

Original Research

The Effect of Pelvic Floor Magnetic Stimulation in Women with Myofascial Pelvic Pain Syndrome: A Prospective Cohort Pilot Study

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Abstract

Background: Chronic pelvic pain (CPP) is a highly prevalent pain condition in which pelvic floor myofascial pain syndrome (MPPS) is also frequently found. Optimal treatments for CPP and MPPS are unknown. The aims of this pilot study were to investigate the effect of pelvic floor magnetic stimulation (MS) in women with MPPS. Treatment effects were compared between patients receiving MS alone, myofascial release therapy (MRT) alone, and MS + MRT. **Methods:** Patients were divided into three groups: MS, MRT, and MS + MRT. Questionnaires including Short-form McGill Pain Questionnaire (SF-MPQ), Pelvic Pain and Urgency/Frequency questionnaire (PUF), Female Sexual Function Index (FSFI), Hamilton Anxiety Scale (HAMA), and clinical global impression scale (CGI) were used to assess changes in subjective symptoms before and after treatment. Pelvic floor muscle function was assessed by the Modified Oxford Scale and Surface electromyography (sEMG). Pain mapping was used to locate trigger points (TPs) and to score the intensity of pain. A Visual Analog Scale (VAS) was used to measure the intensity of pain on a scale of 0 to 10. Changes in the above evaluation indexes within each group and between groups were evaluated after 5 treatment sessions and 10 treatment sessions. **Results:** Nineteen patients completed the treatment between November 2020 and August 2021. The SF-MPQ and PUF scores decreased significantly ($p < 0.01$) after treatment. The VAS score for pelvic floor tenderness also decreased significantly after 5 and 10 treatment sessions ($p < 0.01$). At the end of 10 sessions, the HAMA score was significantly lower than prior to treatment ($p < 0.01$). **Conclusions:** This preliminary study shows that MS is effective for the treatment of MPPS. **Clinical Trial Registration:** ChiCTR2000030881.

Keywords: myofascial pain; chronic pelvic pain; pain syndrome; magnetic stimulation; myofascial release therapy

1. Introduction

Chronic pelvic pain (CPP) is pain symptoms that are perceived to originate from pelvic organs/structures and which last for more than 6 months. CPP is often associated with negative cognitive, behavioral, sexual and emotional consequences, with symptoms that are suggestive of lower urinary tract, sexual, bowel, pelvic floor, myofascial or gynecological dysfunctions. The musculoskeletal system is an overlooked but common cause of chronic pain. Myofascial pain syndrome (MPPS) is characterized by hypertonicity of pelvic floor muscles (PFM), trigger points (TPs), and the shortening of levator ani muscles [1]. Pelvic floor physical therapy is recommended for patients with positive findings for muscle tenderness or TPs [2]. This includes myofascial release therapy (MRT), biofeedback, electrical stimulation, active pelvic floor retraining, and pelvic floor stretching [3].

The 2021 European Association of Urology (EAU) Guidelines on CPP recommend myofascial release as first-line treatment for pelvic floor dysfunction [4]. However, MRT has obvious limitations, such as the lack of standard methods and it is labour intensive requiring repetitive sessions from a skilled practitioner. Intravaginal electrical stimulation is also reported to be effective at treating CPP, with a relief rate of 80% [5]. However, patients suffer uri-

nary tract infections, uncomfortable sensation in the vagina, and worsening pain in the early phases of treatment. Recently, pelvic floor magnetic stimulation (MS) has emerged as a promising new noninvasive and convenient option for the treatment of male chronic pelvic pain syndrome (CPPS) [6]. To date, however, pelvic floor MS has not been used in women with MPPS.

The present study is a pilot investigation of pelvic floor MS in women with MPPS. We compared the outcomes for patients treated with MS alone, with myofascial release therapy (MRT) alone, and with MS + MRT.

2. Material and Methods

This pilot study enrolled 19 women with MPPS who visited the outpatient department of the pelvic floor center between November 2020 and August 2021. The inclusion criteria were: (1) women aged 20–50 years with past sexual experience; (2) musculoskeletal chronic pelvic pain of at least 6 months duration; (3) at least 1 TP palpated in obturator internus muscle or levator ani muscle, with a Visual Analog Scale (VAS) score ≥ 4 ; and (4) written informed consent obtained before screening. Exclusion criteria were: (1) currently pregnant; (2) gynecological abdominal-pelvic masses with malignant clinical features



or other organic lesions; (3) diagnosis of endometriosis; (4) vaginal or pelvic area surgery within the last 6 months; (5) prior history of neurological or psychiatric illness and impaired communication ability; (6) active genital tract infection; (7) active electrical implant in the treatment area, e.g., artificial cochlea or pacemakers; (8) diagnosis of severe hemorrhoids; (9) currently receiving other treatments for CPP; and (10) investigators deeming the participants to be ineligible for inclusion.

Patients were divided into three groups according to their treatment preference.

The MRT group included deep PFM palpation and stretch. This was used to help release PFM and/or paraurethral fascia. It is recommended that PFM relaxation be performed in a precise order for 15 minutes, generally beginning with deep PFM (iliococcygeal muscle) and then moving to the muscles near the vaginal entrance, all while breathing diaphragmatically. Afterwards, palpation of the paraurethral area should relax the paraurethral fascia. The physician applies increasing pressure to the trigger sites and maintains this until the tension is relieved or the sensitivity goes away. Repeat the pelvic muscle relaxation once the paraurethral relaxation is complete.

The MS group was treated with the Magneuro 60F device (Vishee Medical Technology Co., Ltd., Nanjing, Jiangsu, China). This device uses electro-magnetic induction technology for noninvasive PFM stimulation. After urination, the patient sits upright on the treatment chair. Select the pelvic floor pain program. Adjust the stimulus intensity according to the patient's subjective perception. The appropriate position is that the perineum has a sense of contraction, while the thigh and hip have no contraction. The appropriate intensity is the intensity after the patient has a sense of contraction plus 5%. Each patient was given a pelvic pain regimen and then underwent active MS lasting 20 minutes and using the following parameters: 10 Hz, 3 s on, 3 s off, 10 minutes; 30 Hz, 3 s on, 6 s off, 10 minutes.

The MS + MRT group was treated with both MS and MRT. A single session of therapy was comprised of 20 minute pelvic floor MS and 15 minute myofascial release.

The treatment was carried out for one session per day, and for 5 consecutive days per week. The therapy required a total of ten sessions.

2.1 Measures

2.1.1 Questionnaires

Short-form McGill Pain Questionnaire (SF-MPQ), Pelvic Pain and Urgency/Frequency questionnaire (PUF), Female Sexual Function Index (FSFI), and the Hamilton Anxiety Scale (HAMA) were completed at baseline (before treatment) and at the 5-session and 10-session times. Clinical global impression scale (CGI) ratings were also obtained at the 5-session and 10-session times.

2.1.2 VAS for Pelvic Floor Tenderness

Pain mapping developed by the Jantos group [7,8] from Australia was employed to locate TPs and to score the intensity of pain. Palpation pressure was 0.4–0.5 kg/cm² and each patient was reviewed for tenderness by two experienced physicians. Pain intensity was measured using the VAS with a scale of 0 to 10 as follows: 0 = no pain; 1–3 = mild pain; 4–6 = moderate pain; 7–9 = severe pain; 10 = worst pain. The highest pain score was recorded and used in the analysis.

2.1.3 PFM Strength Assessment

The Modified Oxford Scale with a scale of 0 to 6 was used to assess the strength of PFM as follows: 0 = no contraction, no discernible contraction; 1 = flicker, a flicker of pulse is felt under the examiner's fingers; 2 = weak, an increase in tension is detected, without any discernible lift; 3 = moderate, muscle tension is further enhanced and characterized by lifting of the muscle belly and also elevation of the posterior vaginal wall; 4 = good (with lift), increased tension and good contraction are present and are capable of elevating the posterior vaginal wall against resistance; 5 = strong, strong resistance can be applied to the elevation of the posterior vaginal wall; the examiner's fingers are squeezed and drawn into the vagina.

2.1.4 Intrapelvic Surface Electromyography (sEMG) Assessment-Glazer Protocol

Surface electromyography (sEMG) of the pelvic floor muscles was performed using an SA9804 biofeedback device (Vishee Medical Technology Co., Ltd., Nanjing, Jiangsu, China). The participants were asked to empty their bladder prior to electrode application and were evaluated in the supine and semi-reclined positions, with knees in semi-flexion and external rotation of the heels. The probes are inserted into the vagina with the metal sensors parallel to the lateral vaginal walls. One self-adhesive electrode is placed on each side along the muscle fibers of the rectus abdominis, with the top side of the electrode at the same level as the navel. During evaluation, the participants were verbally instructed to perform PFM contraction and relaxation without the use of abdominal, gluteal or hip adductor muscles.

2.2 Statistical Analysis

The Statistical Program for the Social Science (SPSS) version 25.0 (IBM Corp., Armonk, NY, USA) was used to analyze data. Comparisons between groups over time were made using repeated-measures ANOVA. This is a statistically efficient approach that includes all the data points collected during the study. The alpha level was set to 0.05.

3. Results

All 19 patients completed the treatment. However, 5 patients (2 in the MRT group, 2 in the MS group, 1 in the MRT + MS group) did not return for the 1-month follow-

up visit and hence the follow-up data was not analyzed. No treatment-related discomfort was reported by patients during MS. The mean age and mean Body Mass Index (BMI) of patients were not statistically significant different between the three groups ($p > 0.05$). The demographic data for participants is presented in Table 1.

Table 1. Participant demographics.

Items	MRT	MS	MS + MRT
Age (Y)	38.8 ± 5.2	34.0 ± 6.4	35.7 ± 9.4
BMI (kg/m ²)	24.11 ± 3.67	22.75 ± 2.32	23.52 ± 2.19
Deliveries (total)	8	6	14
Occupation			
Office based work	3	3	5
manual labor	2	1	3
Unknown	0	1	1
Newborn birth weight			
≤4 kg	8	6	14
≥4 kg	0	0	0

BMI, Body Mass Index; MRT, Myofascial Release Therapy; MS, Magnetic Stimulation; MS + MRT, Magnetic Stimulation and Myofascial Release Therapy.

3.1 Pain Reported by Patients

Fig. 1 shows the pain level reported by patients, as evaluated by SF-MPQ, PUF and CGI. No differences in the McGill Pain Questionnaire index were found between the three groups using two-way repeated measures ANOVA (Fig. 1A). However, a significant effect of time was observed, with the SF-MPQ pain rating index being lower after 5 and 10 sessions of treatment ($F = 12.928$, $p < 0.01$). No significant difference ($p > 0.05$) in this index was observed between the 5 and 10 session times (Fig. 1A). The SF-MPQ score includes the scores for VAS, Present Pain Intensity and PUF. Each of these scores also decreased significantly ($p < 0.01$) after 5 and 10 sessions of treatment (Fig. 1B–D, respectively). No significant differences between the three groups (MRT, MS, MRT + MS) were observed for pain scores at any of the time points. Fig. 1E shows change in CGI scores after treatment. CGI scores significant further reduction from 5 sessions to 10 sessions ($p < 0.05$). But no significant differences between the three groups at any of the time points ($p > 0.05$).

3.2 Objective Pain Evaluated by Pain Mapping

Fig. 2 shows the pain score for pelvic floor tenderness after treatment. No differences were apparent between the three groups before treatment, however the VAS scores all decreased significantly after 5 and 10 sessions of treatment ($p < 0.01$). The VAS score also showed significant further reduction from 5 sessions to 10 sessions ($p < 0.01$). No significant differences between the three groups were found at the 5 session and 10 session time points ($p > 0.05$).

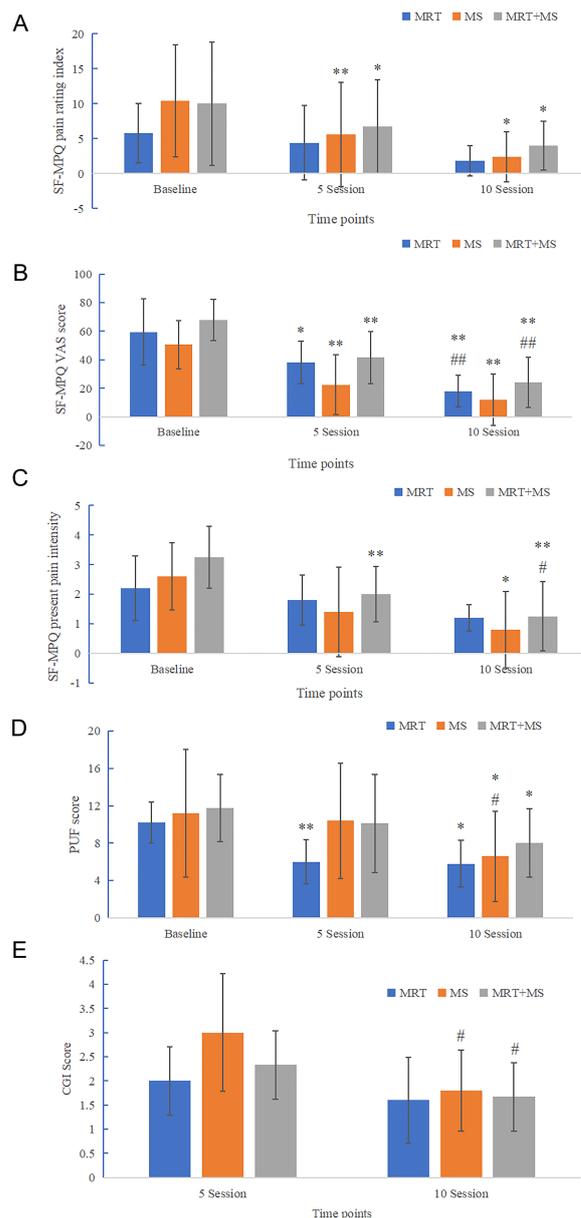


Fig. 1. Pain reported by patients before and after treatment in the three groups. (A) SF-MPQ pain rating index. (B) SF-MPQ VAS score. (C) SF-MPQ present pain index. (D) PUF score. (E) CGI score. The CGI scale represents the overall improvement of the patients after treatment. In this pilot study, we completed the evaluation on the day of 5 treatments and 10 treatments. Therefore, there is no baseline data. MRT, Myofascial Release Therapy; MS, Magnetic Stimulation; MS + MRT, Magnetic Stimulation and Myofascial Release Therapy; SF-MPQ, Short-form McGill Pain Questionnaire; VAS, Visual Analog Scale; PUF, Pelvic Pain and Urgency/Frequency questionnaire; CGI, clinical global impression. *, $p < 0.05$ Compared with that of baseline, **, $p < 0.01$ Compared with that of baseline, #, $p < 0.05$ Compared with that after 5 sessions of treatment, ##, $p < 0.01$ Compared with that after 5 sessions of treatment.

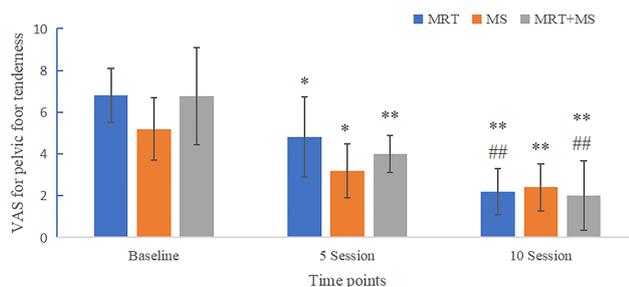


Fig. 2. VAS for pelvic floor tenderness before and after treatment in the three groups. MRT, Myofascial Release Therapy; MS, Magnetic Stimulation; MS + MRT, Magnetic Stimulation and Myofascial Release Therapy; VAS, Visual Analog Scale. *, $p < 0.05$ Compared with that of baseline, **, $p < 0.01$ Compared with that of baseline, ##, $p < 0.01$ Compared with that after 5 sessions of treatment.

3.3 Anxiety Severity after Treatment

Fig. 3 shows changes in the severity of anxiety after treatment, as evaluated by the HAMA score. The scores decreased significantly after 5 sessions of treatment ($F = 11.75$, $p < 0.01$), indicating that anxiety was relieved. HAMA scores were also significantly lower after 10 sessions of treatment compared to before treatment ($p < 0.01$). At each time point, no significant differences were observed between the three groups ($p > 0.05$).

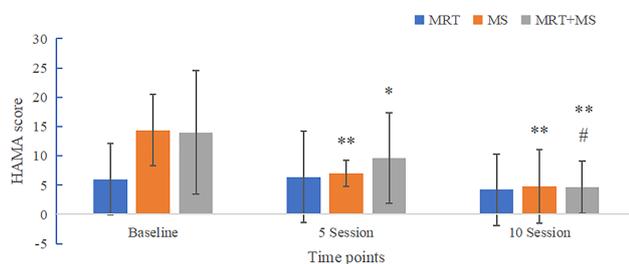


Fig. 3. HAMA scores before and after treatment in the three groups. MRT, Myofascial Release Therapy; MS, Magnetic Stimulation; MS + MRT, Magnetic Stimulation and Myofascial Release Therapy; HAMA, Hamilton Anxiety Scale. *, $p < 0.05$ Compared with that of baseline, **, $p < 0.01$ Compared with that of baseline, #, $p < 0.05$ Compared with that after 5 sessions of treatment.

3.4 Improvement in Sexual Function after Treatment

As shown in Fig. 4, the FSFI increased significantly after 10 sessions of treatment ($F = 11.75$, $p < 0.01$), but not after 5 sessions of treatment ($p > 0.05$).

3.5 Improvement in PFM Function

The PFM strength remained at baseline level after 10 sessions of treatment, as shown in Fig. 5 ($F = 0.854$, $p > 0.05$). Besides the PFM strength measured by vaginal pal-

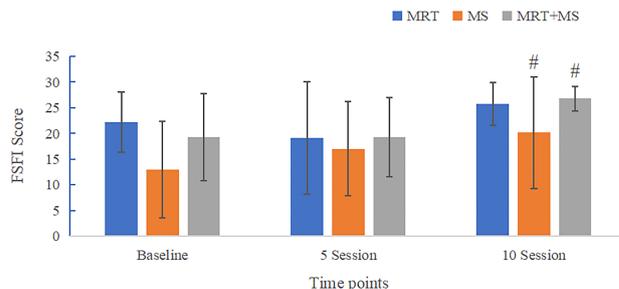


Fig. 4. FSFI scores before and after treatment in the three groups. MRT, Myofascial Release Therapy; MS, Magnetic Stimulation; MS + MRT, Magnetic Stimulation and Myofascial Release Therapy; FSFI, Female Sexual Function Index. #, $p < 0.05$ Compared with that after 5 sessions of treatment.

pation, PFM function as indicated by sEMG also showed no improvement after treatment. No significant improvement in the three groups and at different time points was observed during different phases of the Glazer Protocol ($p > 0.05$).

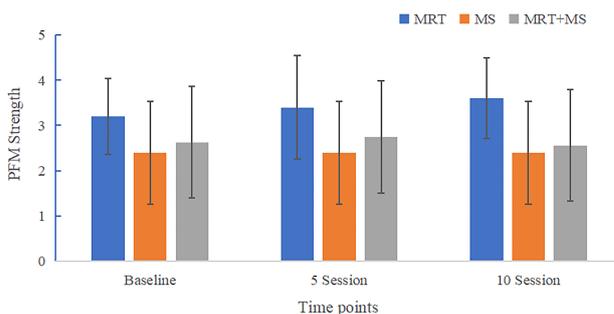


Fig. 5. PFM strength before and after treatment in the three groups. MRT, Myofascial Release Therapy; MS, Magnetic Stimulation; MS + MRT, Magnetic Stimulation and Myofascial Release Therapy; PFM, pelvic floor muscles.

4. Discussion

MPPS is characterized by adverse symptoms that are caused by tender points and myofascial trigger points (MTrPs) in skeletal muscles [9,10]. MTrPs are localized and often extremely painful lumps or nodules in the muscles or associated connective tissue known as fascia. TP are focal points of tenderness that measure a few millimeters in diameter and can be found in multiple areas of the muscles and fascia. The presence of TPs in the pelvic floor fascia is one of the important clinical diagnostic criteria for MPPS [11,12].

Muscles with TPs are often weak, stiff, and have a restricted range of motion. Muscles and fascia with TPs tend to be associated with ischemia, inflammation, and hyperal-

gesia, ultimately resulting in end organ symptoms and pain. The pelvic floor muscles of MPPS patients are constantly in a tense state, eventually leading to poor muscle contraction, fatigue, and markedly reduced pelvic floor muscle strength. These symptoms can seriously affect the quality of life of patients.

Given the above-mentioned pathogenesis, the treatment of MPPS is focused on the management of TPs. According to current guidelines, MRT is one of the recommended methods for treating myofascial pain [4,10]. However, MRT is time-consuming and labor-intensive, with demanding manipulation techniques required of the therapists. Therefore, the goal of this study was to investigate whether the challenges of manual massage could be compensated by other effective techniques for pain management.

The current research is the first to examine the application of pelvic floor MS for female CPP. This pilot study was designed to compare the effects of MRT, MS and MRT + MS. The MRT group was regarded as the positive control in this research. Our aim was to evaluate the effectiveness of pelvic floor MS, which is a more convenient method that has already been used to treat male CPPS with promising results [13]. The earlier study found that MS was effective for the treatment of CPPS, as determined by significantly lower subjective pain scale scores and pelvic floor muscle palpation pain scores following treatment. Furthermore, no adverse reactions were reported.

Extracorporeal magnetic stimulation (EMS) therapy is a neuromodulation therapy based on Faraday electromagnetic induction. It can stimulate electric current in the tissue by time-varying the pulsed magnetic field to regulate pelvic floor nerves and muscles, thereby also improving the blood supply. The therapeutic effect of magnetic field therapy for functional disorders of the pelvic floor has previously been investigated in patients with different pain syndromes, as well as in patients with female urgency and urinary incontinence [14,15]. Pelvic muscle relaxation and neuromodulation through EMS may result in the relief of symptoms for CPPS.

It has been speculated that pelvic floor MS can relieve nerve hypersensitivity and the inflammatory response, as well as breaking the cycle of pelvic muscle spasm and restoring normal pelvic floor muscle activity. In previous reports, the most common treatment strategy involved a weekly or biweekly visit combined with home exercise [16]. However, the major shortcoming of this strategy is that the dropout rate is very high. The current pilot research study was also aimed at validating the acceptability of two lots of 5 consecutive daily sessions. The results showed that consecutive, once-daily treatment is effective. Each patient was given the treatment over a short time, thereby increasing patient compliance without affecting the treatment outcome.

Kim *et al.* [13] treated male patients with CPPS using EMS for 6 weeks and for a total of 12 sessions. The total and subdomain sums for the International Prostate Symptom Score (IPSS) improved significantly after treatment, with the improvements maintained up to 24 weeks. In the present study, we also found significant improvement in the SF-MPQ and PUF scores for the three groups. Significant improvement was observed after the first 5 sessions of treatment, indicating that 5 consecutive sessions is sufficient to produce the desired effects. This study also found that anxiety scale scores improved significantly in the three groups, indicating that MS therapy can improve lower urinary tract symptoms as well as patient anxiety. MS treatment produced the same effects as the MRT and the MS + MRT treatments.

There are some limitations of the pilot study. Our exclusion criteria may have some impact on our study. For example, exclusion of patients with endometriosis is a significant limitation of the study. Some patients with endometriosis who did have MPPS were excluded. Thus, reduced the number of research objects. If patients were receiving other treatment methods, the consistency of the treatment methods cannot be guaranteed, thus interfering with the research results. Therefore, the subjects who had received other treatment in the last three months were excluded. Thus, reduced the number of research objects in the study. Excluding some patients that the researcher did not think suitable for enrollment, there may be certain selection bias. It is hoped that the limitations mentioned above will be improved in a larger study in the future.

The pilot study was designed to assess the short term effects of MS. Due to the study protocol and challenges with follow-up, insufficient data was collected to provide an assessment of long-term outcomes. It is hoped that a multi-center research study will be performed in the future, with the addition of clinical research assistants, strengthened follow-up of patients, and improved patient compliance through appropriate financial compensation.

5. Conclusions

This preliminary study showed that MS therapy for CPPS is effective. It can be offered once a day so that pain can be managed effectively and rapidly, and patient quality of life can be quickly improved.

Availability of Data and Materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Author Contributions

ZWX and YFW provided the idea for the research. TD, SZ and LZ designed the research study. YW and TD analyzed the data and performed the literature search.

TD, SZ and XFZ performed the research. SSZ and YW were responsible for data collection/processing. ZWX, LZ and TD provided oversight and were responsible for the study organization and implementation, and writing of the manuscript. YFW revised the manuscript's intellectual content. All authors contributed to editorial changes in the manuscript. All authors read and approved the final version of the manuscript.

Ethics Approval and Consent to Participate

This study was approved by the Ethics Committee of the Women's Hospital, Zhejiang University School of Medicine, Hangzhou, China (approval number: IRB-20200087-R). All participants agreed to participate in the study and signed an informed consent form.

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Conflict of Interest

The authors declare no conflict of interest.

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