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Original article

Efficacy of leuprolide acetate versus triptorelin pamoate administered every 3 months for treatment of central precocious puberty

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Background: Central precocious puberty (CPP) is typically treated with gonadotropin-releasing hormone (GnRH) agonists. Although numerous GnRH agonist variants are available, limited research has compared the efficacy of leuprolide acetate and triptorelin pamoate administered at 3-month intervals.

Purpose: This study aimed to assess the efficacy of CPP treatment with triptorelin pamoate and leuprolide acetate administered at 3-month intervals.

Methods: This retrospective cohort study included 116 girls with CPP: 71 treated with leuprolide acetate every 3 months and 45 treated with triptorelin pamoate every 3 months. Anthropometric measurements were compared before and after therapy. At 6 months after the therapy, luteinizing hormone (LH) suppression was evaluated.

Results: When administered every 3 months, leuprolide acetate and triptorelin pamoate significantly suppressed LH. The predicted adult height (PAH) and degree of bone age advancement at the end of treatment were comparable.

Conclusion: Treatment with leuprolide acetate and triptorelin pamoate every 3 months did not have significantly different effects on LH suppression or PAH.

Key words: Efficacy, Leuprolide acetate, Triptorelin pamoate, GnRH agonist, Central precocious puberty

Key message

Question: What are the differences in efficacy between leuprolide acetate and triptorelin pamoate administered every 3 months for the treatment of central precocious puberty (CPP)?

Finding: There were no significant intergroup differences in luteinizing hormone suppression or predicted adult height at the end of treatment in girls with CPP.

Meaning: Leuprolide acetate and triptorelin pamoate have comparable efficacy for treating CPP.

Introduction

Central precocious puberty (CPP) occurs when the hypothalamic-pituitary-gonadal (HPG) axis is activated prematurely in girls who are younger than 8 years old.[1)] While multiple variables can contribute to CPP, its underlying cause generally remains unknown.[1,2)] Significantly, instances of unknown cause are significantly more common in girls, accounting up approximately 90% of cases.[2)] A variety of consequences have been associated to the diagnosis of CPP in girls, including early menarche, low adult height as a result of early epiphyseal fusion, and adverse psychological impacts.[1)] Therefore, it is crucial to provide appropriate therapy to girls with CPP for the purpose to reduce these negative consequences.

The cornerstone of treatment for CPP is the administration of GnRH agonist.[3)] By persistently attaching to pituitary GnRH receptors, these analogues suppress gonadotropin production and prevent pubertal activation. The process involves the downregulation of GnRH receptors, which in effect leads to the suppression of the HPG axis.[4,5)] The following are the key elements of a successful therapy: delay the progression of bone age (BA), reduce growth velocity, regress pubertal development, and increase final adult height.[3,6,7)]

Currently, there are a variety of GnRH analogue formulations on the market. The 3-month depot formulation has been recognized for its effectiveness in suppressing

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the pituitary-gonadal axis and pubertal development.[8-10] Leuprolide acetate is a synthetic nonapeptide analogue of naturally occurring gonadotropin-releasing hormone (GnRH or LH-RH). The analogue is more potent than the natural hormone, which is composed of a biodegradable polymer that is dissolved in a biocompatible liquid solvent to form a liquid gel. The drug is released from this leuprolide depot as it biodegrades over time, enabling the continuous administration of leuprolide acetate. The lyophilized microsphere (10–30 mm) drug delivery systems were employed in the earlier depot formulations of leuprolide. In biodegradable form, leuprolide microspheres contain the active compound. 3-month leuprolide acetate has been approved for CPP in Thailand since 2017. The synthetic GnRH analogue triptorelin pamoate is characterized by the substitution of D-tryptophan for L-glycine at the sixth position. This alteration expands the plasma half-life and increases effectiveness by improving resistance to enzymatic degradation and affinity for the pituitary receptor. Since 2019, 3-month triptorelin has been approved for CPP in Thailand. However, there is a lack of comparative studies that evaluate the effectiveness of various formulations, specifically with regard to treatment completion.

This study investigates the results of treating Thai girls with CPP with 3-month intramuscular injections of leuprolide acetate (11.25 mg) versus 3-month intramuscular injections of triptorelin pamoate (11.25 mg). The aim is to evaluate the effectiveness of these treatments in suppressing LH levels after 6 months and assessing PAH at the end of the treatment.

Methods

1. Participants

A total of 116 girl participants diagnosed with CPP were enrolled in the pediatric endocrinology clinic of King Chulalongkorn Memorial Hospital between December 2008 and December 2022. Girls with CPP, which is defined as the beginning of breast growth before the age of 8 and a hormonal profile demonstrating baseline LH >0.3 IU/L or peak LH following a GnRH stimulation test >5 IU/L were required for inclusion. Some individuals received magnetic resonance imaging scans, especially those whose breast start occurred before the age of 6. The treatment regimen consists of the intramuscular administration of either 11.25 mg of leuprolide acetate or 11.25 mg of triptorelin pamoate every 3 months. Individuals with a history of using exogenous hormones and congenital adrenal hyperplasia were excluded.

2. Methodology

Data were collected for this retrospective cohort study both during follow-up visits and at the time of diagnosis. Chronological age (CA; years), age at breast onset (years), weight (standard deviation score [SDS]), height (SDS), body mass index (BMI) (SDS), menarche status (years), breast Tanner stage, BA (years), and predicted adult height (PAH) at treatment initiation (cm, SDS) were among the data gathered. The World Health Organization growth curve was used to calculate the SDS values for weight, height, and BMI. The Greulich and Pyle approach was used by the pediatric endocrinologist to estimate BA, and the Bayley-Pinnuau method was employed to calculate PAH.[11]

3. LH suppression

The LH suppression 6 months after treatment was utilized to evaluate the efficacy of GnRH agonist therapy. Two hours subsequent to the administration of the treatment dose of the gonadotropin-releasing hormone agonist, serum LH levels were collected and quantified using electrochemiluminescent immunoassay. The definition of LH suppression was serum LH concentrations decreasing below 4 IU/L.[1,4]

4. Growth parameter

The growth outcomes following treatment were assessed at the ending of therapy, with a specific emphasis on the final height achieved at the end of treatment. This included height at the end of treatment (SDS), degree of BA advancement (years), PAH at the end of treatment (cm), the difference between PAH at the start of treatment and PAH at the end of treatment (cm), and the difference between PAH at the end of treatment and midparental height (cm).

5. Ethical consideration

This study constitutes a retrospective analysis conducted through the review of medical records and does not involve an examination of the treatment decisions made by physicians. Approval for the study was obtained from the Institutional Review Board (IRB) of the Faculty of Medicine, Chulalongkorn University (IRB No. 0726/66), in accordance with international guidelines for human research protection, including the Declaration of Helsinki, The Belmont Report, CIOMS Guideline, and International Conference on Harmonization in Good Clinical Practice (ICH-GCP).

6. Statistical analysis

Statistical analyses were executed using IBM SPSS Statistics ver. 29.0 (IBM Co., Armonk, NY, USA). Continuous variables, both with and without normal distribution, were reported as mean (standard deviation) and median

(interquartile range), respectively. Categorical data were presented as proportions (percentage). The independent t test was employed to assess differences in continuous variables between the 2 groups, while the chi-square test was utilized to analyze differences in categorical variables. A *P* value of <0.05 was considered statistically significant.

Results

The study involved a cohort of 116 girl participants, of which 71 received a 3-month treatment of leuprolide acetate 11.25 mg, while the remaining 45 participants received a treatment of 3-month triptorelin pamoate 11.25 mg. Initial clinical characteristics and hormonal profiles are shown in Table 1. The demographic data, such as the age at the start of treatment, age of onset, auxological data, BA, and PAH, were found to be comparable in both groups, with no significant differences. Patients are given GnRH agonist medication until their BA reaches roughly 12 years, with the treatment lasting for about 2 years.[12)]

Following 6 months of treatment, the suppression of LH was evaluated and shown in Table 2. The average LH level was found to be similar in the group receiving 3-month leuprolide acetate and triptorelin pamoate therapy (1.85±0.73 and 2.08±1.27, *P*=0.45). In addition, the rate of LH suppression was comparable between the group receiving treatment every 3 months, with rates of 100% and 84.62% (*P*=0.07) respectively. In the group that received 3-month leuprolide acetate and triptorelin pamoate therapy, the estradiol level was comparable (7.05±4.25 and 6.34±3.00, *P*=0.55).

The growth parameters measured at the end of the therapy are presented in Table 3. The difference in BA advancement, measured by subtracting CA from BA (2.22±1.09 and 1.76±1.30, *P*=0.08), and the ratio of BA to CA (1.27±0.14 and 1.21±0.16, *P*=0.11), did not achieve statistical significance. When comparing the levels of PAH at the ending of treatment to the levels at the start of treatment, both groups showed an increase in PAH at the end of treatment in comparison to the start of treatment in Fig. 1. There was no statistically significant difference in the PAH at the

Table 1. Demographic data

Variable	3-Month GnRH agonist		*P* value
	Leuprolide acetate (N=71)	Triptorelin pamoate (N=45)	
Age of onset (yr)	7.35±0.69	7.47±0.58	0.38
Weight kg	33.03±8.71	32.41±8.07	0.70
Weight SDS	1.30±1.27	1.24±1.25	0.79
Height (cm)	134.46±8.18	133.43±6.99	0.49
Height SDS	1.52±1.23	1.39 ±1.13	0.58
BMI (kg/m^2)	17.99±2.98	17.99±3.11	0.99
BMI SDS	0.75±1.27	0.76±1.34	0.96
MPH (cm)	157.78±4.62	157.13±4.45	0.46
Bone age (yr)	10.48±1.45	10.02±1.56	0.12
PAH-av (cm)	152.51±7.38	154.32±7.69	0.22
PAH-av SDS	-0.94±1.56	-0.56±1.62	0.22
PAH-ac (cm)	157.15±7.89	159.90±9.37	0.10
PAH-ac SDS	0.34±1.66	0.61±1.97	0.10
BA–CA (yr)	2.22±1.09	1.76±1.30	0.08
BA/CA	1.27±0.14	1.21±0.16	0.11

Values are presented as mean±standard deviation.
GnRH, gonadotropin-releasing hormone; SDS, standard deviation score; BMI, body mass index; MPH, midparental height; PAH, predicted adult height; PAH-av, PAH with average bone age; PAH-ac, PAH with accelerated bone age; BA, bone age; CA, chronological age.

Table 2. LH Suppression at 6-month of treatment

Variable	3-Month GnRH agonist		*P* value
	Leuprolide acetate	Triptorelin pamoate	
LH level (IU/L)	1.85±0.73	2.08±1.27	0.45
% LH < 4 IU/L	100%	84.45%	0.07
Estradiol level (pg/mL)	7.05±4.25	6.34±3.00	0.55

Values are presented as mean±standard deviation unless otherwise indicated.
LH, luteinizing hormone; GnRH, gonadotropin-releasing hormone.

Table 3. Growth parameter at end of treatment

Variable	3-Month GnRH agonist		*P* value
	Leuprolide acetate	Triptorelin pamoate	
Height (cm)			
Last treatment	145.12±7.71	147.42±7.82	0.32
Last treatment SDS	1.04±1.14	1.13±1.26	0.80
BA/CA			
0 mon	1.27±0.14	1.21±0.16	0.11
End of treatment	1.09±0.20	1.12±0.14	0.66
BA–CA (yr)			
0 Month	2.22±1.09	1.76±1.30	0.08
End of treatment	0.88±2.13	1.23±1.35	0.47
PAH-av (cm)			
0 Month	152.51±7.38	154.32±7.69	0.22
0-Month SDS	-0.94±1.56	-0.56±1.62	0.22
End of treatment	158.90±5.60	158.31±6.87	0.75
End of treatment SDS	0.41±1.17	0.29±1.44	0.75
$PA_{Hend} - PA_{Hstart}$	4.19±4.58	5.01±2.79	0.54
PAH-ac (cm)			
0 Month	157.15±7.89	159.90±9.37	0.10
0-Month SDS	0.34±1.66	0.61±1.97	0.10
End of treatment	163.09±5.80	161.89±8.11	0.56
End of treatment SDS	1.29±1.21	1.04±1.70	0.55
PAH_{end} – PAHstart	3.30±5.55	3.71±3.56	0.80
MPH (cm)			
PAH-av–MPH	1.97±5.21	1.72±7.82	0.90
PAH-ac–MPH	6.09±5.49	5.26±9.26	0.71

Values are presented as mean±standard deviation.
GnRH, gonadotropin-releasing hormone; SDS, standard deviation score; BA, bone age; CA, chronological age; PAH, predicted adult height; PAH-av, PAH with average bone age; PAH-ac, PAH with accelerated bone age; PAHend, PAH at end of treatment; PAHstart, PAH at start treatment; MPH, midparental height.

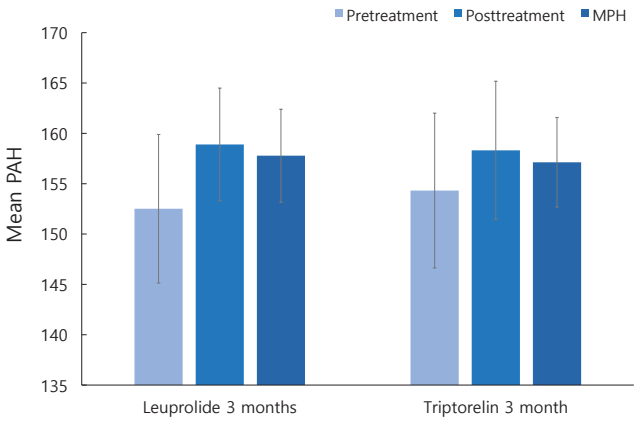

Fig. 1. Predicted adult height (average). MPH, midparental height; PAH, predicted adult height.

conclusion of treatment compared to the commencement of treatment in the group that received treatment every 3 months (4.19±4.58 and 5.01±2.79, *P*=0.54).

Discussion

The most frequently utilized treatment for CPP was the 1-month (4 weeks) depot GnRH analogues until that time. Over the past 7 years, a depot that is available for 3 months has been established. The administration of 2 types of GnRH agonists every 3 months to treat CPP in girls in Thailand has been authorized since 2019. Nevertheless, there is a lack of research that directly compare the effectiveness of these therapy regimens.[13,14] At first, our evaluation primarily focused on assessing their efficacy by analyzing the reduction of LH levels after 6 months of treatment. Criteria for the biochemical efficacy of adequate LH suppression during GnRH analogue therapy are subject to debate. To assess the HPG axis, serum LH or sex steroid can be measured either unstimulated or stimulated (following GnRH analogue administration). The cutoff value for therapeutic monitoring of LH suppression has been investigated using GnRH analogue-stimulated LH levels; however, the appropriate value remains a topic of debate. Based on the International Consortium, the cutoff value for LH suppression in this study was an LH level below 4 IU/L.[15] The results of our study showed that both medications had similar effects in reducing stimulated LH levels in the group receiving treatment every 3 months. The mean LH levels in both groups remained below 4, and there was no noticeable difference in the amount of suppression between the 2 groups. The results align with prior research, which demonstrated LH suppression rates of approximately 84%–100% in both 3 monthly group.[16-23] The present results were also consistent with those from previous studies conducted in predominantly Caucasian populations. In a meta-analysis of earlier trials, it is evident that there are no significant different in outcomes between Caucasian and Asian patients.

Previous research evaluating growth outcomes after 1 year of treatment has not revealed any statistically significant differences in height, the rate at which height increases, or the degree that BA advances between the GnRH agonist preparations.[22,24,25] However, there is a lack of information regarding the assessment of medical effectiveness by analyzing growth characteristics after completing the treatment. The objective of our study was to provide further understanding of the long-term growth effects. Our observation revealed that there was no statistically significant difference in the actual height between individuals who were administered 3-month leuprolide acetate and those who were administered 3-month triptorelin pamoate. The results of the present study are consistent with prior research conducted in Italy,[13] which showed no significant distinction between 1-month injections of leuprolide acetate and 1-month injections of triptorelin acetate in terms of height, height velocity, and the degree of BA advancement within each group. Similarly, the degree of BA progression in both groups (3-month leuprolide acetate and triptorelin pamoate) was comparable in our study, as measured by the difference between BA and CA and the ratio of BA to CA. Both groups experienced a decrease in BA advancement, with no obvious distinction between the 2 groups. This suggests that both treatments were clinically effective.

When the PAH at the end of treatment was compared to its value at the start of treatment, all patients in our analysis experienced an increase in PAH subsequent to receiving treatment with both GnRH agonist. There was not a significant difference between the 2 GnRH agonist treatments with regard to the restoration of growth potential. Furthermore, absolute changes in BA, weight, height, and PAH at the conclusion of treatment did not reveal any significant differences between the 2 groups of patients.

Our study's limitations include its retrospective design, which results in some missing data, and differences in the quantity of data points for particular parameters, making it challenging to compare the 2 groups. Additionally, some participants in this study use basal LH >0.3 IU/L in the diagnosis of CPP, which is not always indicative of 100% specificity. It is important to emphasize that we did not evaluate the precise final adult height because of the reason that the 3-month group started treatment in 2019, and as of now, none of the patients in this group have attained their final adult height. Despite these limitations, our study provides valuable insights into the comparative effectiveness of the two 3-month GnRH agonist regimens

in the treatment of CPP.

In conclusion, both 3-month leuprolide acetate and 3-month triptorelin pamoate treatment regimens demonstrate comparable effectiveness in LH levels and preventing the progression of BA in girl patients undergoing treatment for CPP. PAH is improved in response to both treatment protocols, and there are no significant disparities in PAH observed between the 2 regimens. To validate our findings and assess the ultimate height attained, additional longitudinal research is required.

Footnotes

Conflicts of interest: No potential conflict of interest relevant to this article was reported.

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