

Cost-Consequence Model Comparing Originator r-hFSH-alfa to Other r-FSH-alfa Options in up to Three Complete Ovarian Stimulation Cycles in Assisted Reproductive Technology in China

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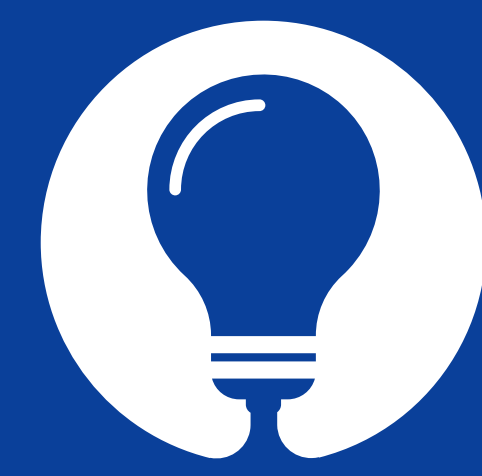
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CONCLUSIONS

Originator r-hFSH-alfa vs Biosimilars



Higher CLBR



Lower costs per live birth



Shorter time to live birth

- Starting and continuing controlled ovarian stimulation (COS) with originator r-hFSH-alfa may reduce time to live birth and cost/cumulative live birth (CLB) compared with biosimilars.
- The % of costs attributed to the originator r-hFSH-alfa in relation to overall assisted reproductive technology (ART) costs is between 15-18 % only, but causes greater difference in cumulative live birth rates (CLBR), time to live birth (TTLB) and overall cost per live birth.
- These findings support more efficient and value-based ART treatment pathways, benefiting both patients and healthcare systems.

INTRODUCTION

- Latest evidence indicate infertility prevalence in China is approximately 18.0% with abnormal ovarian reserve observed in ~25.8% of women.¹
- Follitropin alfa (originator r-hFSH-alfa) remains the gold standard for COS.²
- Recent international evidence indicates that it results in higher CLBR compared to its biosimilars, making it an effective option for COS in ART.²
- With the increasing demand for fertility services in China, it is essential to assess the clinical effectiveness of ART.
- This also includes investigating the clinical effectiveness and efficiency of multiple OS cycles to help optimizing treatment pathways and enhance decision-making in fertility care.



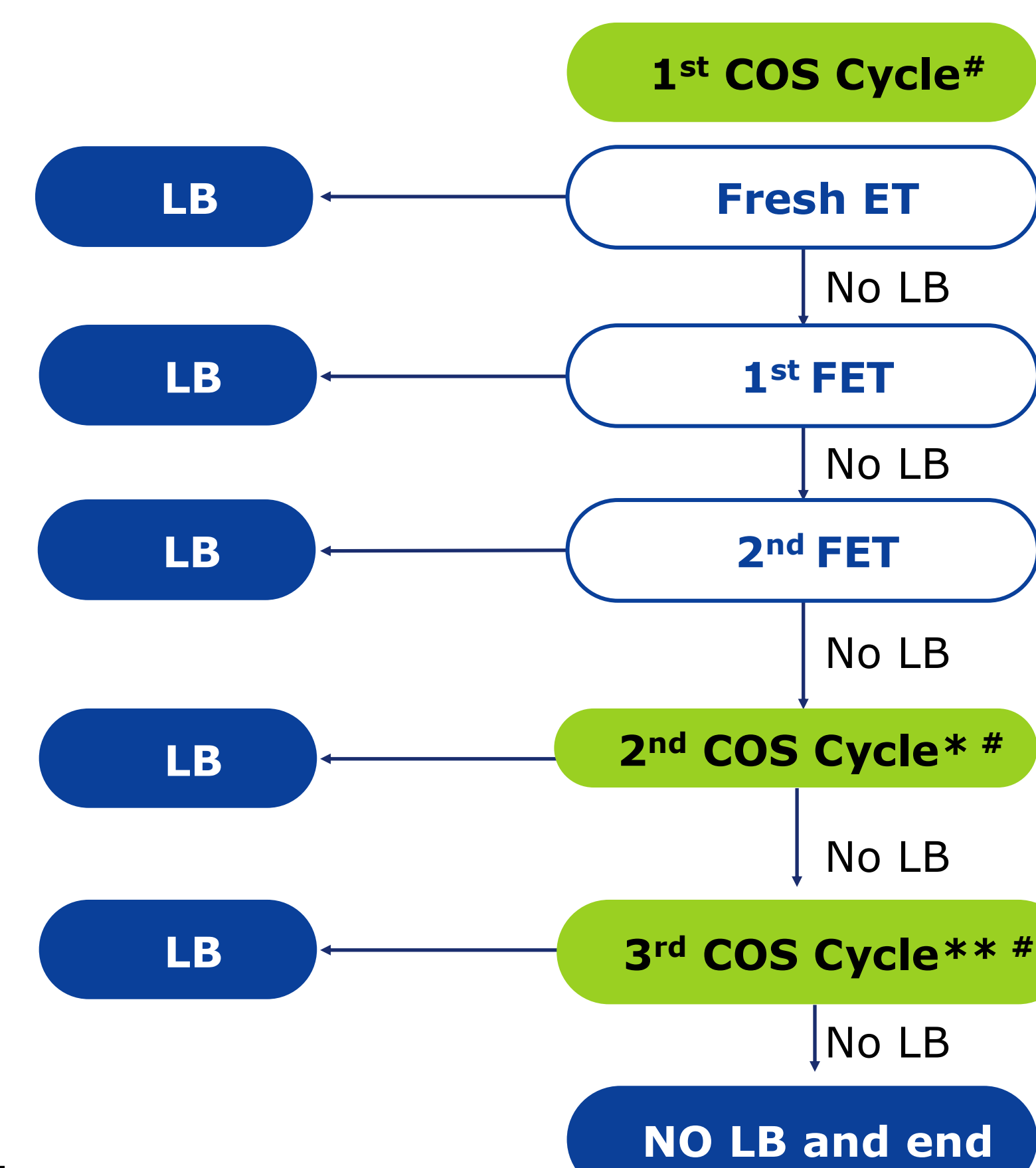
OBJECTIVES

To compare the clinical and economic outcomes of originator recombinant human follicle-stimulating hormone alfa (r-hFSH-alfa [O]) versus other r-FSH-alfa products: A (recombinant human follitropin for injection [Jinsaiheng®]), B (recombinant human follitropin for injection [Anxinbao®]), and C (recombinant human follitropin prefilled syringe [Follitrope®]) during ART across up to three COS cycles.

METHODS

- A decision-tree model was developed in Microsoft Excel to simulate ART treatment pathways for women with infertility, comparing originator r-hFSH-alfa and alternative r-FSH-alfa products/biosimilars and assessed CLBR, TTLB, cost/CLB, and drug cost proportion (**Figure 1**).
- The model evaluated data which were sourced from three Chinese randomized controlled trials and the French SNIRPMA database for Frozen Embryo Transfer (FET) success rates.³⁻⁶
- Treatment started with either originator r-hFSH-alfa or one of the three comparator biosimilar products.
- All other comparative biosimilars launched with phase-3 trial with originator r-hFSH-alfa as the reference drug.
- The treatment protocol began with fresh ET, followed by FET after unsuccessful attempts, and transitioned to new OS cycles after three failed ETs.
- Model structure and assumption were validated by Chinese clinical experts.
- Outcomes measured were CLBR, TTLB, cost/CLB, and drug cost proportion.
- All costs are in local currency (Chinese Yuan [CNY;¥]).

Figure 1. Model structure



*Same steps as in the 1st COS Cycle
**Same steps as in the 1st and 2nd COS Cycle
#OS induced with originator r-hFSH-alfa or any of the three biosimilars from the start

RESULTS

- In a single OS cycle, CLBR for O was 68.1% versus 59.8% for A, 53.6% O versus 46.3% for B, and 62.6% O versus 54.6% for C (**Table 1**).
- In up to three OS cycles, CLBR and TTLB for O versus A were 94.5% and 552.4 days versus 90.3% and 609.2 days, respectively (**Table 1**).

Table 1: Cost per CLB and CLBR% for single and up to three COS cycle

Products		O	A	O	B	O	C
1 Stimulation cycle including 1 fresh ET & 2 frozen ET	CLBR%	68.1%	59.8%	53.6%	46.3%	62.6%	54.6%
	Cost per CLB	¥ 57,938	¥ 65,164	¥ 72,179	¥ 82,372	¥ 60,690	¥ 68,736
3 Stimulation cycles with 1 fresh ET & 2 frozen ET	CLBR%	94.5%	90.3%	86.1%	79.8%	91.9%	86.8%
	Cost per CLB	¥ 60,333	¥ 68,646	¥ 76,718	¥ 88,461	¥ 63,668	¥ 72,923

- The difference in cost/CLB was - ¥7,226 (O vs. A), - ¥10,193 (O vs. B), and - ¥8,046 (O vs. C) in a single OS cycle, and - ¥8,313 (O vs. A), - ¥11,743 (O vs. B), and - ¥9,255 (O vs. C) for up to three cycles (**Table 1**).
- The % of costs attributed to the originator r-hFSH-alfa in relation to overall ART costs is between 15-18 % in 1 stimulation cycle scenario (**Table 2**).

Table 2: Proportion of costs in relation to overall ART costs

Products	O	A	O	B	O	C
1 Stimulation cycle including 1 fresh ET & 2 frozen ET	18%	17%	16%	15%	16%	16%

A (recombinant human follitropin for injection [Jinsaiheng®]), B (recombinant human follitropin for injection [Anxinbao®]), C (recombinant human follitropin prefilled syringe [Follitrope®]), and O (originator recombinant human follicle-stimulating hormone alfa [r-hFSH-alfa])

Abbreviations: ART, assisted reproductive technology; CLBR, cumulative live birth rates; COS, controlled ovarian stimulation; CLB, cumulative live birth; ET, embryo transfer; FET, Frozen Embryo Transfer; LB, live birth; r-hFSH-alfa, recombinant human follicle-stimulating hormone; TTLB, time to live birth
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