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Diagnostic value of basal sex hormone levels and pelvic B-mode ultrasound in central precocious puberty among female children

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Abstract

Background: This study aims to explore the diagnostic significance of basal sex hormone levels and pelvic B-mode ultrasound in the context of central precocious puberty (CPP) in female children. **Methods**: A cohort study was conducted at the Third Affiliated Hospital of Wenzhou Medical University from January 2014 to January 2024. The study enrolled female children exhibiting early breast development before the age of 8 and subjected them to gonadotropin-releasing hormone (GnRH) stimulation tests. Subsequently, the participants were categorized into a CPP cohort and a non-CPP cohort, each comprising 75 individuals. Comparative analysis was performed on the basal luteinizing hormone (LH) levels, uterine length and ovarian volume between the two cohorts. **Results**: The results show no significant differences were observed in age and body mass index (BMI) between the CPP and non-CPP groups (both $p > 0.05$). However, basal LH levels, uterine length, and ovarian volume were significantly higher in the CPP group compared to the non-CPP group (all $p < 0.05$). Binary logistic regression analysis revealed that basal LH levels, uterine length, and ovarian volume were independent risk factors for CPP in female children (all $p < 0.05$). Receiver Operating Characteristic (ROC) curve analysis showed that the area under the curve (AUC) for basal LH, ovarian volume, and uterine length were 0.823, 0.752 and 0.730, respectively. The combined diagnosis of these three factors significantly improved diagnostic performance, with an AUC of 0.931 (95% confidence interval (CI) : 0.891–0.972), a sensitivity of 88.00%, and a specificity of 86.70%. **Conclusions**: The integration of basal levels of sex hormones and pelvic B-mode ultrasound holds considerable importance in the diagnosis of CPP in young girls, offering a non-invasive, accessible and cost-effective method for clinical assessment. Therefore, its utilization is highly recommended.

Keywords

Luteinizing hormone; Pelvic B-mode ultrasound; Female children; Central precocious puberty; Diagnosis

Valor diagnóstico de los niveles hormonales sexuales basales y la ecografía en modo B del pelvis en la pubertad precoz central en niñas

Resumen

Antecedentes: Este estudio tiene como objetivo explorar la importancia del diagnóstico basado en los niveles de las hormonas sexuales basales y la ecografía en modo B del pelvis en el contexto de la pubertad precoz central (PPC) en niñas. **Métodos**: Se realizó un estudio de cohorta en el Tercer Hospital Afiliado a la Universidad de Medicina de Wenzhou desde enero de 2014 hasta enero de 2024. El estudio incluyó niñas que presentaron desarrollo precoz de los senos antes de los 8 años y se sometieron a pruebas de estimulación con la hormona liberadora de gonadotropina (GnRH). Posteriormente, las participantes fueron clasificadas en un cohorto PPC y un cohorto no PPC, cada uno con 75 individuos. Se realizó un análisis comparativo de los niveles de la hormona luteínizante (HL) basal, la longitud uterina y el volumen ovárico entre los dos cohortos. **Resultados**: Los resultados mostraron que no se observaron diferencias significativas en la edad y el índice de masa corporal (IMC) entre el grupo PPC y el grupo no PPC (ambos $p > 0.05$). Sin embargo, los niveles de hormona luteínizante basal, la longitud uterina y el volumen ovárico fueron significativamente más altos en el grupo PPC en comparación con el grupo no PPC (todos $p < 0.05$). El análisis de regresión logística binaria reveló que los niveles de hormona luteínizante basal, la longitud uterina y el volumen ovárico fueron factores de riesgo independientes para PPC en niñas (todos $p < 0.05$). El análisis de la curva Característica Operativa del Receptor (ROC) mostró que el área bajo la curva (AUC) para hormona luteínizante basal, volumen ovárico y longitud uterina fueron 0.823, 0.752 y 0.730, respectivamente. El diagnóstico combinado de estos tres factores mejoró significativamente el rendimiento diagnóstico, con un AUC de 0.931 (95% intervalo de confianza (IC) : 0.891–0.972), una sensibilidad del 88.00% y una especificidad del 86.70%. **Conclusiones**: La integración de los niveles basales de las hormonas sexuales y la ecografía en modo B del pelvis tiene una gran importancia en el diagnóstico de PPC en niñas, ofreciendo un método no invasivo, accesible y costoefectivo para la evaluación clínica. Por lo tanto, su utilización es muy recomendable.

Palabras Clave

Hormona luteinizante; Ecografía en modo B del pelvis; Niñas; Pubertad precoz central; Diagnóstico

1. Introduction

Physiological puberty refers to the maturation of sexual organs in adolescents (10–20 years old); Early puberty refers to the signs of early puberty development in children (8–9 years old for girls and 9–10 years old for boys); Precocious puberty is defined as the premature onset of secondary sexual characteristics in girls under the age of 8 and boys under the age of 9. Early puberty is a medical condition marked by atypical pubertal progression, showing a notably higher prevalence in girls compared to boys, with a ratio of around 5 to 10 times higher [1]. CPP in female children, as a common endocrine disorder, has seen a rising incidence rate year by year, posing a significant impact on children's physical and mental health [2–5]. CPP is caused by the early activation of the hypothalamic-pituitary-gonadal axis (HPGA), resulting in elevated levels of gonadotropin-releasing hormone (GnRH). This, in turn, stimulates gonadal growth and the production of sex hormones, leading to the premature development of both internal and external genitalia as well as secondary sexual characteristics [6]. CPP not only threatens the growth potential of female children but also has long-term impacts on their mental health [7, 8]. Basal sex hormone level testing and pelvic B-mode ultrasound examination are two indispensable auxiliary diagnostic tools with significant diagnostic value for assessing CPP in young girls [9, 10]. The assessment of basal sex hormone levels involves the measurement of serum gonadotropins (such as LH and follicle-stimulating hormone (FSH)) as well as sex hormones (such as estradiol (E2)). This evaluation provides a direct reflection of the hormonal secretion status in female children. It plays a crucial role as an indicator to ascertain if the HPGA has been prematurely activated [11]. Meanwhile, pelvic B-mode ultrasound examination provides direct visualization of the development of female genitalia such as the uterus and ovaries, enabling the measurement of parameters like uterine length, ovarian volume, and follicle size, offering direct radiological evidence for the diagnosis of precocious puberty [12]. Nonetheless, the use of a solitary diagnostic tool frequently comes with constraints, hindering a thorough and precise evaluation of the sexual development status of young girls. Hence, integrating basal sex hormone level analysis with pelvic B-mode ultrasound screening can significantly improve the diagnostic precision and sensitivity in assessing sexual development among female children.

This paper aims to explore the diagnostic value of basal sex hormone levels and pelvic B-mode ultrasound in CPP among female children. By analyzing the application of these two diagnostic tools of precocious puberty in female children, we assess their diagnostic performance and clinical significance, aiming to provide clinicians with more scientific and reasonable diagnostic basis and treatment recommendations.

2. Materials and methods

2.1 General information

Female children who presented with breast development before the age of 8 years, suspected to be CPP and underwent GnRH stimulation testing at the Third Affiliated Hospital of Wenzhou Medical University between January 2014 and January 2024 were included in this study. Inclusion criteria:

(1) Female children aged less than 8 years with breast development before this age. (2) All female children underwent GnRH stimulation testing to assess the nature of precocious puberty. Exclusion criteria: (1) Other endocrine disorders: Female children with other endocrine diseases that could affect sex hormone levels, such as thyroid dysfunction or adrenal diseases. (2) Medication effects: Recent use of medications that could affect sex hormone levels, including corticosteroids or sex hormone therapy. (3) Severe systemic diseases: Female children with severe or chronic systemic diseases that could impact growth and development or hormone levels. (4) Congenital developmental abnormalities: Conditions such as chromosomal abnormalities or congenital gonadal dysplasia. (5) Prior treatment for precocious puberty: Female children who had already started treatment for precocious puberty, as this could alter hormone levels and ultrasound findings of reproductive organs.

Null hypothesis (H_0): There is no significant difference between the CPP group and the non-CPP group, and the mean values of the key indicators for the two groups are equal or the difference does not exceed the allowable error δ. Alternative hypothesis (H_1): There is a significant difference between the two groups. The study power was set at a minimum of 80% with a two-sided alpha level of 5% to reject the null hypothesis of no difference between groups. The sample size estimation formula used was $n = \frac{2 \times \left(z_{1-\alpha/2} + z_{1-\beta}\right)^2 \times \sigma^2}{\delta^2}$. For a two-sided significance level of 5%, $z_{1-\alpha/2} \approx 1.96$; for a power of 80%, $z_{1-\beta} \approx 0.84$; σ, the assumed population standard deviation, was 1.6; and δ, the allowable error, was 0.53. Plugging these values into the formula yielded n = 71.4, requiring approximately 71 samples per group. However, to ensure the robustness of the study, 75 female children were included in each group, totaling 150 female children. After conducting the GnRH stimulation test, female children were divided into two groups based on the results. Those with an LH peak >5 U/L and an LH peak/FSH peak ratio >0.6 were categorized into the CPP group, while the remaining participants were placed in the non-CPP group, resulting in 75 cases in each group [13].

2.2 Methods

All girls are required to collect fasting serum samples between 8 and 9 am in the morning. Triptorelin acetate injection (Chengdu Tiantai Mountain Pharmaceutical Co., Ltd., Chengdu, China, H20058648, Specification: 1 mL: 0.1 mg) was administered at a dose calculated based on the child's weight, 2.5 μg/kg, with an upper limit of 100 μg. The injection was quickly given (within 15–30 seconds) through a needle inserted in the forearm, with the goal of keeping the blood vessels open to facilitate proper drug uptake. Venous blood samples of 2 mL were obtained at four specific time intervals: prior to the injection, as well as at 30, 60 and 90 minutes following the injection. These samples were preserved at room temperature until they were analyzed in the laboratory. Highly precise chemiluminescent immunoassay methods were used to measure LH, FSH levels and the dynamic changes of LH and FSH during the GnRH stimulation test. The entire detection process strictly followed the instructions of the reagent kit to ensure the accuracy and reliability of the results. According to "Causes, diagnosis and treatment of central precocious puberty" [13], LH peak >5 U/L and LH peak/FSH peak >0.6 are considered CPP.

The advanced Philips EPIQ7 ultrasound diagnostic system (Ultrasound Diagnostic System, Philips, Amsterdam, Netherlands) was utilized for pelvic ultrasonography. Female children were instructed to fill their bladders adequately before being positioned in a supine stance. Detailed assessments of the uterus and bilateral ovaries were then conducted using a 7.5 MHz high-frequency probe via the transabdominal approach. Parameters such as uterine thickness, width, length, cervical length, endometrial thickness, as well as the dimensions of both ovaries were carefully documented during the examination.

In blind assessment, doctors or researchers only determine the possibility of precocious puberty based on LH peak and LH peak/FSH peak, without considering other clinical information of the patient. Doctors or researchers will only rely on ultrasound images to determine whether there are characteristics of precocious puberty.

2.3 Statistical analysis

Statistical analysis of the collected data was performed using SPSS 26.0. (IBM Corp. Armonk, NY, USA). The uterine length, ovarian volume and basal LH levels were found to be normally distributed and were described using means, with *t*-tests performed. Subsequently, binary logistic regression analysis was conducted on uterine length, ovarian volume and basal LH to assess their correlation with CPP diagnosis. ROC curves were plotted, and the diagnostic efficacy of each indicator was compared by calculating the AUC values. The optimal cut-off values (based on the maximum Youden index) were determined using the sensitivity and specificity of the ROC curves. A p-value < 0.05 was considered statistically significant.

3. Results

3.1 Comparison of general information

There were no significant differences in age and BMI between the CPP group and the non-CPP group ($p > 0.05$ for both). However, the basal LH, uterine length, and ovarian volume were significantly higher in the CPP group compared to the non-CPP group ($p < 0.05$ for all). See Table 1 for details.

3.2 Multifactorial logistic regression analysis for diagnosis of CPP in girls

Using basal LH, uterine length, and ovarian volume as independent variables, and the presence or absence of CPP as the dependent variable (assigned value of 2 for CPP and 1 for non-CPP), a logistic regression analysis was performed. The results showed that basal LH, uterine length and ovarian volume were all independent risk factors for the diagnosis of CPP in girls ($p < 0.05$ for all). See Table 2 for details.

TABLE 1. Comparison of general information.

Project	CPP group (n = 75)	Non-CPP group (n = 75)	*t*	*p*
Age (yr)	7.00 ± 0.27	6.91 ± 0.41	1.588	0.115
BMI (kg/m^2)	23.35 ± 1.16	23.53 ± 1.21	0.929	0.354
Basic LH (U/L)	0.55 ± 0.22	0.29 ± 0.16	8.351	<0.001
Uterine length (cm)	3.70 ± 0.83	2.94 ± 0.85	5.518	<0.001
Ovarian volume (cm^3)	1.62 ± 0.46	1.17 ± 0.40	6.417	<0.001

CPP; central precocious puberty; BMI: body mass index; LH: luteinizing hormone.

TABLE 2. Multifactorial logistic regression analysis for diagnosis of CPP in girls.

Factors	β	SE	Wald χ^2	*p*	OR	95% CI
Basic LH (U/L)	8.243	1.657	24.736	<0.001	3801.448	147.624–97890.855
Uterine length (cm)	1.430	0.349	16.816	<0.001	4.177	2.109–8.272
Ovarian volume (cm^3)	3.171	0.727	19.001	<0.001	23.828	5.727–99.147

LH: luteinizing hormone; SE: Standard Error; OR: Odds Ratio; CI: Confidence Interval.

3.3 ROC curve analysis of basal LH, uterine length and ovarian volume

ROC curve analysis demonstrated AUC values of 0.823, 0.752 and 0.73 for basal LH, ovarian volume and uterine length, respectively. When considering these three factors together, the diagnostic performance was notably enhanced, resulting in a combined AUC of 0.931 (95% CI = 0.89–0.972), with a sensitivity of 88.00% and a specificity of 86.70%. Further information can be found in Table 3 and Fig. 1.

4. Discussion

The GnRH stimulation test is widely regarded as the most reliable method for diagnosing CPP. A peak LH(P-LH)/FSH peak ratio ≥0.6 and P-LH levels ≥5.0 IU/L are indicative of CPP. Additionally, some studies suggest that a LH peak ≥5 mIU/mL and/or a LH/FSH ratio ≥0.66 may also signal the presence of CPP [14, 15]. However, this test requires the administration of GnRH, followed by blood sampling at multiple time points after injection, which can cause pain, fear and low compliance among children due to its lengthy procedure. Therefore, there is a pressing need to explore more convenient and accurate diagnostic methods for CPP in girls. Pelvic ultrasound, especially B-mode ultrasonography of the uterus and ovaries, provides a clear view of the growth and condition of female reproductive organs [16]. Moreover, the assessment of baseline sex hormone levels combined with pelvic ultrasound represents a straightforward, speedy, non-intrusive and intuitive approach that carries substantial importance in the detection of CPP in female individuals [17]. These modalities not only minimize discomfort and anxiety for children but also enhance the diagnostic accuracy and efficiency, making them highly desirable for clinical application.

LH, a type of glycoprotein hormone produced by the anterior pituitary gland, holds a crucial position in the human endocrine system, especially in overseeing the growth and operational coordination of the reproductive system [18]. In the GnRH stimulation test, an LH peak/FSH peak ratio > 0.6 is considered as a diagnostic indicator for CPP. However, due to its pulsatile secretion characteristics, a single basal LH measurement may not be sufficient for a definitive diagnosis. According to global specialists, a basal LH level exceeding 0.2 U/L is advised as a marker for monitoring the initiation of sexual maturation [19]. The diagnostic accuracy of morning serum LH in detecting CPP in girls varies from 60% to 100%, mainly due to discrepancies in cutoff values and laboratory testing methods employed [20]. The results of this study show that the basal LH levels in the CPP group were significantly higher than those in the non-CPP group with simple breast development. Using 0.495 U/L as the cutoff value, basal LH demonstrated a high diagnostic efficiency for CPP in girls (AUC = 0.823, 95% CI = 0.759–0.887), with a sensitivity of 60% and a specificity of 90.7%. A study by Shu-Nin Yeh *et al.* [21] involving 313 patients revealed that a basal serum LH ≥0.2 IU/L predicted CPP in girls with a sensitivity of 70% and a specificity of 70%. Conversely, Doğuş Vurallı *et al.* [22] found in their study of 344 girls that a basal LH ≥0.65 IU/L predicted CPP with a sensitivity of 78% and a specificity of 100%. The findings of this study align more closely with those of Doğuş Vurallı, as high basal LH levels showed moderate sensitivity but high specificity in diagnosing CPP in girls. Notably, the substantial difference in specificity compared to Shu-Nin Yeh *et al.*'s [21] study is primarily attributed to the significant variation in the selected cutoff values for basal serum LH. The baseline LH value can influence the GnRH agonist stimulation test. According to certain researchers, setting a threshold of 4.1 IU/L for the LH peak shows a significantly elevated level of sensitivity (94%) and specificity (95%) [23]. Additionally, other scholars have pointed out that a baseline LH value greater than 0.535 mIU/L can be used to diagnose CPP without the need for a GnRH agonist stimulation test [24].

B-mode ultrasound allows for the direct observation of the progression of the reproductive organs, including the uterus and ovaries. This imaging technique is particularly useful in detecting specific changes such as an increase in ovarian size,

TABLE 3. Diagnostic efficacy of basal LH, uterine length, and ovarian volume for CPP in girls.

Variable	Cut-off	AUC	SE	*p*	95% CI	Sensitivity (%)	Specificity (%)	PPV	NPV	+LR	−LR
Basic LH (U/L)	0.495	0.823	0.033	<0.001	0.759–0.887	60.00	90.70	0.600	0.947	6.45	0.44
Ovarian volume (cm^3)	1.165	0.752	0.038	<0.001	0.677–0.828	84.00	50.70	0.867	0.507	1.70	0.32
Uterine length (cm)	3.495	0.730	0.040	<0.001	0.651–0.809	58.70	74.70	0.635	0.804	2.32	0.55
Combined diagnosis	0.462	0.931	0.021	<0.001	0.891–0.972	88.00	86.70	0.954	0.917	6.62	0.14

Note: PPV: Positive Predictive Value; NPV: Negative Predictive Value; +LR: Positive Likelihood Ratio; −LR: Negative Likelihood Ratio; AUC: area under the curve; LH: luteinizing hormone; SE: Standard Error; CI: Confidence Interval.

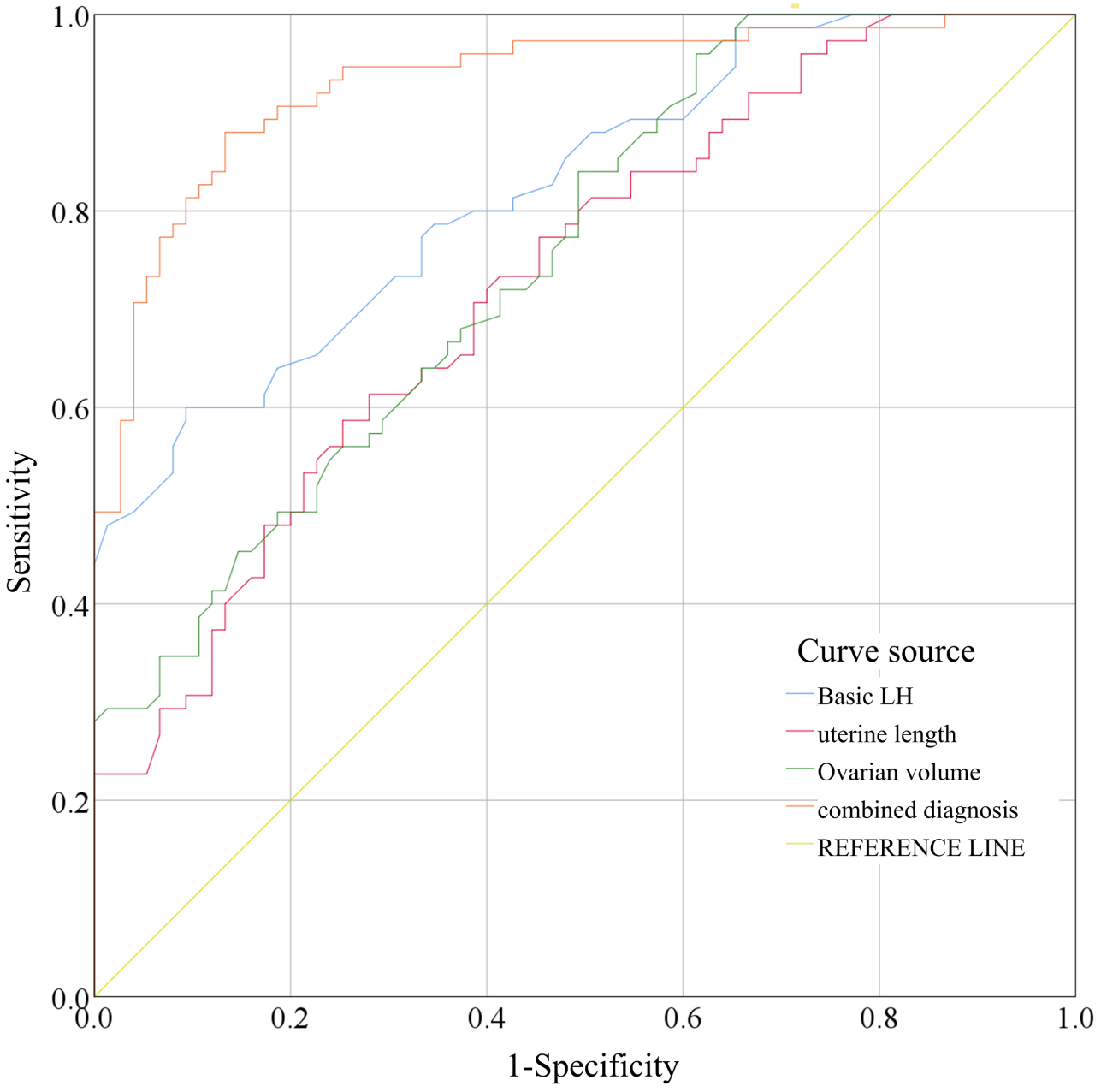

FIGURE 1. ROC Curve for Diagnosis of CPP in Girls Based on Basal Hormone Levels and Pelvic Ultrasound. LH: luteinizing hormone.

a higher number of follicles and an enlargement in follicle size. These changes play a crucial role in the identification of CPP [25]. The increase in uterine length and ovarian volume is a direct manifestation of the development of the reproductive system in precocious puberty girls. When girls' uterine length surpasses a specific range of 3.4–4.0 cm, and the ovarian volume escalates to 1–3 mL (calculated using the formula: length $\times$ width $\times$ thickness $\times$ 0.5233), coupled with the existence of numerous follicles with diameters equal to or greater than 4 mm, it indicates the initiation of pubertal progression in girls and signifies the potential for CPP [26]. The results of this study show that the uterine length (3.7 ± 0.83 cm) and ovarian volume (1.62 ± 0.46 cm^3) in the CPP group were significantly higher than those in the non-CPP group. Nevertheless, when considering the diagnosis of CPP in girls, the effectiveness of solely relying on ovarian volume and uterine length was found to be only moderate. This was highlighted in the research conducted by Valeria Calcaterra [27], the sensitivity and specificity of uterine length $\geq$3.5 cm alone were 65.7% and 57.6%, respectively, while those of ovarian volume $\geq$2 cc alone were 67% and 51.5%, respectively. Compared with Valeria Calcaterra's study, the cutoff value for ovarian volume in this study (1.165 cm^3) was significantly lower, leading to a higher diagnostic sensitivity. Moreover, while the uterine length cutoff value in this research closely resembled that of Valeria Calcaterra's study, the specificity of using uterine length as a sole diagnostic tool for CPP was found to be higher. This disparity in results could potentially be attributed to variations in racial demographics. Valeria Calcaterra's study focused on the Italian population, while the research subjects in this paper are Chinese. There exist variations in pelvic bone structures among different races.

The results of this study demonstrate that the combined diagnosis of basal LH, uterine length and ovarian volume can significantly enhance diagnostic efficiency, with an AUC of 0.931 (95% CI = 0.891–0.972), a sensitivity of 88.00%, and a specificity of 86.70%. Compared to individual diagnoses, the combined diagnosis integrates information from multiple indicators, providing a more comprehensive reflection of the endocrine and reproductive organ development status of girls. Basal LH levels mirror fluctuations in sex hormone levels, whereas uterine length and ovarian volume provide direct assessments of morphological changes in reproductive organs via imaging tests [28]. Various factors, such as age, menstrual cycle and individual differences, can impact single indicators, potentially resulting in misdiagnosis or overlooked diagnoses. In contrast, a comprehensive evaluation of multiple indicators in a combined diagnosis helps mitigate the influence of these factors, ultimately enhancing diagnostic precision [29]. In the diagnosis of CPP in girls, the combined diagnosis exhibits significant advantages over the individual diagnoses of basal LH, uterine length, and ovarian volume, primarily in terms of improved diagnostic accuracy, balanced sensitivity and specificity, better diagnostic performance, and clinical application value. Therefore, in clinical practice, the combined diagnosis method should be prioritized for identifying CPP in girls. This study, through an in-depth evaluation of the application of baseline hormone levels and pelvic ultrasound in the diagnosis of CPP in girls, provides a simple and effective non-invasive diagnostic method for clinical practice. Not only does it enhance the diagnostic process and boost accuracy in diagnosis, but it also provides a crucial framework for tailoring personalized treatment strategies, thus establishing a strong groundwork for subsequent research in this field.

5. Conclusions

However, this study also has certain limitations. It primarily focuses on biological indicators such as basal LH, uterine length and ovarian volume, without fully considering other factors that may influence the diagnosis of CPP, including genetic and environmental factors. Future research can further explore the roles of these factors in the development of CPP for developing a more comprehensive diagnostic model. The findings of this research suggest that basal LH, uterine length, and ovarian volume each play a distinct role as risk factors for diagnosing CPP in girls. Through ROC curve analysis, it was observed that integrating these three factors for diagnosis yields an AUC value of 0.931, indicating a notable diagnostic precision with a sensitivity of 88.00% and a specificity of 86.70%. These results underscore the importance of early detection of CPP in clinical settings. By consistently enhancing diagnostic techniques and procedures, CPP can be identified and addressed at an earlier stage, leading to enhanced treatment results and a better quality of life for children affected by the condition.

AVAILABILITY OF DATA AND MATERIALS

The data presented in this study are available on reasonable request from the corresponding author.

AUTHOR CONTRIBUTIONS

WMJ and ZSL—designed the research study; wrote the manuscript. WMJ, MGZ and JX—performed the research; provided help and advice on the research; analyzed the data. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Ethical approval was obtained from the Ethics Committee of the Third Affiliated Hospital of Wenzhou Medical University (Approval no. YJ2024137). Written informed consent was obtained from a legally authorized representative for anonymized patient information to be published in this article.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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