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ORIGINAL RESEARCH

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Efficacy of Jiaotai Gujing Formula combined with psychosexual therapy for premature ejaculation: a randomized controlled trial

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Abstract

Background: Premature ejaculation (PE) is a prevalent male sexual dysfunction with significant psychological and relational impacts. While selective serotonin reuptake inhibitors are commonly used as first-line treatments, their adverse effects and limited efficacy necessitate alternative approaches. Traditional Chinese medicine, particularly Jiaotai Gujing Formula (JGF), has shown promise in preclinical studies, but its combined effect with psychosexual therapy remains underexplored. **Methods**: This randomized controlled trial enrolled 120 PE patients, allocated equally to a treatment group (JGF plus psychosexual therapy) and a control group (JGF alone). Psychosexual therapy included structured counseling and assessments of anxiety and depression. Primary outcomes were measured by intravaginal ejaculatory latency time (IELT), with secondary outcomes including Hamilton Anxiety (HAM-A) and Hamilton Depression (HAM-D) scales, Chinese Medicine Symptom Score (CMSS), and Clinical Global Impression (CGI). **Results**: Of 110 completers (56 in the treatment group, 54 in the control group), the treatment group demonstrated superior outcomes. IELT increased significantly in both groups (211.11 $\pm$ 103.22 *vs.* 174.74 $\pm$ 86.82 seconds, $p < 0.05$), with a greater improvement observed in the treatment group ($p < 0.05$). HAM-A and HAM-D scores decreased more markedly in the treatment group (7.70 $\pm$ 3.25 and 6.45 $\pm$ 1.92, respectively) than in the control group (9.89 $\pm$ 3.94 and 8.59 $\pm$ 4.47, $p < 0.05$). After treatment, the CMSS of both groups was significantly lower than that at baseline ($p < 0.05$). However, there were no significant differences between the two groups in CGI scores. Safety profiles were favorable, with no severe adverse events reported. **Conclusions**: JGF combined with psychosexual therapy significantly prolongs IELT and alleviates psychosomatic symptoms in PE patients, offering a safe and effective integrative treatment. **Clinical Trial Registration**: This study was registered in ITMCTR (registration number: ITMCTR2024000718) and can be accessed at http://itmctr.ccebtcm.org.cn/zh-CN/Home/ProjectView?pid=238e5723-9556-422b-ac9f-0c8c41ecdc0b.

Keywords

Premature ejaculation; Traditional Chinese medicine; Psychosexual therapy; Randomized controlled trial; Anxiety; Depression

1. Introduction

Premature ejaculation (PE) is a common male sexual dysfunction characterized by difficulties in ejaculation control that have existed since the beginning of sexual intercourse [1]. According to the 2014 definition by the International Society for Sexual Medicine, PE is identified by a consistent inability to delay ejaculate, which occurs either before or within approximately one minute of vaginal penetration during the first sexual experience, and during nearly all subsequent penetrative encounters [1]. PE is typically classified into four types: lifelong, acquired, subjective, and variable. It is estimated that approximately 30% of men experience PE [2]. PE not only affects quality of life and self-confidence but may also negatively affect marital relationships and, in severe cases, contribute to psychological distress [3]. First-line pharmacological treatments for PE, including selective 5-hydroxytryptamine reuptake inhibitors (SSRIs) and tricyclic antidepressants, can prolong the ejaculation time to varying degrees. However, these treatments are often associated with adverse effects, risk of dependence, and, according to some studies, negative impact on sperm quality. Consequently, they may be unsuitable for patients planning to conceive. Furthermore, the etiology of PE often involves complex factors, in-

cluding interpersonal dynamics and psychological conditions, making it difficult for conventional pharmacotherapy alone to provide effective, comprehensive treatment.

The holistic concept of traditional Chinese medicine (TCM) treatment offers a simplified approach to complex conditions and provides advantages in personalized or individualized care [4]. Many studies have demonstrated the efficacy and safety of TCM in the treatment of male sexual dysfunction [5–7]. Moreover, TCM has been shown to alleviate mental symptoms related to sexual dysfunction and improve patients' quality of life [8]. Jiaotai Gujing Formula (JGF) is derived from the classic TCM formula "Jiaotai Pill", was evaluated in our preclinical study using a before-and-after controlled clinical trial method. Thirty-five PE patients included in the study were given JGF. The results showed that compared with the baseline, the intravaginal ejaculatory latency time (IELT), Chinese medicine symptom score (CMSS), and overall satisfaction improved significantly after 8-week treatment ($p < 0.01$), with no serious adverse effects reported [9]. However, there are limitations to this study because we did not assess patient-related psychosomatic symptoms. It is well known that several psychological factors, such as anxiety and depression, contribute to PE [10], while cognitive perception of PE often leads to "performance anxiety". In one study, the prevalence of anxiety and depression among the men with PE was 82.07% (444/541) and 74.68% (404/541), respectively, out of 958 participants [11]. This reciprocal relationship between PE and psychological distress has led to the integration of psychosexual therapy in treatment plans [12]. In conclusion, current guidelines recommend a comprehensive approach to PE treatment, combining pharmacological and psychological interventions [13]. Therefore, to further evaluate the impact of JGF on psychosomatic symptoms in patients with PE, and to investigate the efficacy and safety of JGF combined with psychological intervention in the treatment of PE, we propose this randomized controlled trial.

2. Materials and methods

2.1 Study subjects

Our study was registered in the International Traditional Medicine Clinical Trial Registry (ITMCTR) (http://itmctr.ccebtcm.org.cn/), with the registration number ITMCTR2024000718.

2.2 General information

A total of 120 patients diagnosed with PE were recruited from the Department of Andrology at Three Gorges Hospital of Chongqing, China, between November 2024 to May 2025. Participants were randomly assigned to the treatment group (n = 60) and the control group (n = 60). This study was reviewed and approved by the Ethics Committee of Three Gorges Hospital of Chongqing University (Approval No. 2023095).

2.3 Inclusion and exclusion criteria

2.3.1 Inclusion criteria

Participants were eligible for inclusion if they met the following criteria: ① Age 20~50 years; ② Duration of the disease ≥6 months; ③ Stable sexual activity with the partner ≥4 times per month; ④ Met the diagnostic criteria of PE [14]; ⑤ Met the TCM diagnostic criteria for heart-kidney disharmony subtype of PE [9]; ⑥ Willing to participate voluntarily and provide written informed consent.

2.3.2 Exclusion criteria

Participants were excluded if they met any of the following conditions: ① Inability to engage in sexual intercourse due to genital malformations; ② Participants with genitourinary tract infection; ③ Participants with erectile dysfunction (International Index of Erectile Function-5 ≤21 points); ④ Known allergy or hypersensitivity to any components of the treatment; ⑤ Participants with severe cardiovascular, cerebrovascular, renal, or other major organ disease; ⑥ Participants with psychiatric illnesses and with symptoms such as severe anxiety confirmed by Hamilton Depression Inventory and Hamilton Anxiety Inventory; ⑦ Participants with severe liver diseases including liver failure and other liver diseases.

2.4 Method

2.4.1 Grouping method

In this study, a total of 120 participants were randomly allocated to either the treatment group or the control group using a computer-generated random number table. The randomization procedure was conducted as follows: eligible participants were sequentially numbered according to their order of enrollment. Subsequently, participants were assigned to their respective groups based on the parity of their random numbers, *i.e.*, those with odd numbers were allocated to the treatment group (n = 60), while those with even numbers were assigned to the control group (n = 60).

2.4.2 Intervention methods

Participants in the treatment group received both JGF and psychosexual therapy. JGF was supplied by our hospital's granular pharmacy, and its medicinal composition includes Rhizoma Coptidis 10 g, Cinnamomum Cassia 5 g, Gorgon euryale seed 15 g, Fructus Rosae Laevigatae 30 g, Fructus Schisandrae chinensis 10 g, Os Draconis 30 g, Ostreae Concha 30 g, Lotus seeds 15 g, Radix Bupleurum Chinense 15 g, Mantidis Ootheca 15 g, Indian Bread with Pine 30 g, Glycyrrhizae Radix et Rhizoma 15 g, Astragali Complanati Semen 30 g, and Hordei Fructus Germinatus 30 g [9]. Participants were instructed to dissolve the granules in 200 mL of warm water and take the preparation orally. The TCM treatment was administered twice daily for 8 weeks.

Psychosexual therapy was delivered by qualified counselors at the hospital. The process included: A detailed medical history review, including assessment using Hamilton Anxiety Rating Scale (HAM-A) and Hamilton Depression Rating Scale (HAM-D) to evaluate psychological status. Structured interviews covering the patient's sexual history (including sexual initiation, education, and experiences), personality traits, marital dynamics, family influences, and emotional fluctuations.

Based on the evaluation, participants received individualized sexual psychotherapy aimed at correcting sexual misconceptions, improving marital relationships, and alleviating anxiety and other negative emotions. Each participant received two sessions of psychosexual counselor will give one session of psychotherapy: one before starting JGF, and the second during week 4 of treatment. Moreover, participants in the control group received JGF treatment only, following the same dosage and duration protocol as the treatment group.

2.5 Outcome measures

2.5.1 Primary efficacy indicators

Intravaginal Ejaculation Latency Time (IELT) refers to the duration from the initiation of vaginal intromission to ejaculation. It serves as an objective parameter for assessing male ejaculatory function and is a key diagnostic criterion for PE.

2.5.2 Secondary efficacy indicators

The Hamilton Anxiety Rating Scale (HAM-A) is a widely used clinical tool designed to measure the severity of anxiety symptoms [15]. It remains one of the most common scales for assessing anxiety in both research and clinical practice. The total score ranges from 0 to 56, with the following cut-offs: <17: Mild anxiety; 18–24: Mild to moderate anxiety; 25–30: Moderate to severe anxiety; >30: Severe anxiety.

The Hamilton Depression Rating Scale (HAM-D) is a widely used clinician-administered assessment tool designed to measure the severity of depressive symptoms in individuals [15]. It also remains one of the most common scales for evaluating depression in clinical and research settings. The total score ranges: <7: Normal (no depression); 8–13: Mild depression; 14–18: Moderate depression; 19–22: Severe depression; ≥23: Very severe depression.

The Clinical Global Impression Scale (CGI) is primarily used in clinical practice to rapidly assess patients' treatment response and overall improvement [16]. It is widely applied in psychiatric, neurological, and other chronic disease research to evaluate therapeutic efficacy.

The Chinese Medicine Symptom Score (CMSS) is a quantitative assessment tool used in TCM to evaluate the severity and progression of disease-related symptoms and syndromes [17].

2.6 Sample size calculation

The sample size was calculated based on the expected change in IELT, an indicator of efficacy, which was estimated as the change in IELT from baseline at the end of treatment. According to our preclinical study, the mean increase in IELT for patients treated with JGF combined with psychosexual therapy was 135.67 ± 51.02 seconds, compared to 104.82 ± 39.51 seconds in those treated with JGF alone. With a two-sided α of 0.05 and a β of 0.10 (corresponding to 90% power), and assuming a 1:1 group allocation, the required sample size was calculated to be 50 participants per group. To ensure study quality and account for an estimated 20% dropout rate, the final sample size was set at 120 participants, with 60 in the treatment group and 60 in the control group.

2.7 Statistics

The clinical data were analyzed using SPSS 26.0 software (IBM Corp, Armonk, NY, USA). Continuous variables were analyzed by *t*-test and expressed as mean ± standard deviation ($\bar{x} \pm s$); categorical variables were analyzed by χ^2 test. A $p < 0.05$ was considered statistically significant.

3. Results

During the study period, 4 participants in the treatment group withdrew (3 due to non-adherence to the full course of medication and 1 lost to follow-up). In the control group, 6 participants withdrew (3 due to non-adherence and 3 lost to follow-up). As a result, a total of 110 participants completed the study and were included in the final analysis, 56 in the treatment group and 54 in the control group (Fig. 1).

3.1 General data

As shown in Table 1, there were no statistically significant differences between the treatment and control groups in terms of age, disease duration, International Index of Erectile Function-5, and Premature Ejaculation Diagnostic Tool (PEDT) ($p > 0.05$).

3.2 IELT

As depicted in Table 2, there was no significant difference in IELT between the two groups before treatment ($p > 0.05$). After treatment, IELT significantly increased in both groups compared to their respective pre-treatment values ($p < 0.05$). Furthermore, the treatment group showed a significantly greater increase in IELT compared to the control group at the same time point ($p < 0.05$).

3.3 HAM-A

As shown in Table 2, there were no significant differences in HAM-A scores between the two groups before treatment ($p > 0.05$). Following treatment, both groups exhibited a significant reduction in HAM-A scores compared to baseline ($p < 0.05$). Furthermore, the treatment group demonstrated significantly lower HAM-A scores than the control group after treatment ($p < 0.05$).

3.4 HAM-D

As presented in Table 2, pretreatment HAM-D scores showed no significant intergroup differences ($p > 0.05$). Both groups displayed significant reductions in HAM-D scores on post-treatment relative to baseline measurements ($p < 0.05$). Notably, the treatment group had a statistically significant improvement in HAM-D ($p < 0.05$).

3.5 CMSS

As given in Table 1, the baseline CMSS scores of the treatment and control groups were comparable and showed no significant differences ($p > 0.05$). After 8 weeks of treatment, both groups demonstrated a significant reduction in CMSS scores compared to their baseline values ($p < 0.05$). However, no

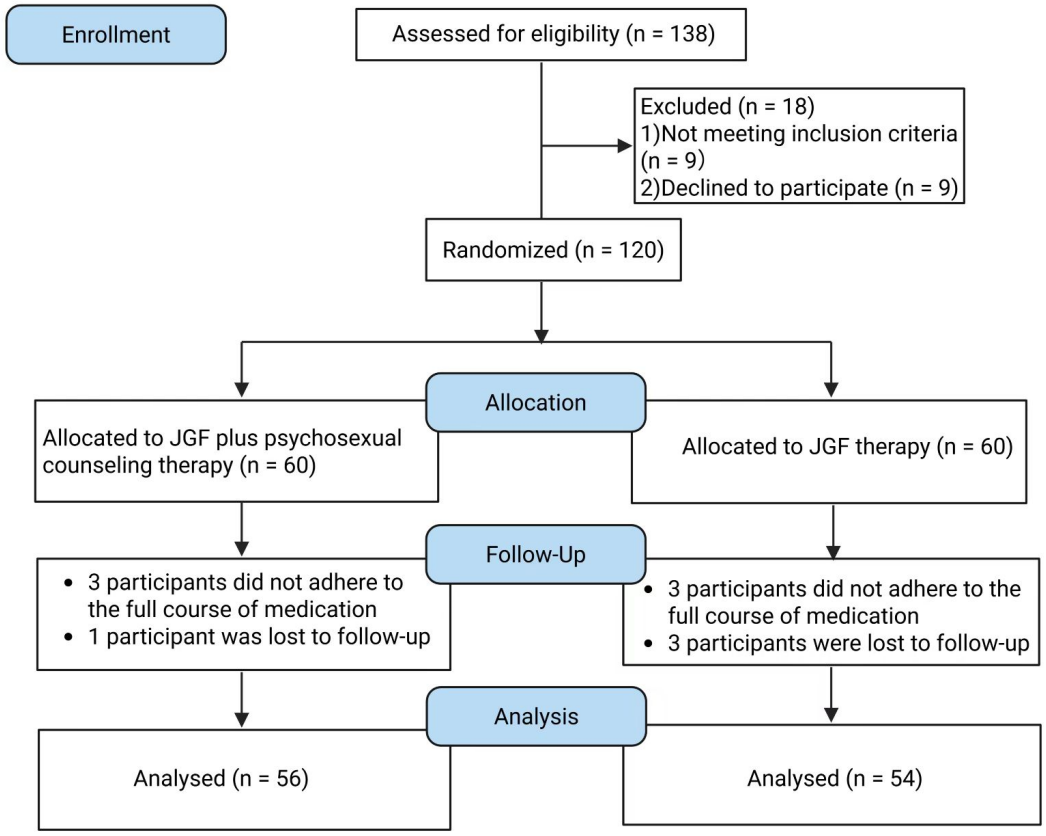

FIGURE 1. Flowchart of participant recruitment. JGF: Jiaotai Gujing Formula.

TABLE 1. General data between the two groups.

Characteristic	Treatment group (n = 56)	Control group (n = 54)	*p* value
Mean age (yr)	32.18 ± 7.48	31.76 ± 7.27	0.766
Disease duration (mon)	37.86 ± 19.55	38.82 ± 18.09	0.790
IIEF-5	23.50 ± 0.95	23.50 ± 1.04	1.000
PEDT	14.98 ± 1.64	14.98 ± 1.67	0.998
IELT	67.32 ± 26.17	68.56 ± 28.49	0.814
HAM-A	15.50 ± 6.20	14.15 ± 5.92	0.245
HAM-D	12.27 ± 5.09	12.04 ± 6.00	0.829
CMSS	19.43 ± 2.51	20.17 ± 2.87	0.153

IIEF-5: International Index of Erectile Function-5; PEDT: Premature Ejaculation Diagnostic Tool; IELT: Intravaginal Ejaculatory Latency Time; HAM-A: Hamilton Anxiety Rating Scale; HAM-D: Hamilton Depression Rating Scale; CMSS: Chinese medicine symptom score.

statistically significant difference in the CMSS improvement was observed between the two groups after treatment, as shown in Table 2 ($p > 0.05$).

3.6 CGI

As shown in Table 3, there were no statistically significant differences in CGI scores between the two groups. However, the proportion of participants rated as "better" or "much better" was slightly higher in the treatment group compared to the control group.

3.7 Safety assessment

Before enrollment, the study process was thoroughly explained to all participants. They were instructed to promptly report any adverse events occurring during the intervention period. The research team assessed the severity of any reported reactions and provided appropriate guidance. The safety indicators of both groups of participants, including routine blood and urine tests, liver and kidney function, and electrocardiogram results before and after treatment, showed no significant abnormalities. During the study, no significant adverse reactions were observed in the treatment group. In the control group, two

TABLE 2. Comparison of IELT, HAM-A, HAM-D, and CMSS between the two groups ($\bar{x} \pm s$).

Characteristic	Treatment group (n = 56)	Control group (n = 54)	*p* value
IELT			
Before treatment	67.32 ± 26.17	68.56 ± 28.49	0.048
After treatment	211.11 ± 103.22*,#	174.74 ± 86.82*	
HAM-A			
Before treatment	15.50 ± 6.20	14.15 ± 5.92	0.002
After treatment	7.70 ± 3.25*,#	9.89 ± 3.94*	
HAM-D			
Before treatment	12.27 ± 5.09	12.04 ± 6.00	0.001
After treatment	6.45 ± 1.92*,#	8.59 ± 4.47*	
CMSS			
Before treatment	19.43 ± 2.51	20.17 ± 2.87	0.615
After treatment	7.96 ± 3.01*	8.24 ± 2.72*	

**Compare with the pretreatment $p < 0.05$; #Compare with the control group $p < 0.05$.*
IELT: Intravaginal Ejaculatory Latency Time; HAM-A: Hamilton Anxiety Rating Scale; HAM-D: Hamilton Depression Rating Scale; CMSS: Chinese medicine symptom score.

TABLE 3. Clinical global impression of change.

Characteristic	Worse	No change	Slightly better	Better or much better
Treatment group (n = 56)	3 (5.4%)	5 (8.9%)	25 (44.6%)	23 (41.1%)
Control group (n = 54)	4 (7.4%)	7 (13.0%)	24 (44.4%)	19 (35.2%)

participants experienced diarrhea. Upon further inquiry, one participant consumed cold beverages after a meal, while the other developed diarrhea after drinking alcohol. Following guidance from the research team, both participants' symptoms resolved, and no participants withdrew from the study due to adverse events.

4. Discussion

The etiology of PE is complex and may involve a combination of physiological, psychological, and environmental factors [18, 19]. Among these, psychological factors also play a significant role in the development and persistence of PE [20]. For example, sexual performance anxiety can lead to excessive worry, which impairs ejaculatory control and contributes to the condition [21]. Additionally, misconceptions about sex, inadequate sex education, and the development of negative sexual attitudes may also predispose individuals to PE [22]. Early sexual experiences, including sexual abuse or emotional trauma, have likewise been identified as contributing psychological factors [23].

The impact of PE extends beyond sexual performance, potentially affecting patients' psychological, emotional, and social well-being [1]. Individuals with PE may suffer from diminished self-esteem, reduced confidence, and even psychological issues such as depression and anxiety [20]. These factors highlight the importance of adopting a comprehensive, multidisciplinary treatment strategy, which includes psychosexual therapy alongside pharmacological interventions [24, 25]. Psychosexual counseling has been widely used worldwide to treat sexual dysfunctions. It is effective in resolving misconceptions and negative attitudes toward sex, overcoming unhealthy psychological barriers, and enhancing patients' understanding of sexual response and function [25, 26]. Pavone *et al.* [27] reported that psychotherapy not only benefits patients when psychological mechanisms are more relevant but also reduces anxiety, decreases relapse rates, and enhances coping mechanisms in PE management. Similarly, McMahon *et al.* [28] emphasized that PE is often accompanied by a range of psychosocial issues and that many patients benefit from tailored psychotherapeutic interventions.

Previous meta-analyses have shown that dapoxetine can improve IELT in PE patients, but its efficacy remains limited [29]. The effectiveness of SSRIs, tramadol, and phosphodiesterase type 5 inhibitors remains unclear due to high heterogeneity in randomized controlled trial data, indicating a need for further drug research. Many studies have focused on using a single treatment method to improve the sexual dysfunction of PE patients, including the sole application of Western medicine or TCM [30–32]. However, there is growing recognition of the potential advantages of combined therapy for managing PE.

Meanwhile, the clinical efficacy of oral administration of Chinese herbal medicine in treating PE has also been confirmed in a clinical trial [33]. Moreover, the combination of TCM and sexual psychological therapy may offer greater benefits in improving both the sexual quality of life and sexual

psychological status of PE patients. To our knowledge, no previous clinical trials have reported on this specific combination therapy. In our study, we evaluated the efficacy and safety of integrated TCM with psychosexual therapy. Our results demonstrated that the combination of JGF and psychosexual therapy was more effective than JGF alone in prolonging IELT, reducing HAM-A and HAM-D scores. Notably, our preliminary clinical study had confirmed the efficacy of JGF in extending IELT, but its limitation was the neglect of potential psychological factors in PE participants. The current study indicates that while JGF improves IELT, it also alleviates psychological symptoms in PE participants, though the combined therapy (JGF plus psychosexual therapy) showed superior benefits compared to JGF alone. Recently, TCM has been widely used in male sexual dysfunction [34]. Numerous studies have demonstrated the significant role of TCM in improving emotional disorders [35], especially for patients with male urological diseases accompanied by psychological symptoms [36]. From the TCM perspective, emotional regulation is achieved through mechanisms such as "soothing the liver and relieving depression" or "nourishing the heart". Some studies have indeed confirmed the potential of certain active ingredients in Chinese herbs in anti-depression, which is in line with the mechanism of action of TCM in soothing the liver and nourishing the heart [37, 38]. Although the Clinical Global Impression (CGI) results did not show a statistically significant difference between the two groups, the proportion of patients reporting "better" or "much better" outcomes was higher in the treatment group, suggesting a favorable trend that may have been limited by the sample size. Importantly, no serious adverse events were observed in either group, further supporting the safety profile of JGF in treating PE.

This study proposed a novel treatment protocol combining TCM therapy with psychosexual counseling therapy, emphasizing the importance of psychosexual counseling therapy and TCM therapy in PE treatment. However, several limitations should be acknowledged. The small clinical sample size, short treatment duration, absence of blinding, and lack of post-treatment follow-up may have affected the clinical outcomes. These factors increase the risk of evaluation bias and may compromise the statistical power and generalizability of the findings. In particular, the lack of follow-up may also affect the assessment of the sustained efficacy of TCM and the combination of TCM and psychosexual therapy.

To strengthen future research, it will be necessary to incorporate blinding procedures to reduce bias and extend the follow-up period to evaluate sustained treatment effects, and conduct larger, high-quality multicenter clinical trials to generate more robust and reliable evidence on the comparative efficacy of the TCM and integrative therapeutic strategies.

5. Conclusions

In conclusion, the combination of JGF and psychosexual counseling therapy is both effective and safe for the treatment of PE. This integrative approach significantly prolongs the IELT and alleviates psychosomatic symptoms of the PE patients, highlighting its potential as a comprehensive therapeutic strategy.

AVAILABILITY OF DATA AND MATERIALS

The authors declare that all data supporting the findings of this study are available within the paper and any raw data can be obtained from the corresponding author upon request.

AUTHOR CONTRIBUTIONS

DS and JG—designed the research study. FZ—performed the research; analyzed the data. GD and WY—provided help and advice on methods. DS, YW and SW—wrote the manuscript. 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 Three Gorges Hospital of Chongqing University (Approval no. 2023095). Written informed consent was obtained from legally authorized representatives for anonymized patient information to be published in this article.

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Not applicable.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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