differences between groups. Count data were expressed as rates, and χ^2 analysis was

Table 1 Basic clinical data of children in the two groups (mean ± SD)

Group		Control group	Observation group	t/χ^2	*P* value
Case (*n*)		42	42		
Age	Maximum	10	11	0.079	0.694
	Minimum	6	6		
	Average	8.79 ± 1.08	8.87 ± 1.17	0.354	0.443
Height (cm)	Maximum	141	144	3.977	0.051
	Minimum	113	111		
	Average	126.59 ± 2.52	125.34 ± 2.40	1.679	0.098
Body quality (kg/m^2)	Highest	20.69	21.38	0.760	0.308
	Lowest	15.35	15.30		

Table 2 Comparison of clinical efficacy between the two groups

Group	Control group	Observation group	t/χ^2	*P* value
Case (*n*)	42	42		
Healing	0	5		
Significant	17	25		
Effective	15	9		
Invalid	10	3		
Total effective rate, *n* (%)	32 (76.19)	39 (92.86)	17.163	0.001

used to compare differences between groups. A P value < 0.05 was considered statistically significant.

RESULTS

General clinical data of the two groups of children

As shown in Table 1, there was no statistically significant difference in basic clinical data such as height and weight between the two groups of children, indicating comparability (P > 0.05).

Comparison of clinical efficacy

After 6 months of intervention, the clinical efficacy of the observation group was higher than that of the control group, and the differences were statistically significant (P < 0.05) (Table 2).

Comparison of growth indicators

Before intervention, there was no statistically significant difference in growth and development indicators between the two groups of children (P > 0.05). After the intervention, the growth rate, height, and bone age indicators of girls with precocious puberty and rapidly progressive puberty in the observation group were significantly lower than those in the control group (P < 0.05). Specific numerical values can be seen in Table 3.

Comparison of ovarian function

Before intervention, there was no statistically significant difference in various ovarian function indicators between the two groups of children (P > 0.05). After 6 months of intervention, the levels of P, T, E2, PRL, LH, and FSH in the observation group were lower than those in the control group, with the differences being statistically significant (P < 0.05) (Table 4).

Comparison of adverse reactions

There was no statistically significant difference in the incidence of adverse reactions between the two groups of children (P > 0.05), as shown in Table 5.

Table 3 Comparison of growth indicators between the two groups of children (mean ± SD)

Group	Control group	Observation group	*t*	*P* value
Growth rate (%)				
Before intervention	4.56 ± 0.61	4.81 ± 0.75	1.715	0.090
After intervention	3.56 ± 0.59	2.25 ± 0.89	8.190	0.001
Height (cm)				
Before intervention	125.26 ± 3.00	125.11 ± 2.95	0.222	0.829
After intervention	133.44 ± 2.33	127.81 ± 2.43	10.934	0.001
Bone age (year)				
Before intervention	8.80 ± 0.50	8.91 ± 0.64	0.941	0.348
After intervention	9.24 ± 0.64	7.21 ± 0.33	18.836	0.001

Table 4 Comparison of ovarian function indicators between the two groups of children (mean ± SD)

Group	Control group	Observation group	*t*	*P* value
P (ng/mL)				
Before intervention	4.76 ± 1.60	4.83 ± 1.69	0.141	0.891
After intervention	2.94 ± 0.73	2.14 ± 0.64	5.466	0.001
T (nmol/L)				
Before intervention	6.78 ± 2.16	6.73 ± 2.22	0.148	0.881
After intervention	4.46 ± 1.44	3.11 ± 1.12	4.757	0.001
E2 (pg/mL)				
Before intervention	30.34 ± 5.72	30.85 ± 5.69	0.387	0.706
After intervention	18.76 ± 2.92	11.44 ± 2.75	11.814	0.001
PRL (ng/mL)				
Before intervention	12.76 ± 3.51	13.05 ± 3.64	0.370	0.712
After intervention	11.00 ± 2.54	8.93 ± 2.79	3.591	0.001
LH (U/L)				
Before intervention	3.16 ± 0.08	3.19 ± 0.08	0.569	0.572
After intervention	2.14 ± 0.36	1.51 ± 0.27	9.314	0.001
FSH (IU/L)				
Before intervention	15.22 ± 5.26	15.36 ± 5.15	0.123	0.913
After intervention	8.76 ± 2.57	6.27 ± 2.35	4.615	0.001

P: Progesterone; T: Testosterone; E2: Estradiol; PRL: Prolactin; LH: Luteinizing hormone; FSH: Follicle-stimulating hormone.

DISCUSSION

Precocious puberty is an abnormal puberty development condition characterized by the premature appearance of puberty characteristics compared to children of the same age[14]. Due to differences in pathological mechanisms, precocious puberty is classified into central and peripheral types, each requiring distinct treatment approaches and having different prognoses[15,16]. The etiology of precocious puberty is complex, and the condition progresses rapidly. Without timely and effective treatment, it may lead to premature epiphyseal closure, early menstruation, breast development, and pubic hair growth, severely impacting the physical and mental health of affected children[5,17]. Therefore, accurate and timely diagnosis becomes crucial.

Here, the mechanism by which Zhibai dihuang pills inhibit precocious puberty involves multiple pathways. Zhibai dihuang pills contain ingredients like Rhizoma Anemarrhenae, Cortex Phellodendri, Radix Rehmanniae Preparata, Rhizoma Dioscoreae, Cortex Moutan, and Rhizoma Alismatis, which have anti-inflammatory and antioxidant properties,

Table 5 Comparison of adverse reactions between the two groups of children, *n* (%)

Group	Control group	Observation group	*Z*	*P* value
Case	42	42		
Sweat	1 (2.38)	0 (0)		
Back pain	1 (2.38)	0 (0)		
Dizziness	0	0		
Dry mouth	1 (2.38)	1 (2.38)		
Adverse reaction rate	3 (7.14)	1 (2.38)	0.216	0.641

helping to reduce oxidative stress and inflammatory responses, thereby modulating hormone levels[18]. Additionally, these pills may influence the expression of genes related to puberty onset and progression by downregulating the expression of ESR1 in the uterus and ovaries[18].

In this study, the clinical efficacy of the observation group was significantly higher than that of the control group, indicating the significant effectiveness of Zhibai dihuang pills combined with leuprorelin microspheres and dietary intervention in treating girls with precocious puberty. Compared to the control group, after treatment, the growth rate and bone age of children in the observation group were lower. Additionally, the observation group exhibited greater height, higher predicted adult height, lighter weight, and younger bone age than the control group. Research has shown that early control of rapid weight gain in children is beneficial for reducing the incidence of precocious puberty[19,20]. Additionally, after the intervention, the children in the observation group exhibited superior status in terms of height, weight, and bone age, suggesting that controlling the rate of weight gain may help reduce the risk of precocious puberty.

LH-releasing hormone (LHRH) is a peptide hormone primarily produced by the hypothalamus, which acts on the anterior pituitary gland to stimulate the release of LH and FSH[21]. Before puberty, the secretion of LH and FSH already exhibits a diurnal rhythm, with higher levels at night. In the early stages of puberty, LH levels increase only at night, while in the mid-late stages of puberty, LH levels increase both during the day and at night[22,23]. In this study, observations of ovarian function indicators in children revealed that after 6 months of intervention, the levels of P, T, E2, PRL, LH, and FSH in the observation group were lower than those in the control group. This indicates that Zhibai dihuang pills combined with leuprorelin microspheres and dietary intervention can suppress metabolic and hormone levels in affected children, thereby improving ovarian function. The combination of dietary intervention, Zhibai dihuang pills, and leuprorelin microspheres may regulate hormone levels in affected children through various mechanisms, restoring them to levels comparable to those of children of the same age and slowing down the maturation process of bone cells. Additionally, adverse reactions such as sweating, back pain, and dry mouth were observed in the control group, while in the observation group, except for one child experiencing dry mouth, no other significant adverse drug reactions were observed, indicating a higher level of safety in this treatment approach.

CONCLUSION

For girls with precocious puberty and rapidly progressive puberty, Zhibai dihuang pills combined with leuprorelin microspheres and dietary intervention demonstrate significant clinical efficacy. This intervention regimen positively regulates the growth rate and ovarian function of affected children. These findings suggest that controlling the rate of weight gain may help reduce the risk of precocious puberty and rapidly progressive puberty. Additionally, the sample size was relatively small and limited to a single hospital, which may affect the generalizability of our findings. Future studies should include larger, multi-center trials with extended follow-up periods to validate our findings.

FOOTNOTES

Author contributions: Wang XM contributed to the conceptualization, formal analysis, project administration, software, supervision, validation, visualization, writing-original draft, and writing-review & editing of this manuscript; Wang XM and Li W participated in the data curation; Wang XM, Li W, and Yang LQ took part in the investigation and methodology of this manuscript; Luo R and Zhang CC were involved in the resources.

Institutional review board statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by Institutional Review Board of Ma'anshan Maternal and Child Health Hospital.

Clinical trial registration statement: This study was registered at Ma'anshan Maternal and Child Health Hospital clinical trial registry. Hospital Clinical Trial Registry, Registration number: MASSFYBJY-LLWYH26.

Informed consent statement: All the study subjects provided informed consent.

Conflict-of-interest statement: All the authors report no relevant conflicts of interest for this article.

Data sharing statement: The data in this study can be obtained from the corresponding author upon reasonable request.

CONSORT 2010 statement: The authors have read the CONSORT 2010 Statement, and the manuscript was prepared and revised according to the CONSORT 2010 Statement.

Country of origin: China

ORCID number: Xue-Mei Wang 0009-0005-6121-1359.

S-Editor: Wang JJ
L-Editor: A
P-Editor: Che XX

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