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The Therapeutic Effect of Dabuyin Wan on Male Breast Development and Its Impact on Sex Hormone Levels

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Abstract: *Objective*: To investigate the efficacy of Dabuyin Wan (Concentrated Pills) in the treatment of prepubertal gynecomastia in boys and to analyze its impact on sex hormone levels. *Methods*: A total of 100 boys with gynecomastia diagnosed and treated in our hospital from July 2022 to February 2025 were selected and randomly divided into two groups using a random number table, with 50 cases in each group. The control group received non-pharmacological treatment, while the observation group was treated with Dabuyin Wan (Concentrated Pills). Both groups continued treatment for 6 months. Clinical efficacy, TCM syndrome scores, sex hormone levels [estradiol (E2), luteinizing hormone (LH), testosterone (T), prolactin (PRL)], and adverse reactions were compared between the two groups. *Results*: The total clinical effective rate in the observation group was higher than that in the control group ($\chi^2 = 5.316$, $P < 0.05$). After treatment, the TCM syndrome score in the observation group was lower than that in the control group ($t = 15.513$, $P < 0.05$). After treatment, E2, LH, and PRL levels in the observation group were lower than those in the control group, while the T level in the observation group was higher than that in the control group ($t = 5.819$, 11.000, 7.275, 9.524, respectively; $P < 0.05$ for all). There was no significant difference in the incidence of adverse reactions between the two groups. *Conclusion*: The use of Dabuyin Wan (Concentrated Pills) for prepubertal gynecomastia in boys can improve clinical outcomes, alleviate clinical symptoms, modulate sex hormone levels, and demonstrate a favorable safety profile.

Keywords: Prepubertal gynecomastia in boys; Dabuyin Wan (Concentrated Pills); Efficacy; Sex hormones

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1. Introduction

Gynecomastia in boys is mainly manifested by unilateral or simultaneous bilateral breast enlargement, accompanied by enlargement of the nipple and areola, with painless or dull-aching masses palpable locally [1]. Currently, the clinical treatment of gynecomastia in boys primarily relies on anti-estrogen drugs, which can inhibit the secretion of estrogen in the body, reduce estrogen levels, and thereby improve the clinical symptoms of

affected children [2]. However, long-term use of Western medications can easily lead to adverse reactions, affecting the physical health of the children. In traditional Chinese medicine, gynecomastia in boys is classified under the category of "Ruli" (a traditional Chinese medical term). It is believed that insufficient kidney Yin affects liver Yin, leading to an imbalance of Yin and Yang in the kidneys and an excess of ministerial fire. Treatment primarily focuses on nourishing Yin and reducing fire [3]. Dabuyin Wan (Concentrated Pill) has the effects of clearing heat, reducing fire, nourishing Yin, and cooling blood. In view of this, this study aims to explore the efficacy of Dabuyin Wan (Concentrated Pill) in treating gynecomastia in boys and its impact on sex hormone levels. The report is as follows.

2. Materials and methods

2.1. General information

A total of 100 boys with gynecomastia treated at the hospital from July 2022 to February 2025 were included in the study, and the families of the children all signed informed consent forms. The children were randomly divided into two groups using a random number table method, with 50 cases in each group. The control group ranged in age from 9 to 16 years, with an average age of (11.98 ± 1.82) years; the body mass index ranged from 19.52 to 25.87 kg/m^2, with an average of (22.67 ± 1.46) kg/m^2; the diameter of the masses ranged from 1 to 10 cm, with an average of (5.70 ± 2.13) cm; the disease duration ranged from 3 to 6 months, with an average of (4.32 ± 0.84) months; the affected side: 11 cases on the left, 10 cases on the right, and 29 cases bilaterally; breast Tanner staging [4]: 19 cases in stage II and 31 cases in stage III. The observation group ranged in age from 9 to 16 years old, with an average age of (12.20 ± 1.55) years old; the body mass index ranged from 17.79 to 25.38 kg/m², with an average of (22.09 ± 1.50) kg/m^2; the diameter of the masses ranged from 1 to 10 cm, with an average of (5.52 ± 2.07) cm; the disease duration ranged from 2 to 6 months, with an average of (4.26 ± 0.80) months; the affected side: 13 cases on the left, 12 cases on the right, and 25 cases bilaterally; breast Tanner staging: 23 cases in stage II and 27 cases in stage III. Comparison of general information between the two groups ($P > 0.05$) indicated comparability.

2.2. Inclusion criteria

Inclusion criteria: (1) Western medicine diagnostic criteria: Presence of unilateral or bilateral breast enlargement symptoms, with breast ultrasound indicating the existence of breast tissue with a diameter ≥ 0.5 cm; (2) Traditional Chinese medicine (TCM) diagnostic criteria: Conforming to kidney Yin deficiency syndrome in Modern TCM Breast Disease [5], with primary symptoms including unilateral or bilateral breast enlargement and non-tender lumps; secondary symptoms including obesity, hot flashes, five-center heat (sensation of heat in the palms, soles, and chest), irritability, dry throat and mouth; tongue and pulse manifestations: red tongue with scanty coating, and thin and rapid pulse; (3) No prior relevant medication treatment; (4) The child is mentally clear, has good compliance, and can cooperate with this study.

Exclusion criteria: (1) Endocrine disorders such as incomplete development of secondary sexual characteristics, Hashimoto's thyroiditis, Klinefelter syndrome, and nephrotic syndrome; (2) Concomitant benign or malignant breast tumors; (3) Abnormal breast development caused by long-term oral administration of drugs such as estrogen, isoniazid, and digitalis; (4) Intolerance or allergy to the study drugs; (5) Concomitant cardiac, hepatic, or renal dysfunction.

2.3. Treatment methods

The control group received non-pharmacological treatment, including dietary and exercise management. The observation group was treated with Dabuyin Wan (concentrated pills, 3 g per bag), with each bag containing 0.65 g of prepared rehmannia root, 0.45 g of salt-fried anemarrhena rhizome, 0.45 g of salt-fried phellodendron bark, 0.65 g of processed tortoise shell, and 0.8 g of pig spinal cord. The dosage was 3 g each time, taken twice daily. Both groups received continuous treatment for 6 months.

2.4. Observation indicators

(1) Clinical efficacy

Clinical efficacy was evaluated based on Modern TCM Breast Disease. Cure: disappearance of breast lumps; Improvement: reduction of breast lumps by more than 1/2; Ineffective: no disappearance or reduction of lumps. The effective rate = cure rate + improvement rate.

(2) TCM syndrome score: Before treatment and at 6 months of treatment, the severity of symptoms such as unilateral or bilateral breast enlargement, non-tender lumps, obesity, hot flashes, five-center heat, irritability, and dry throat and mouth were quantified and assigned values as follows: no symptoms: 0 points, mild: 1 point, moderate: 2 points, severe: 3 points. Tongue and pulse manifestations were scored as 1 point for presence and 0 points for absence, with a total score ranging from 0 to 24 points.

(3) Sex hormone levels: Before treatment, at 6 months of treatment, and at other time points, 5 mL of fasting venous blood samples were collected, respectively. After centrifuging the samples for 5 minutes, the serum was obtained and tested using the chemiluminescence method, including serum estradiol (E2), luteinizing hormone (LH), testosterone (T), prolactin (PRL), etc.

(4) Adverse reactions: Record the occurrences of vomiting and diarrhea.

2.5. Statistical analysis

Data were processed using SPSS 25.0 software, with mean ± standard deviation (SD) representing measurement data and t-tests; percentages representing count data and χ^2 tests, and rank sum tests for ordinal data. Statistical significance was set at $P < 0.05$.

3. Results

3.1. Efficacy

The efficacy in the observation group was higher than that in the control group ($P < 0.05$). See **Table 1**.

Table 1. Efficacy analysis table [*n*(%)]

Group	Number of cases	Cured, *n* (%)	Improved, *n* (%)	Ineffective, *n* (%)	Effective rate, *n* (%)
Control group	50	13 (26.00%)	26 (52.00%)	11 (22.00%)	39 (78.00%)
Observation group	50	22 (44.00%)	25 (50.00%)	3 (6.00%)	47 (94.00%)
Statistic (Z/χ^2)	—		$Z = 2.460$		$\chi^2 = 5.316$
P-value	—		0.014		0.021

3.2. TCM syndrome scores

The syndrome scores in the observation group after treatment with Dabuyin Wan were lower than those in the control group ($P < 0.05$). See **Table 2**.

Table 2. TCM syndrome score analysis table (mean ± SD, points)

Group	n	Before treatment (Mean ± SD)	After treatment (Mean ± SD)	*t*-value (Within-group)	*P*-value (Within-group)
Control group	50	13.78 ± 1.82	9.28 ± 1.44	13.854	< 0.001
Observation group	50	13.12 ± 1.79	5.16 ± 1.20	25.872	< 0.001
t-value		1.827	15.513		
P-value		0.071	<0.001		

3.3. Sex hormone level

After treatment with Dabuyin Wan, the levels of sex hormones such as E2, LH, and PRL in the observation group were lower than those in the control group, while T was higher than that in the control group ($P < 0.05$). See **Table 3**.

Table 3. Sex hormone analysis table (mean ± SD)

Time	Group	n	E_2 (pmol/L)	LH (IU/L)	T (nmol/L)	PRL (ng/mL)
Before treatment	Control group	50	53.47 ± 12.21	13.61 ± 2.62	6.81 ± 1.12	21.40 ± 4.52
	Observation group	50	53.69 ± 12.89	13.54 ± 2.75	6.79 ± 1.10	21.14 ± 4.19
	t-value		0.088	0.130	0.046	0.310
	P-value		0.930	0.897	0.963	0.758
After treatment	Control group	50	43.85 ± 10.29[a]	7.95 ± 0.83[a]	8.05 ± 1.11[a]	17.57 ± 3.61[a]
	Observation group	50	31.75 ± 10.51[a]	6.27 ± 0.69[a]	10.93 ± 1.82[a]	12.65 ± 3.14[a]
	t-value		5.819	11.000	9.524	7.275
	P-value		< 0.001	< 0.001	< 0.001	< 0.001

Note: Compared with the same group before treatment, [a]$P < 0.05$

3.4. Adverse reactions

No obvious adverse reactions occurred in the control group. In the observation group, there was one case of vomiting and one case of diarrhea, resulting in a total of 2 cases (4.0%). No significant difference in the incidence of adverse reactions was observed between the two groups.

4. Discussion

The development of male breast tissue in boys is primarily associated with hormonal imbalances in the blood circulation, particularly involving sex hormones. During puberty, boys experience rapid development of male characteristics, but if their testes secrete insufficient androgens while there is relatively higher estrogen secretion in the body, estrogen can stimulate breast tissue, ultimately leading to breast development [6]. Tamoxifen is a commonly used medication in clinical treatment for male breast development. It belongs to the triphenylethylene

derivatives and can bind to estrogen receptors in target tissues, blocking the effects of estrogen, reducing estrogen levels, and thereby regulating the balance between estrogen and androgens, ultimately alleviating clinical symptoms in affected children [7]. However, the drug instructions for tamoxifen clearly state that no experiments have been conducted on its use in children, and there are no reliable references available. Additionally, long-term use can easily lead to adverse reactions, affecting the physical health of children. Therefore, it is necessary to seek safer and more effective treatment options. Traditional Chinese medicine holds that the nipple is associated with the liver, and the male breast is associated with the kidneys, indicating a close relationship between breast diseases and the liver and kidneys. Children are considered to have delicate and immature organs and qi circulation, making them prone to imbalances in Yin and Yang. The kidneys are considered the foundation of the body's innate constitution. If kidney Yin is insufficient and unable to restrain Yang, the ministerial fire will become overly vigorous, disrupting the harmony between water and fire, and leading to breast development. Therefore, treatment should primarily focus on nourishing Yin and reducing fire [8,9].

The results of this study show that the observation group had a higher overall clinical effectiveness rate and lower scores for traditional Chinese medicine syndromes, indicating that Dabuyin Wan(concentrated pills) has a good therapeutic effect in treating male breast development and can alleviate clinical symptoms. The reason for this may be that in Dabuyin Wan(concentrated pills), prepared rehmannia root nourishes Yin, replenishes the kidneys, and enriches essence and marrow, serving as the principal herb; anemarrhena rhizome (salt-fried) clears heat, reduces fire, nourishes Yin, and moistens dryness, while phellodendron bark (salt-fried) clears heat, dries dampness, reduces fire, and eliminates steaming heat. Together, these three herbs work synergistically to clear heat and reduce fire, serving as adjuvant herbs. Vinegar-processed tortoise shell nourishes liver Yin and kidney Yin, serving as an assistant herb; while pig spinal cord nourishes Yin, strengthens Yang, fortifies tendons and bones, serving as both an assistant and messenger herb [10]. When combined, these herbs work together to nourish Yin, generate fluids, clear heat, and reduce fire, thereby inhibiting breast development in children and alleviating their clinical symptoms.

T, E_2, LH, and PRL are commonly used indicators for clinical sex hormone tests. Among them, T is the primary male sex hormone, which promotes male pubertal development and inhibits breast growth. E_2, with high biological activity among estrogens, acts on breast ducts, accelerating breast hyperplasia, while stimulating the development of ducts and adjacent lobular tissues, ultimately leading to ductal elongation and even branching, thereby stimulating breast development. LH, secreted by the adenohypophysis, promotes breast growth and development. PRL, a protein hormone, facilitates the growth and development of breast tissue [11,12]. In male children with breast development, hyperfunction of the hypothalamic-pituitary-gonadal axis leads to decreased T levels and increased E_2, LH, and PRL levels, resulting in hormonal imbalances and premature breast development. The results of this study show that the observation group had lower E_2, LH, and PRL levels and higher T levels compared to the control group, indicating that Dabuyin Wan (concentrated pill) can improve sex hormone levels in male children with breast development. This can be attributed to the fact that the vinegar-processed tortoise shell in Dabuyin Wan (concentrated pill), composed of organic substances such as keratin and bone, has kidney-tonifying and antipyretic effects. *Rehmannia glutinosa* can enhance renal function, improve kidney Yin deficiency, and nourish the liver and kidneys. The combined use of these herbs can strengthen kidney-tonifying effects and alleviate kidney Yin deficiency in children. The total saponins of *Anemarrhena asphodeloide*s in salt-processed Anemarrhena can inhibit the increase in LH levels, thereby reducing E2 secretion and improving sex hormone levels. *Phellodendron amurense* can stimulate androgen secretion, inhibit the function of the hypothalamic-

pituitary-gonadal axis, and effectively regulate the body's hormonal and endocrine levels [11]. Therefore, the combined use of these herbs can tonify kidney Yin deficiency, reduce hypothalamic neuronal functional activity, regulate dysfunction of the hypothalamic-pituitary-gonadal axis, and thereby improve sex hormone levels. Additionally, this study observed low incidences of adverse reactions in both groups during treatment, indicating that Dabuyin Wan (concentrated pill) has a low incidence of adverse reactions and good safety in the treatment of male children with breast development.

5. Conclusion

In summary, Dabuyin Wan (concentrated pill) can enhance the therapeutic effect on male children with breast development, alleviate clinical symptoms, improve sex hormone levels, and demonstrate high safety.

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Disclosure statement

The authors declare no conflict of interest.

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