Intermittent Catheterization Continuity Care on Bladder Function Recovery and Quality of Life in Patients After Radical Hysterectomy for Cervical Cancer: A Quasi-Experimental Study

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Background: Bladder dysfunction is a common complication following radical hysterectomy, affecting patients' QOL. Exploring interventions, particularly IC continuity care, is crucial for identifying strategies to enhance postoperative outcomes. This study aimed to assess the impact of continuous intermittent catheterization (IC) care on bladder function recovery and quality of life (OOL) in patients undergoing radical hysterectomy for cervical cancer.

Methods: The primary outcome measured was the time to bladder function recovery, with secondary outcomes comprising EORTC OLO-C30 assessments at 3 and 6 months post-surgery, as well as EORTC OLO-CX24 evaluations. Meanwhile, urinary complications, readmissions, and outpatient follow-up were also compared.

Results: Among the 128 participants, with 64 in each group, indwelling catheterization durations were similar. However, the IC continuity care group exhibited significantly shorter IC duration and bladder recovery time. This group demonstrated superior QOL, lower occurrence rates post-IC, reduced urethral injuries, and higher readmission and outpatient follow-up rates.

Conclusion: This study underscores continuous IC care emerges as a beneficial intervention, facilitating accelerated bladder function recovery and improved QOL in patients following radical hysterectomy for cervical cancer.

Keywords: intermittent urethral catheterization, cervical cancer, urinary bladder neurogenic dysfunction, continuity of patient care, rehabilitation

Introduction

Cervical cancer is the second most common cancer in women worldwide and the third most common cause of female cancer mortality. The incidence of cervical cancer has been on the rise in recent years, especially among young women.² Radical hysterectomy is commonly used for cervical cancer, 3,4 but it may involve extensive tissue resection and nerve damage, affecting patients' quality of life (OOL).^{5,6}

Neurogenic bladder and bladder dysfunction are the most common complications after radical hysterectomy, 6 significantly impacting patients' urinary function, QOL, and mental health. 7,8 Transient urinary dysfunction can be managed using urinary catheterization until spontaneous resolution, usually occurring a few days or weeks after surgery. Traditional indwelling catheters increase the risk of infection and negative emotions. 10,11 Therefore, intermittent catheterization (IC) has become a new direction for postoperative care in gynecologic oncology patients. ¹² IC involves inserting a catheter when urination is needed, emptying the bladder, and removing the catheter, which helps restore bladder function and reduce infection risk.¹³ The International Continence Society recommends IC as the preferred method to treat neurogenic bladder dysfunction. 13 The early removal of indwelling catheters and IC can lower the

complication rate, promote bladder function recovery, reduce urinary tract infections and hospitalization time, and improve QOL. ^{14–16} IC can be self-performed by the patient, alleviating the requirements on the healthcare system and giving the patient more freedom. ^{17–19}

Continuity of care, also known as continuous care or continuous rehabilitation, refers to a set of nursing activities that enable patients to receive continuous and coordinated care services when transferring to different healthcare facilities or levels of healthcare institutions.^{20,21} It is a recent nursing model developed in the past 20 years and aims at extending nursing from hospitals to families, compensating for the difficulties in obtaining information and meeting the healthcare needs of the patients after discharge, providing a basis for improving patients' self-care behavior and abilities, and promoting recovery.^{20,21} Continuity of care is associated with more positive patient experience, higher satisfaction, higher treatment adherence, and better patient outcomes.^{21–24} Continuity of care is also associated with a lower rate of avoidable hospitalizations²⁵ and lower mortality.²⁶

For those patients with cervical cancer after radical hysterectomy, routine catheterization care nursing includes IC operation training, catheter care, pelvic floor rehabilitation exercises, hydration guidance, urine observation, and follow-up guidance by phone call after discharge. For IC continuity care nursing, a multicenter continuity of care team is established for the patients. Before discharge, a more systematic discharge assessment and personalized education scheme are applied to each patient. After discharge, a more strict personal follow-up record is established for continuous monitor and questions response. Currently, the continuity care plan for IC in Chinese patients with cervical cancer after radical hysterectomy is still in its early stages. This study used the Delphi method to develop an evidence-based continuity care plan for patients with cervical cancer undergoing IC after a radical hysterectomy. Therefore, this study aimed to investigate the impact of IC continuity of care on bladder function recovery and QOL in patients after radical hysterectomy for cervical cancer.

Methods

Study Design and Participants

This quasi-experimental study included patients who underwent laparoscopic radical hysterectomy for cervical cancer and developed postoperative bladder dysfunction at Chongqing Medical University Affiliated First Hospital, the First Affiliated Hospital of Army Medical University, and Sichuan Provincial People's Hospital between December 2021 and June 2022. The study was approved by the medical ethics committee of Chongqing Medical University Affiliated First Hospital (2021-448) and each other participating centers. Following the ethical guidelines and standards outlined in the Declaration of Helsinki, we hereby confirm that our study fully complies with these principles. Written informed consent was obtained from all participants. The inclusion criteria were 1) adult patients, 2) underwent a laparoscopic radical hysterectomy, 3) subsequent bladder dysfunction, 4) received IC, 5) capable of self-IC or able to perform it with the assistance from family members, 6) clear consciousness and able to cooperate, and 7) willing to participate in the study and signed the informed consent form. The exclusion criteria were 1) severe cardiovascular, cerebrovascular, or other important organ diseases, 2) a history of severe urinary system diseases or previous urinary system surgeries, or 3) severe urinary system infections.

Intervention

In the routine catheterization care group, the nursing measures included 1) operation training, 2) catheter care, 3) pelvic floor rehabilitation exercises, instructing patients on pelvic floor exercises, abdominal muscle training, and leg lifting exercises, 4) hydration guidance and urine observation, and 5) follow-up guidance. The details are provided in the Appendix. In the IC continuity care group, the nursing measures included four dimensions. 1) Establishing a multicenter continuing care team. Prior to implementing the intervention, an expert meeting was convened, and each center established a multidisciplinary continuity of care team comprising nurses from departments such as gynecology, rehabilitation, and urology. An IC workshop was organized to clarify the responsibilities and assignments of team members. 2) Discharge assessment. When the patients were preparing for IC, each hospital used an IC nursing problem assessment form to conduct early, comprehensive, accurate, and continuous dynamic evaluations of the patients. The results were analyzed and provided as feedback.

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Based on the examination results and referring to the evaluation outcomes from the IC assessment form, personalized nursing measures were formulated for the patients. 3) Discharge education. Prior to discharge, medical personnel provided the patients with printed IC-related image handbooks. The patients were guided to maintain a daily total water intake between 1500 and 2000 mL. Appropriate catheter products were selected for each patient. The patients were instructed to ensure that the urination diary covered a continuous 72-h period before each visit and to maintain accuracy. The emotional responses of patients were closely monitored when the patients visited the IC outpatient clinic. In addition, during the IC period at home, the patient was followed up by medical staff through WeChat and phone calls. Timely and accurate assistance was provided to help patients cope positively throughout the entire course of their illness. 4) External follow-up and supervision. Each patient established a personal follow-up record, with an assigned nurse responsible for continuous monitoring and available to answer any questions. The details are provided in the Appendix.

Outcome

The baseline information was collected from the patients, including age, marital status, educational level, type of medical insurance, pathological type, tumor stage, drug allergies, and history of other diseases and comorbidities. Medical insurance was categorized as either full coverage (medical insurance or commercial insurance covering all expenses) or partial coverage (requiring the patients to bear some costs). Tumor staging was performed according to FIGO 2017 criteria into stages I to III.²⁷

The primary outcome was the time to bladder function recovery, defined as the period from discharge until patients regained autonomous voiding function without symptoms such as urinary frequency, urgency, or dysuria. Urine routine and urine culture results had to be negative, and post-void residual urine volume had to be <100 mL.

The secondary outcomes included the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire C30 (EORTC QLQ-C30)²⁸ at 3 and 6 months post-surgery, the EORTC Quality of Life Questionnaire for Cervical Cancer Patients (EORTC QLQ-CX24),²⁹ duration of indwelling catheter usage, IC time, number of readmissions, outpatient follow-up visits, and emergency room visits. The duration of indwelling urinary catheter use was defined as the time from surgery until the IC begins upon patient discharge. The IC time was defined as the time from discharge until the urinary catheter is removed after the patient's bladder function has recovered.

The EORTC QLQ-C30 consists of 30 items covering five functional domains, three symptom scales, a global health and quality of life scale, and six single items. The functional domains assess the patient's physical, emotional, role, cognitive, and social functioning, while the symptom scales measure the severity of symptoms related to fatigue, pain, and nausea/vomiting. The standardized score was 100 for each domain. The Cronbach's alpha coefficient for the scale was 0.86, and the KMO value was 0.75.²⁸

The EORTC QLQ-CX24 comprises 24 items (items 1–19 are mandatory, and items 20–24 are optional). The four functional scales include body image, sexual activity, enjoyment, and functioning, while the five symptom scales include general symptoms, lymphedema, peripheral neuropathy, menopausal symptoms, and sexual concerns. Each item is scored on a 4-point scale: "not at all", "a little", "quite a bit", and "very much", corresponding to scores of 1, 2, 3, and 4, respectively. Higher scores indicate better physical functioning (for items related to sexual activity and enjoyment) and more severe symptoms (for other items).²⁹

Safety Assessment

The safety indicators included whether there were severe urethral injuries during IC and the presence of urological complications, such as urinary tract infections, bladder stones, and hydronephrosis, as adverse events. The diagnostic criteria for urinary tract infections were 1) Gram stain of a fresh midstream urine sediment showing >1 bacterium per field under oil immersion microscopy, 2) midstream urine bacterial culture count $\geq 10^5$ CFU/mL, or 3) positive urine culture from a bladder puncture.³⁰

Statistical Analysis

Statistical analysis was performed using SPSS 22.0 (IBM, Armonk, NY, USA). Normally distributed continuous data were presented as means \pm standard deviations and analyzed using the independent sample t-tests. Non-normally

distributed continuous data were presented as medians (Q1, Q3) and analyzed using the Mann-Whitney U-test. The categorical data were presented as n (%) and analyzed using the chi-square test. Two-sided P-values <0.05 were considered statistically significant.

Results

A total of 138 complete patient records were ultimately collected. One patient with severe urinary system infection, two patients with symptomatic coronary heart disease, one patient with urinary system surgery, and one patient with ischemic stroke and complications were excluded. The IC continuity care group comprised 67 patients, while the routine catheterization care group comprised 66 patients. During the follow-up period, two patients from the IC continuity care group were lost to follow-up, and one was switched to an indwelling catheter. In the routine catheterization care group, one patient was lost to follow-up, and one was switched to an indwelling catheter. Ultimately, there were 64 patients in each group. Their baseline characteristics are presented in Table 1. There were no significant differences in patient characteristics between the two groups.

The duration of indwelling catheterization was similar between the two groups (9.48±2.75 vs 9.92±5.69 days, P=0.58), but the IC duration (15.777±6.95 vs 18.39±9.20 days, P<0.001) and bladder recovery time (25.27±5.85 vs 29.02±8.93 days, P<0.001) were shorter in the IC continuity care group than in the routine catheterization care group (Table 2).

Compared with the routine catheterization care group, the IC continuity care group showed better QOL, as shown by lower EORTC QLQ-C30 total scores (median, 33.33 vs 66.67, P<0.001), as well as for physical functioning (P<0.001), cognitive functioning (P<0.001), social functioning (P<0.001), fatigue (P<0.001), pain (P<0.001), and dyspnea (P=0.02) (Table 3). There were no significant differences in the QLQ-CX24 general symptom scores at 3 months between the two

Table I Baseline Characteristics

Variables	Routine Catheterization Care Group (n=66)	IC Continuity Care Group (n=67)	P
Age (years)	52.46±8.45	51.66±6.12	0.79
Marital status (%)			>0.999
Married	58 (87.9%)	58 (12.1%)	
Unmarried/divorced/widowed	8 (86.6%)	9 (13.4%)	
Education level (%)			0.558
No formal education	7 (10.61%)	8 (11.94%)	
Primary/secondary school	29 (43.94%)	32 (47.76%)	
High school/university	30 (45.45%)	27 (40.30%)	
Health insurance type (%)			>0.999
Fully reimbursed	4 (6%)	5 (7.5%)	
Partially reimbursed	58 (88%)	57 (85%)	
Fully self-funded	4 (6%)	5 (7.5%)	
Pathological type (%)			0.667
Squamous cell carcinoma	52 (78.8%)	55 (82.1%)	
Adenocarcinoma	14 (21.2%)	12 (17.9%)	
Tumor Stage (%)			0.759
Stage I	43 (65.15%)	42 (62.69%)	
Stage II	15 (22.73%)	16 (23.88%)	
Stage III	8 (12.12%)	9 (13.43%)	
Drug allergy history			0.68
None	63 (95.45%)	65 (97.01%)	
Present	3 (4.55%)	2 (2.99%)	
Comorbidities			0.816
None	55 (83.33%)	57 (85.07%)	
Present	11 (16.67%)	10 (14.93%)	

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Table 2 Indwelling Catheterization Duration, Intermittent Catheterization Time, and Bladder Function Recovery Time

Grouping	IC Continuity Care Group (n=64)	Routine Catheterization Care Group (n=64)	P
Intermittent catheterization duration before indwelling catheterization (days) Intermittent catheterization duration (days) Bladder recovery time (days)	9.48±2.75	9.92±5.69	0.58
	15.77±6.95	18.39±9.20	<0.001
	25.27±5.85	29.02±8.93	<0.001

Table 3 EORTC QLQ-C30 Scores

Scoring items	Routine Catheterization Care Group (n=64)	IC Continuity Care Group (n=64)	P
Functional domain			
Physical functioning	92.39±9.49	98.44±3.89	<0.001
Role functioning	93.76±11.69	95.05±12.49	0.42
Emotional functioning	92.85±11.96	95.57±11.78	0.12
Cognitive functioning	92.45±13.59	97.01±7.02	<0.001
Social functioning	91.41±15.71	95.57±12.68	<0.001
Symptom domain			
Fatigue	0.00 (0.00,11.11)	11.11 (0.00,11.11)	<0.001
Nausea and vomiting	0.00 (0.00,0.00)	0.00 (0.00,0.00)	0.23
Pain	0.00 (0.00,0.00)	0.00 (0.00,33.33)	<0.001
Isolated item			
Dyspnea	0.00 (0.00,0.00)	0.00 (0.00,33.33)	0.02
Sleep disturbances	33.33 (0.00,33.33)	33.33 (0.00,33.33)	0.11
Loss of appetite	0.00 (0.00,0.00)	0.00 (0.00,33.33)	0.23
Constipation	0.00 (0.00,33.33)	0.00 (0.00,33.33)	0.32
Diarrhea	0.00 (0.00,0.00)	0.00 (0.00,33.33)	>0.099
Financial difficulties	0.00 (0.00,0.00)	0.00 (0.00,0.00)	0.61
Overall Quality of Life	33.33 (33.33,66.67)	66.67 (33.33,100.00)	<0.001

groups (P=0.91), but the IC continuity care group showed better scores at 6 months than the routine catheterization care group (15.63 \pm 4.90 vs 20.98 \pm 5.43, P<0.001), as well as in lymphedema at 6 months (P=0.002), sexual functioning at 6 months (P<0.001), sexual activity at 6 months (P<0.001), and sexual enjoyment at 6 months (P<0.001) (Table 4).

Table 4 Specific Quality of Life Scores Using the QLQ-CX24 Questionnaire

QLQ-CX24 Items	IC Continuity Care Group (n=64)	Routine Catheterization Care Group (n=64)	P
General symptoms (3 months)	24.20±10.72	24.38±7.57	0.91
General symptoms (6 months)	15.63±4.90*	20.98±5.43	<0.001
Body image (3 months)	74.31±8.83	71.08±9.84	0.06
Body image (6 months)	76.56±7.44	74.31±7.89	0.09
Lymphedema (3 months)	0.00 (0.00,33.33)	33.33 (0.00,33.33)	0.075
Lymphedema (6 months)	0.00 (0.00,16.67)	33.33 (0.00,33.33)	0.002
Peripheral neuropathy (3 months)	0.00 (0.00,33.33)	33.33 (0.00,33.33)	0.09
Peripheral neuropathy (6 months)	33.3 (0.00,33.33)	33.33 (0.00,33.33)	0.09

(Continued)

Table 4 (Continued).

QLQ-CX24 Items	IC Continuity Care Group (n=64)	Routine Catheterization Care Group (n=64)	P
Menopausal symptoms (3 months)	31.25±20.47	34.38±8.33	0.26
Menopausal symptoms (6 months)	30.21±17.54	31.25±10.07	0.68
Sexual functioning (3 months)	-	-	-
Sexual functioning (6 months)	63.89±23.35*	33.33±12.03	<0.001
Sexual concerns (3 months)	53.12±19.44	52.08±19.44	0.77
Sexual concerns (6 months)	47.92±16.67	48.96±17.79	0.73
Sexual activity (3 months)	33.33 (0.00,33.33)	33.33 (0.00,33.33)	0.082
Sexual activity (6 months)	33.33 (0.00,33.33)	66.67 (66.67,75.00)	<0.001
Sexual enjoyment (3 months)	33.33 (0.00,33.33)	33.33 (0.00,33.33)	0.09
Sexual enjoyment (6 months)	33.33 (0.00,33.33)	66.67 (66.67,66.67)	<0.001

Table 5 Urinary System Complications, Number of Readmissions, Outpatient Follow-Up Visits, and Emergency Visits

	IC Continuity Care Group (n=64)	Routine Catheterization Care Group (n=64)	P
Urinary tract infections, n (%)			
Before intermittent catheterization	23 (35.94)	24 (37.5)	0.85
After intermittent catheterization	6 (9.4)	15 (23.4)	0.03
Urethral injuries (Cases)	5 (7.8)	14 (21.9)	0.03
Bladder stones (Cases)	0	0	_
Hydronephrosis (Cases)	0	0	_
Number of readmissions	3.61±3.58	1.92±2.04	<0.001
Number of outpatient follow-ups	6.17±2.85	3.13±1.19	<0.001
Number of emergency visits	0.23±0.96	0.00±0.00	0.05

There were no significant differences in urinary tract infections before IC (35.94% vs 377.550%, P=0.85), but the occurrence was lower in the IC continuity care group after IC (9.40% vs 23.40%, P=0.03). The IC continuity care group showed lower frequencies of urethral injuries (7.80% vs 21.9%, P=0.03) but higher numbers of readmissions (3.6 \pm 3.6 vs 1.9 \pm 2.0, P<0.001), outpatient follow-ups (6.2 \pm 2.9 vs 3.1 \pm 1.2, P<0.001), and emergency room visits (0.2 \pm 1.0 vs 0 \pm 0, P=0.05) (Table 5).

Discussion

Continuity of care, as a recent nursing model developed in the past 20 years and aims at extending nursing from hospitals to families, is a series of nursing actions that allow the patients to receive continuous and coordinated care services when transferring to different healthcare facilities or levels of healthcare institutions.^{20,21} Continuity of care leads to a more positive experience with healthcare and higher satisfaction, translating into higher treatment adherence and better patient outcomes.^{21–26}

For those patients who received radical hysterectomy, nerve injury, and bladder dysfunction are the common complications after surgery.⁷ Previous studies showed that clean self-IC combined with a drinking plan is effective in decreasing late bladder dysfunction after radical hysterectomy for cervical cancer.^{14–16,19} The standard self-IC care usually includes 1) operation training, 2) catheter care, 3) pelvic floor rehabilitation exercises, instructing patients on pelvic floor exercises, abdominal muscle training, and leg lifting exercises, 4) hydration guidance and urine observation, and 5) follow-up guidance. Compared with standard self-IC, the key features of continuity of care nursing for self-IC

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include the personal nursing scheme drafted based on the careful discharge assessment, the proper teaching of the technique, and the personal follow-up that ensures the patient continues to practice the technique properly. Previous studies have shown that the continuity of care strategy was associated with better patient outcomes.^{21–26} Here we evaluated the improvement of bladder function recovery and QOL for patients who received continuous self-IC care compared with those who received standard self-IC after radical hysterectomy.

One of the main advantages of self-IC is a better QOL, ^{14–16} as observed in the present study. Continuity of care is also associated with a better QOL, 21-26 but the present study was not designed to be able to examine the independent contribution of self-IC and continuity of care. Sekido et al²⁷ showed that although the short-term OOL of patients with IC after hysterectomy was poorer than in patients with spontaneous voiding, the difference disappeared with time, and the patients with IC ultimately had a QOL similar to those with spontaneous voiding. Of course, the early recovery of bladder function and independence from the urinary catheter are major factors contributing to improving the patient's QOL. Still, the extended nursing approach used in the IC continuity care group in the present study can also have contributed to better QOL. Indeed, the patients could feel safer and more adequately taken in charge, improving their QOL. 17 The improved sense of availability from the nurses in continuity of care can also contribute to a better QOL. 28 A higher number of positive and a lower number of negative behaviors can help maintain and improve physical, mental, and social health and OOL.²⁹ Nevertheless, a study showed that 90% of patients with hysterectomy for cervical cancer were unwilling to trade survival for less severe treatment-related symptoms, including urinary, bowel, and sexual functions.³⁰ Therefore, the patients can adapt with time, which can contribute to an improved QOL during self-IC, especially with the help of proper nursing. In addition, the personalized continuity care program offered by the continuity of care covers more areas of information than routine care, and it can focus on specific areas according to the needs or clinical specificaties of a specific patient. Better knowledge can translate into better attitudes and practices toward IC, improving QOL and the sense of empowerment. Self-IC is also conducive to a better sense of autonomy, improving QOL.¹⁷ Depression and anxiety are common issues after cancer surgery.^{31,32} Improving empowerment can contribute to managing those detrimental emotions and lead to a better sense of independence and confidence. 33,34

The personalized continuity care program offered by the continuity of care covers more areas of information than routine care, and it can focus on specific areas according to the needs or clinical specificities of a specific patient. The nurses participating in personalized care will take the initiative to examine the patient's specific conditions and propose information and solutions before the patient expresses the need. All of these make the patients feel safer and more adequately taken in charge. Furthermore, the personal follow-up improves the sense of availability from the nurses in continuity of care, which combined with well-teaching of self-IC technique, contributes to a better QOL. All these advantages, in addition to reduced risk of urinary tract infections and iatrogenic injuries, form positive feedback for continuous self-IC care and reduce depression and anxiety after cancer surgery, resulting in short time for bladder function recovery and improvement of QOL.

Finally, an important advantage of self-IC is a higher safety, particularly a reduced risk of urinary tract infections and iatrogenic injuries, ^{14–16} as observed in the present study. Indeed, the most common complication of IC is urinary infection. ^{35,36} Proper teaching of the patient on the principles of clean self-IC is essential for the safety of the procedure and a reduced risk of infection, and the present study showed that extended nursing teaching could be beneficial in decreasing the risk of infection compared with routine care. The present study also showed a lower frequency of urethral injuries. Indeed, the patient can feel whether there is pain and immediately stop the movement, while another person performing catheterization (eg, a nurse) will always have a response delay between the patient's expression of pain and stopping the insertion movement. On the other hand, the IC continuity care group showed higher readmission rates. Although it can increase the healthcare costs for the patient, it also indicates that the patients were more aware of the signs and symptoms that should prompt a medical consultation or readmission (owing to the extended nursing teaching), probably contributing to better patient outcomes.

This study is limited by the quasi-experimental and three-center nature of the research and the sample size. No power analysis was performed to verify whether it was adequately powered. Further prospective, multicenter, large-sample randomized clinical trials are required to provide higher-level evidence. The follow-up was relatively short. Even though bladder function had recovered in all patients, sexual function did not entirely return, possibly affecting the final QOL

assessment. Due to the follow-up being conducted only at 3 and 6 months postoperatively, some questions in the EORTC QLQ-CX 24 questionnaire were left unanswered. As a result, it could potentially affect the study outcomes. In future clinical work, an extended follow-up period should be implemented further to explore patients' overall quality of life, thereby obtaining more authentic clinical data. The barriers to IC (eg, lack of public restrooms hygienic enough to perform IC) were not assessed either. Finally, no analyses of the factors influencing bladder function recovery or QOL could be performed.

In conclusion, IC continuity care improves bladder function recovery and QOL in patients after radical hysterectomy for cervical cancer. This strategy is worth further study and implementation in the clinic.

Data Sharing Statement

All data generated or analyzed during this study are included in this published article.

Ethics Approval and Consent to Participate

This study was approved by the Ethics Committee of the First Affiliated Hospital of Chongqing Medical University (2019-116), and informed consent was obtained from all participants. Following the ethical guidelines and standards outlined in the Declaration of Helsinki, we hereby confirm that our study fully complies with these principles.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis, and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

All authors declare that they have no competing interests in this work.

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