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RESEARCH ARTICLE

Study of the effectiveness of different pelvic floor muscle training methods for improving urinary incontinence in patients with prostate cancer after radical prostatectomy

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ABSTRACT

Introduction: To compare the effects of different pelvic floor muscle training (PFMT) modes on improving iatrogenic stress urinary incontinence (SUI) recovery in prostate cancer (PCa) patients after radical prostatectomy (RP). **Methods**: PCa patients who underwent RP were prospectively enrolled and randomized into standard PFMT (S-PFMT) group, somatosensory interactive PFMT (SI-PFMT, an enhanced PFMT) group, and standard PFMT combined with magnetic stimulation (S-PFMT+MS) group. SUI status was evaluated through the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) scores and 1-hour pad test. **Results**: 101 subjects were enrolled, including 48 in S-PFMT group, 39 in SI-PFMT group, and 14 in S-PFMT+MS group. All groups showed significant ICIQ-UI SF score improvement at 3 and 6 months post-RP compared with baseline (all $p < 0.001$). At 6 months post-RP, significant improvement of 1-hour pad test result was observed ($p = 0.012$). Compared with those in the other two groups, patients in the S-PFMT+MS group exhibited significantly better SUI improvement ($p = 0.033$ vs. S-PFMT; $p = 0.011$ vs. SI-PFMT) at 6 months. Bayesian survival analysis revealed the superior efficacy of the S-PFMT+MS intervention over an extended period. **Conclusions**: PCa patients may benefit from magnetic stimulation in addition to standard PFMT for post-RP SUI recovery.

CLINICAL TRIAL REGISTRATION: HKUCTR-3029, https://www.hkuctr.com/

Introduction

Prostate cancer (PCa), the second most common cancer among men worldwide [1], has become a significant global public health challenge. The latest global cancer statistics indicate that new cases of PCa diagnosed annually in China and deaths caused by PCa account for 8.2% and 13.6% of the global totals, respectively [2]. These data highlight the importance of PCa for men's health in China and worldwide. More concerning is that these proportions are expected to continue to increase. With the widespread use of prostate-specific antigen (PSA) testing, early-stage localized PCa is detected through screening in an increased number of patients. According to the latest PCa treatment guidelines from the National Comprehensive Cancer Network (NCCN), radical prostatectomy (RP) is the most appropriate treatment

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for patients with clinically localized PCa who can undergo complete surgical resection, have a life expectancy of ≥10 years, and have no severe comorbidities [3]. Among different RP methods, laparoscopic RP is the primary surgical approach.

However, since laparoscopic RP inevitably causes damage to the urethral sphincter or pelvic floor nerves, postoperative stress urinary incontinence (SUI) is a common complication. The incidence of SUI is approximately 63.3% at 1 month postsurgery, approximately 36.7% at 3 months, and approximately 22.4% at 6 months [4]. Post-RP SUI can severely affect the quality of life of PCa patients and places a significant burden on their physical and mental health [5]. According to the 2019 American Urological Association (AUA) guidelines for the management of incontinence after laparoscopic RP, clinicians should provide pelvic floor muscle training (PFMT) immediately after RP [6]; this therapy may be combined with biofeedback, electrical stimulation, magnetic stimulation, and other auxiliary methods [7]. However, Cochrane systematic reviews have reported that the value of conservative treatments remains uncertain and that the evidence is still contradictory [8]. Therefore, the way in which early PFMT should be effectively applied to improve urinary continence in patients after RP is a key issue in current research.

Currently, the routine practice for the implementation of PFMT in patients after RP relies mainly on verbal instructions and paper-based educational materials. However, due to factors such as varying levels of patient education, this approach may not effectively ensure that patients fully understand or adhere to the recommended rehabilitation exercises. Moreover, while several conservative treatment methods have been established for post-RP SUI, their efficacy remains uncertain. Therefore, this study aims to compare the effectiveness of different noninvasive PFMT modalities to identify a relatively better approach for the Chinese population.

Subjects and methods

Study subjects

This multicenter prospective randomized controlled trial (RCT, study identifier: HKUCTR-3029, https://www.hkuctr.com/) reports interim findings from one study center. From January 2024 to August 2024, 201 PCa patients were screened. The inclusion criterion was PCa patients aged 18–85 years who had undergone laparoscopic RP. The exclusion criteria included patients currently participating in other clinical trials and those unable to cooperate with study interventions and follow-up procedures due to specific factors. This study was approved by the Institutional Review Board of each research center, and each participant who was ultimately included provided informed consent and signed the study agreement. The CONSORT 2025 Checklist served as a basis for the reporting guidelines.

Study interventions

This study employed a block randomization design to allocate patients into three intervention groups: the standard PFMT group (S-PFMT; 48 patients), the somatosensory interactive PFMT group (SI-PFMT; 39 patients), and the standard PFMT combined with pelvic floor magnetic stimulation therapy group (S-PFMT+MS; 14 patients). Randomization was conducted on a weekly basis via computer-generated random sequences, with each intervention group assigned an equal number of recruitment weeks in the randomized sequence. All patients enrolled during a given week were assigned to the same intervention group. No allocation concealment was applied, as the intervention group assignment was predetermined weekly and was known to the recruiting staff. Due to the nature of the interventions, the blinding of participants and treating staff was not feasible.

Sample size estimation was performed via G*Power version 3.1.9.7 (Heinrich Heine University Düsseldorf, Düsseldorf, Germany) for the Mann–Whitney U test [9]. A medium effect size of 0.5 was specified, with a two-tailed significance level (α) of 0.05 and a desired statistical power (1 − β) of 0.85. On the basis of these parameters, the required sample size was calculated to be 49 participants per group. Initially, the intended number of patients for each group was comparable (50 patients per group). However, some patients refused the study interventions for various reasons and were not formally

enrolled. Consequently, the final number of patients who agreed to participate in each group was as stated above.

Preoperatively, all patients received PFMT under the guidance of digital rectal examination, and their pelvic floor muscle function was graded according to the Oxford Grading System (grades 0–5), which ensured the suitability of subsequent PFMT. After surgery, all the enrolled subjects avoided any medications for SUI. The subjects in the S-PFMT group received traditional verbal instructions and paper-based educational materials. For the SI-PFMT group, an interactive experiential education model was adopted. First, an educational video introduced the importance and basic information of postoperative PFMT. Then, primary training modes (each contraction and relaxation lasting 3–5 s) and advanced training modes (each contraction and relaxation lasting 5–10 s) were designed, which provided synchronized PFMT guidance through a combination of audio and video. In the S-PFMT+MS group, on the basis of traditional verbal and paper-based education, pelvic floor magnetic stimulation therapy was applied via a pelvic floor magnetic stimulator (Nanjing Weisi, MagNeuro Magnetic Stimulator) operated by the same experienced rehabilitation physician. The stimulation frequency was set at 10 Hz, and stimulation was administered in cycles of 5 seconds on followed by 5 seconds off. Each treatment session lasted 20 minutes and was conducted twice per week for a total of 10–12 sessions.

For the above interventions, the S-PFMT and SI-PFMT groups initiated treatment after urinary catheter removal post-RP (10–14 days after surgery), while pelvic floor magnetic stimulation therapy began 1 month post-RP. The primary endpoint was the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) score at 1, 3, and 6 months after surgery. The secondary endpoint was the urine leakage volume from the 1-hour pad test at each follow-up time point.

Follow-up and data collection

Preoperatively, basic clinical information, including age, body mass index (BMI), prostate volume, serum total PSA (tPSA), free PSA (fPSA), [-2]proPSA (p2PSA), prostate health index (*phi*), percentage of positive prostate biopsy cores, prostate biopsy Gleason Grade Group, and preoperative pelvic floor muscle function grade, was collected. The ICIQ-UI SF was also used to assess and record patients' urinary continence status before RP. Patients were then evaluated at 1 (baseline level), 3 and 6 months postoperatively via the ICIQ-UI SF and the 1-hour pad test as mentioned above.

1-Hour pad test protocol

The 1-hour pad test used in this study followed the standard protocol recommended by the International Continence Society (ICS) [10]. First, the weight of a dry urinary pad was measured and recorded. The subject is not required to void or defecate before putting on the dry pad. From 0 to 15 minutes, the subject was instructed to drink 500 mL of water and rest in a seated position. From 15 to 45 minutes, the subject was instructed to walk around nearby and to walk up and down one flight of stairs. From 45 to 60 minutes, the subject was instructed to perform the following activities in order: 1) stand up and sit down 10 times; 2) cough vigorously 10 times; 3) run in place for 1 minute; 4) squat down and stand up 5 times; and 5) wash hands in cold running water for 1 minute. After the test, the weight of the urinary pad was measured and recorded again. The urine leakage volume was calculated as the difference between the two measurements.

Statistical analysis

Comparisons of preoperative baseline clinical characteristics among the three intervention groups were conducted *via* the Kruskal–Wallis H test (for continuous variables) and the Jonckheere–Terpstra trend test (for ordered categorical variables). For comparisons of preoperative and postoperative ICIQ-UI SF scores, the Wilcoxon signed-rank test was used. For comparisons of ICIQ-UI SF scores and 1-hour pad test results at 1, 3, and 6 months after surgery, the Mann–Whitney U test was used. The Bayesian survival analysis was conducted via the R packages "brms" version 2.22.0 (University of Münster, Münster, Germany) and "BayesSurvival" version 0.2.0 (Amsterdam UMC, Amsterdam, The Netherlands). Statistical

analyses and figures were generated using R version 4.4.1 [11] and GraphPad Prism version 10.3.0 (GraphPad Software Inc., La Jolla, CA) for Windows. A two-tailed p value of < 0.05 was considered statistically significant.

Results

The clinical characteristics of the 101 enrolled subjects are summarized in Table 1. No significant differences were observed in the preoperative baseline characteristics, including age and pelvic floor muscle function grade, among the different intervention groups. A significant increase in the ICIQ-UI SF score (i.e. worsening UI status) was observed between the preoperative assessment and the assessment 1 month after RP for all patients (Figure 1(A); mean ± standard deviation [SD] = 0.61 ± 2.13 $vs.$ 9.81 ± 5.11, $p < 0.001$). Following the treatments, significant improvements in SUI were noted at 3 and 6 months post-RP compared with the baseline level at 1 month after RP (Figure 1(B); at 3 months: mean ± SD = 4.13 ± 4.04, $p < 0.001$; at 6 months: mean ± SD = 3.43 ± 5.53, $p < 0.001$). The urine leakage during the 1-hour pad test did not significantly improve at 3 months after RP; however, a significant reduction in leakage was observed 6 months after the surgical procedure (Figure 2; at 3 months: mean ± SD = 4.66 ± 4.78, $p = 0.074$; at 6 months: mean ± SD = 2.63 ± 2.95, $p = 0.012$).

Similar to the aforementioned results of the 1-hour pad test, intergroup comparisons revealed no significant differences in SUI improvement among the subjects in the different intervention groups at 1 and 3 months postsurgery (Figure 3(A,B)). However, at 6 months postsurgery, patients in the S-PFMT+MS group exhibited significantly greater SUI improvement than did those in the other two training groups (Figure 3(C); $p = 0.033$ $vs.$ S-PFMT; $p = 0.011$ $vs.$ SI-PFMT). According to the data collected thus far, patients in the S-PFMT+MS group achieved complete remission of SUI by 6 months after RP.

Table 1. Preoperative baseline clinical characteristics of study subjects in each intervention group.

Clinical Characteristics[a]	Combined Cohort ($n = 101$)	S-PFMT[b] ($n = 48$)	SI-PFMT[c] ($n = 39$)	S-PFMT+MS[d] ($n = 14$)	p[e]
Age (years), median (IQR)	70.0 (65.0–74.0)	70.5 (67.0–74.0)	67.0 (65.0–74.0)	71.0 (66.3–75.0)	0.398
BMI, median (IQR)	24.4 (22.6–26.4)	24.4 (23.1–26.4)	24.5 (22.4–25.8)	24.7 (22.7–26.7)	0.764
Prostate volume (mL), median (IQR)	35.1 (24.7–44.2)	34.9 (24.7–43.2)	35.2 (26.3–38.9)	33.1 (22.2–58.3)	0.998
Total PSA (ng/mL), median (IQR)	8.8 (5.5–13.2)	8.0 (5.2–14.1)	9.7 (6.4–13.9)	8.6 (6.5–11.0)	0.494
Free PSA (ng/mL), median (IQR)	1.1 (0.7–1.7)	1.0 (0.5–1.5)	1.3 (0.7–1.8)	1.3 (1.0–1.7)	0.448
Free/total PSA, median (IQR)	0.12 (0.09–0.19)	0.11 (0.09–0.20)	0.12 (0.09–0.18)	0.15 (0.11–0.18)	0.482
p2PSA (pg/mL), median (IQR)	17.8 (10.3–33.0)	14.9 (9.4–21.7)	17.8 (11.2–42.4)	21.3 (14.8–25.6)	0.195
phi, median (IQR)	46.8 (33.8–71.9)	44.6 (31.8–63.1)	57.3 (32.9–102.1)	53.7 (41.8–61.8)	0.282
Percentage of positive cores, median (IQR)	33.3 (16.7–58.3)	28.6 (16.7–58.3)	45.8 (26.3–66.7)	32.1 (18.8–39.6)	0.120
Gleason group for prostate biopsy, n (%)					
1(Gleason Score ≤ 6)	24 (25.3)	13 (28.9)	9 (25.0)	2 (14.3)	p for trend = 0.678
2(Gleason Score = 3 + 4)	25 (26.3)	9 (20.0)	14 (38.9)	2 (14.3)	
3(Gleason Score = 4 + 3)	24 (25.3)	12 (26.7)	7 (19.4)	5 (35.7)	
4(Gleason Score = 8)	16 (16.8)	6 (13.3)	5 (13.9)	5 (35.7)	
5(Gleason Score ≥ 9)	6 (6.3)	5 (11.1)	1 (2.8)	0 (0.0)	
Pelvic floor muscle function grade, n (%)					
2	1 (1.1)	0 (0.0)	0 (0.0)	1 (8.3)	p for trend = 0.546
3	9 (9.8)	4 (9.8)	4 (10.3)	1 (8.3)	
4	24 (26.1)	13 (31.7)	10 (25.6)	1 (8.3)	
5	58 (63.0)	24 (58.5)	25 (64.1)	9 (75.0)	

[a]BMI: body mass index; PSA: prostate-specific antigen; p2PSA: [-2]proPSA; phi: Prostate Health Index. Pelvic floor muscle function is scored according to the Oxford Grading System for Pelvic Floor Muscles (grades 0–5).
[b]S-PFMT: standard pelvic floor muscle training.
[c]SI-PFMT: somatosensory interactive pelvic floor muscle training.
[d]S-PFMT+MS: standard pelvic floor muscle training combined with pelvic floor muscle magnetic stimulation.
[e]p for trend was calculated by the Jonckheere-Terpstra trend test; a two-tailed $p < 0.05$ was considered statistically significant.
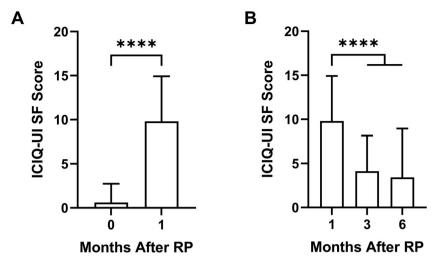
Figure 1. Changes in ICIQ-UI SF scores over time after RP. (A) Comparison of ICIQ-UI SF scores between the preoperative assessment and 1 month post-RP. (B) Changes in ICIQ-UI SF scores at 3 and 6 months post-RP compared with 1 month post-RP. All the data are presented as the means ± standard deviations (SDs). Statistical significance: $p < 0.05$.
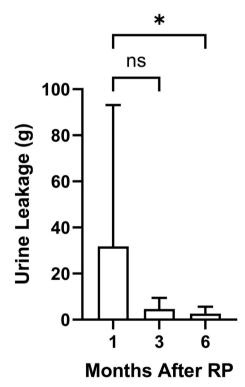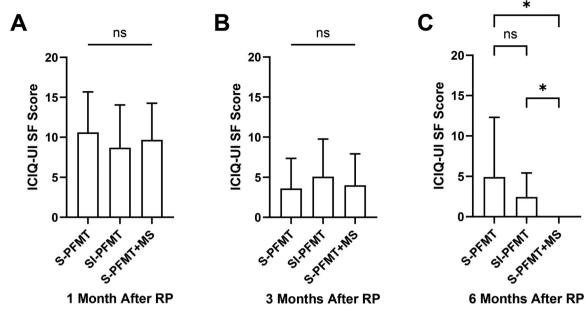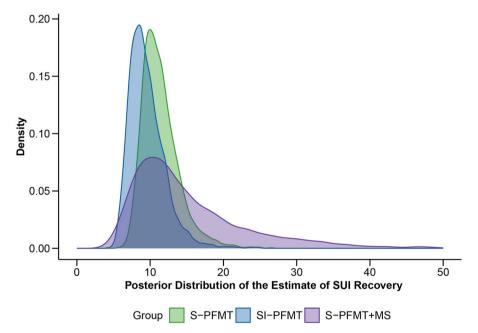

Figure 2. Changes in urine leakage over time after RP. The amount of urine leakage was measured via the 1-hour pad test at 1, 3, and 6 months after RP. All the data are presented as the means ± SDs. Statistical significance: $p < 0.05$.

Analysis of specific items in the questionnaire suggested that the significant intergroup differences were mainly reflected in the patient-reported frequency of urine leakage ($p = 0.025$ *vs.* S-PFMT; $p = 0.012$ *vs.* SI-PFMT).

Furthermore, since data collection is ongoing and longer follow-up data are still being supplemented, a Bayesian survival analysis was conducted to predict the long-term improvement in SUI among the three intervention groups. The posterior distributions of SUI recovery estimates across different groups are presented in Figure 4. Although the differences among the groups did not reach the threshold for

Figure 3. Comparison of ICIQ-UI SF scores among different intervention groups over time after RP. ICIQ-UI SF scores at 1 (A), 3 (B), and 6 months (C) post-RP among the three intervention groups. S-PFMT: standard pelvic floor muscle training group; SI-PFMT: somatosensory interactive pelvic floor muscle training group; S-PFMT+MS: standard pelvic floor muscle training combined with pelvic floor magnetic stimulation therapy group. All the data are presented as the means ± SDs. Statistical significance: $p < 0.05$.

Figure 4. Posterior distributions of the estimate of SUI recovery across different intervention groups. Posterior distribution plot of the estimates of SUI recovery for each intervention group: S-PFMT (standard pelvic floor muscle training, in green), SI-PFMT (somatosensory interactive pelvic floor muscle training, in blue), and S-PFMT+MS (standard pelvic floor muscle training combined with pelvic floor magnetic stimulation, in purple).

statistical significance (Table S1), a trend was observed over the extended period, and individuals in the S-PFMT+MS group consistently showed a higher probability of achieving an ICIQ-UI SF score of zero than did those in the other two intervention groups (Figure 5).
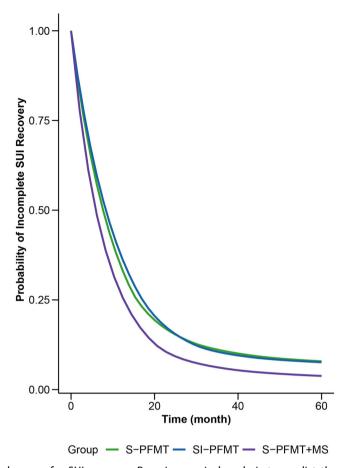
Figure 5. Bayesian survival curves for SUI recovery. Bayesian survival analysis to predict the probability of achieving an ICIQ-UI SF score of zero (indicating SUI recovery) over time across the three intervention groups. S-PFMT (in green): standard pelvic floor muscle training group; SI-PFMT (in blue): somatosensory interactive pelvic floor muscle training group; and S-PFMT+MS (in purple): standard pelvic floor muscle training combined with pelvic floor magnetic stimulation therapy group.

Discussion

In this study, the therapeutic effects of three different PFMT approaches on postoperative SUI were compared in patients undergoing RP: standard PFMT (S-PFMT), modified somatosensory interactive PFMT (SI-PFMT), and S-PFMT combined with pelvic floor muscle magnetic stimulation (S-PFMT+MS). Within a shorter post-RP period (within 3 months), no significant differences in efficacy were found among the three approaches. However, at the 6-month follow-up, we found that S-PFMT+MS was significantly more effective than the other two treatments. These findings suggest that the addition of magnetic stimulation to standard PFMT could facilitate a more rapid recovery of urinary continence.

PFMT is a typical conservative management approach for post-RP SUI. However, as a traditional approach, it has notable limitations. Unsupervised home-based PFMT programs often result in poor long-term adherence and execution. A meta-analysis by Baumann et al. [12] that included 20 RCTs reported that unsupervised PFMT yielded outcomes similar to those of no intervention. A more recent review revealed that short-term adherence to PFMT can be high but typically declines over time [13]. These findings raise the concern that PFMT alone may not be effective enough for the long-term recovery of SUI in post-RP patients and that newly developed combination therapies may be needed.

To increase the effectiveness of PFMT, researchers have proposed the combination of PFMT with biofeedback, electrical stimulation, or digital tools. However, the supporting evidence remains inconsistent. A recent systematic review of 11 RCTs concluded that adjunctive devices, including biofeedback and electrical stimulation, provided no clear additional benefit over PFMT alone [14]. Many such devices involve invasive sensors (e.g. anal probes), which can reduce patient acceptability and adherence. Furthermore, cost and personnel training requirements limit their routine clinical use. Digital

technologies such as mobile apps and wearables may improve adherence to some extent via reminders and visual feedback [15]. However, current RCTs have not conclusively shown that digital tools improve continence outcomes, and issues such as digital literacy and data privacy remain unresolved.

The initial evidence supporting the superior efficacy of extracorporeal magnetic innervation (ExMI) over conventional PFMT in patients with post-RP SUI was demonstrated by Yokoyama et al. in a randomized controlled trial [16]. However, few subsequent studies have systematically investigated the effects of combined therapies. While some small-scale trials suggest that external magnetic innervation may offer benefits, the supporting evidence remains limited [8]. Other studies have concluded that although ExMI is not significantly superior to conventional PFMT in terms of overall outcomes, it may accelerate the reduction of leakage episodes [17]. These conflicting findings highlight the need for further research, such as this study, to validate the efficacy of magnetic stimulation. Additionally, concerns about high costs and potential side effects have sometimes discouraged the use of magnetic stimulation in certain settings [18]. In contrast, this study revealed no adverse events in the S-PFMT+MS group, and the entire treatment protocol was both cost-effective and accessible. These findings suggest that S-PFMT+MS is a promising therapeutic option that warrants consideration for broader clinical application.

This study, however, has several limitations. First, the sample size was relatively small and unevenly distributed among the intervention groups, which may have affected the statistical power of the results. Specifically, the group sample sizes showed a certain degree of disparity (S-PFMT: 48 patients; SI-PFMT: 39 patients; S-PFMT+MS: 14 patients), which may have led to potential biases and may limit the generalizability of the findings. Due to insufficient sample sizes, differences in the Bayesian survival analysis observed between groups did not reach statistical significance. Additionally, long-term follow-up data on SUI are lacking. To address these limitations, extended follow-up with the current cohort is planned, along with the integration of data from other research centers in a multicenter study. This will enable a more comprehensive and scientifically robust evaluation of the efficacy of different PFMT modalities.

Moreover, previous studies have suggested that factors such as BMI [19], prostate volume [20], and preoperative magnetic resonance imaging (MRI) features [21] may help predict the risk of post-RP SUI. By incorporating these baseline clinical data and imaging results and developing a preoperative multifactorial risk prediction model, it may be possible to personalize post-RP PFMT strategies, which could improve the effectiveness of current training protocols.

Conclusion

While all PFMT modalities led to significant improvements in SUI among PCa patients after RP, the combination of standard PFMT with pelvic floor magnetic stimulation resulted in superior SUI recovery at 6 months post-RP. These findings suggest that the incorporation of magnetic stimulation into PFMT may offer a relatively better noninvasive treatment option for enhancing post-RP SUI recovery in this population.

Acknowledgments

Author contributions

CRediT: **Ruofan Shi**: Data curation, Formal analysis, Investigation, Software, Visualization, Writing – original draft; **Zhiyang Ma**: Data curation, Investigation, Validation; **Yuen Bing Tse**: Investigation, Resources, Validation; **Tsun Tsun Stacia Chun**: Project administration, Resources; **Da Huang**: Data curation, Investigation, Resources; **Fang Luo**: Investigation, Resources; **Ping Xu**: Project administration, Resources; **Dan Zhao**: Investigation; **Sau Loi Ng**: Conceptualization, Methodology, Resources, Supervision; **Ying Xu**: Conceptualization, Methodology, Resources, Supervision; **Danfeng Xu**: Conceptualization, Methodology, Supervision, Writing – review & editing; **Rong Na**: Conceptualization, Methodology, Supervision, Writing – review & editing.

Ethics approval and consent to participate

The study protocol was approved by the Ethics Committee of Shanghai Ruijin Hospital (IRB No. KY 2024-214) and the Institutional Review Board of the University of Hong Kong/Hospital Authority Hong Kong West Cluster (IRB No. UW 24–001). All the subjects involved in the study provided informed consent prior to their participation.

Availability of data and materials

The original data used or analyzed in the study are included in the article and the Supplementary material, and further inquiries can be directed to the corresponding authors.

Disclosure statement

The authors report that there are no competing interests to declare.

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