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Compare the safety and efficacy of integrated securement device versus suture securement for centrally inserted central venous catheters: a prospective cohort study

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The securement of centrally inserted central venous catheters is crucial for their safe use. However, a standardized approach to centrally inserted central venous catheters securement has not been established, and securement methods remain controversial. This study is aimed to compare the safety and efficacy of integrated securement device with suture securement for centrally inserted central venous catheters, analyzing the differences in the incidence rates of catheter-related complications between the two methods, thereby providing evidence to inform clinical decision-making regarding centrally inserted central venous catheter securement strategies. From May to June 2025, 271 hospitalized patients with indwelling centrally inserted central venous catheters at a tertiary hospital in Zhejiang, China, were enrolled in this study. Demographic characteristics and catheter insertion details were collected for all participants on the day of catheter placement. Comfort scores were assessed within 48–72 h post-insertion, and patients were monitored daily until catheter removal for complications including catheter dislodgement (complete or partial), catheter-associated skin injury, and catheter-related bloodstream infection. Chi-square tests and Mann-Whitney U test were used, as appropriate, to compare complication rates between patients managed with the two different securement methods. The enrolled patients had a mean age of 63.46 ± 14.13 years, with a slightly higher proportion of males (57.6%) than females. The majority of catheters were placed in surgical patients (84.5%), with double-lumen catheters predominating (93.4%). Right-sided insertion was the most common approach(97.8%). The mean catheter dwell time was 9.01 ± 4.62 days. No significant differences were observed between the suture cohort and the integrated securement device cohort regarding complete catheter dislodgement, partial catheter dislodgement, or catheter-associated skin injury. Neither cohort experienced catheter-related bloodstream infections. However, the integrated securement device cohort demonstrated higher comfort scores and longer average maintenance intervals compared to the suture cohort, with both differences being statistically significant. The integrated securement device could be suggested as a "safe alternative" to suture securement for centrally inserted central venous catheters stabilization, and simultaneously improves patient comfort, extends maintenance intervals, may reduces nursing workload.

Keywords Centrally inserted central venous catheters, Suture securement, Integrated securement device, Catheter dislodgement

Abbreviations

CICCs	Centrally inserted central venous catheters
ICU	Intensive Care Unit
CRBSI	Catheter-related Bloodstream Infections

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INS	Infusion Nursing Society
ASD	Adhesive Securement Device
SASS	Subcutaneous Anchor Securement System
SSD	Sutureless Securement Devices
TA	Tissue Adhesive
ISD	Integrated Securement Device
CHG	Chlorhexidine Gluconate
CASI	Catheter-associated Skin Injury
SD	Standard Deviation

Background

Centrally inserted central venous catheters (CICCs) are indwelling devices inserted via the subclavian, jugular, or femoral veins, with the catheter tip positioned within the superior or inferior vena cava[1]. As an indispensable vascular access tool in clinical practice, CICCs are extensively utilized in critical care and surgical settings for hemodynamic monitoring, chemotherapy administration, parenteral nutrition support, and prolonged antibiotic therapy[2,3]. The use of CICCs effectively reduces the need for repeated venipuncture and vascular damage. According to 2025 market projections, the global CICC market is poised for substantial growth, with an estimated compound annual growth rate of 6.6%. The market value is anticipated to rise from USD 3.09 billion in 2025 to nearly USD 5.86 billion by 2035, primarily driven by demand in intensive care unit (ICU), oncology wards, and emergency departments[4]. However, the frequent use of CICCs is accompanied by complications, among which catheter dislodgement is a commonly reported adverse event. Studies have consistently identified CICCs as having the highest dislodgement rate compared to other central venous access devices, such as peripherally inserted central catheters, both in pediatric oncology patients and hospitalized adults[5,6]. Inadequate securement can lead to catheter accidental dislodgement, causing treatment interruptions, the need for catheter reinsertion, and associated complications. Such incidents not only compromise the quality of healthcare and increase medical costs but also impose unnecessary operational burdens on clinical staff. More critically, they pose life-threatening risks to patients and may trigger medical disputes. Therefore, implementing appropriate securement methods to maintain CICC stability should not be neglected in clinical practice, ensuring safe catheter retention and utilization.

In the selection of securement methods, suture has been regarded as the 'gold standard' for CICCs. In China, suture-based securement remains the predominant clinical practice for CICC stabilization. A nationwide survey revealed that 66.51% of ICU in Chinese tertiary hospitals utilize suture securement[7]. Moreover, data from secondary and tertiary hospitals at the provincial level demonstrated an even higher adoption rate of 98%[8]. Previous studies have explored various suture securement techniques to enhance catheter stability and safety[9,10]. However, the associated risks demand critical attention, including needlestick injuries, biofilm formation, infection, skin integrity compromise, and patient discomfort[11]. Suture securement may disrupt the local cutaneous microenvironment. Moreover, this technique necessitates securing the catheter by suturing through the wings of a butterfly fixation device to the skin, creating a concealed interface beneath the clamp that compromises disinfectant penetration during antisepsis procedures. This may lead to bacterial colonization, thereby elevating the risk of catheter-related bloodstream infections (CRBSI). Additionally, suture breakage caused by patient movement may also weaken the securement effect and increase the difficulty and time of the nurse's operation when removing the catheter[9].

Within this context, the Infusion Nursing Society (INS) Standards of Practice for Infusion Therapy recommend supplemental securement methods as alternatives to suture securement, such as adhesive securement device (ASD), subcutaneous anchor securement system (SASS), sutureless securement devices (SSD), or tissue adhesive (TA)[11]. Each securement method exhibits distinct advantages and limitations. TA significantly enhances dressing durability compared to SSD, reducing dressing change frequency and patient discomfort[12]. However, the use of TA may increase the risk of skin irritation or damage and the rate of failed catheter securement[12,13]. Besides, a study conducted in patients with peripherally inserted central catheters(PICCs) demonstrated that ASD demonstrate higher CRBSI incidence versus SASS[14]. The Integrated Securement Device (ISD), recommended by the INS standard, combines dressing and securement functions. It features a transparent, semipermeable window and a bordered fabric collar with built-in securement technology, such as chlorhexidine gluconate (CHG) dressings[11]. A pilot randomized controlled trial conducted in adult ICU demonstrated that ISD achieved the lowest securement failure rate compared to SSD, standard care, and TA groups[15]. Although these sutureless securement methods offer advantages in reducing tissue trauma and enhancing procedural efficiency, concerns regarding their long-term stability persist among clinicians. Inadequate adhesive strength may result in catheter dislodgement due to patient movement, perspiration, or skin sebum production. Furthermore, evidence comparing the efficacy and complication rates of various securement methods remains limited, preventing consensus on optimal CICC stabilization strategies. This prospective cohort study investigates the incidence of catheter dislodgement and other related complications in CICCs secured by suture securement versus ISD. The findings aim to establish clinical evidence for CICC stabilization strategies, while also expected to provide partly complication incidences information for different securement techniques.

Methods

A prospective cohort study was conducted at a tertiary hospital in Zhejiang, China, between May and June 2025, to compare the incidence of complications associated with different CICC securement methods. Two cohorts were recruited: one comprised patients whose CICCs were inserted and secured by anesthesiologists using

subcutaneous sutures combined with sterile transparent dressings, while the other consisted of patients whose CICCs were inserted and secured by the Vascular Access Specialist Team (VAST) using ISD (CHG dressings). There are 10 VAST members and 12 anesthesiologists who perform this procedure.

Participants

Participants were recruited using convenience sampling from hospitalized patients with indwelling CICCs. Inclusion criteria were as follows: ①Age ≥ 18 years; ②Hospitalized patient with an indwelling CICC; ③Intact skin at the intended catheter insertion site prior to placement; ④Voluntary participation with signed informed consent. Exclusion criteria were:① CICC inserted via the femoral vein; ②Known allergy to CHG or sterile transparent dressings; ③Patients with cognitive impairment. Withdrawal criteria included:①Participant voluntarily withdrew from the study; ②CICC dwell time < 3 days; ③Development of altered cognitive function (e.g., delirium, agitation) during catheterization due to changes in clinical status.

Sample size

The sample size for this study was calculated using the formula for comparing two independent proportions. With the significance level (α) set at 0.05 and the power (1-β) at 80% (β = 0.2), baseline complication rates were derived from the literature: $p_1 = 2\%$ (intervention group) and $p_2 = 12\%$ (control group)[16]. The initial calculation indicated a required sample size of 99 participants per group. To accommodate the study design and an anticipated attrition rate of 20%, the target sample size was increased to 119 participants per cohort, resulting in a total sample size of 238 participants.

Variables

Socio-demographic variables

Age, gender, education level, and marital status.

Catheter insertion variables

History of catheterization, intended use of the catheter, insertion site, number of lumens, length of the inserted catheter, and catheter dwell time.

Primary outcome

Dislodgement: Complete dislodgement means CICC completely leaves the vein, and partial dislodgement refers to CICC migrating outward from its original position by 1 centimeter or more[15,17].

Secondary outcomes

CRBSI Diagnosed if the same organism is isolated from a blood culture and the tip culture and the quantity of organisms isolated from the tip is greater than 15 colony forming units[11].

Catheter-associated skin injury(CASI): An abnormality including, but not limited to, erythema, vesicle, bulla, erosion or tear, at a peripheral or central vascular access device (VAD) site that is noted in the area of the device dressing and/or securement device and that is observable for 30 min or more after dressing/securement removal[11].

Comfort score: Assessed at 48–72 hours post-catheterization using a 10-cm Visual Analogue Scale. Patients marked a vertical Line on the 10-cm VAS ruler anchored by 'worst imaginable discomfort' (0 cm) and 'complete comfort' (10 cm), with higher scores indicating greater comfort.

Average maintenance intervals: Calculated by dividing the catheter dwell time by the number of maintenance procedures performed during the indwelling period.

Data collection

The research team underwent training to ensure clarity on the study's purpose and to standardize the definitions of complications. Data collection began at the time of catheter insertion and continued daily by designated research team members until participants' CICCs were removed. Comfort scores were specifically collected at 48-72h post-insertion.

Quality control

Before the study began, all operators responsible for CICC insertions completed training on standard operating procedures and underwent competency assessments in catheter securement techniques, ensuring procedural consistency among all participants. Concurrently, surgical ward nurses who might manage CICC patients received training on dressing change protocols and criteria for assessing complications to standardize catheter maintenance throughout the dwell time. The standard procedure for dressing change was every 7 days, with immediate replacement required upon detection of exudate or bleeding. Additionally, two trained research assistants conducted daily follow-ups. The pre-study training provided them with definitions and criteria for recognizing catheter-related complications, a follow-up schedule, and data collection protocols (including daily monitoring for complications, and recording of catheter maintenance time, removal time, and removal reasons). We conducted calibration exercises to ensure at least 90% inter-rater agreement in the identification of complications. The principal investigator performed systematic daily verification of all recorded data to ensure its completeness and accuracy.

Statistical analysis

Data entry and statistical analyses were performed using Excel and IBM SPSS Statistics software (version 26.0). Categorical data are presented as frequencies and percentages, whereas continuous data are expressed as means

and standard deviations (SDs). The chi-square test was used to compare complication rates, comfort scores and average maintenance intervals between the two cohorts. A p-value of less than 0.05 was considered significant differences.

Results

A total of 299 participants were initially enrolled, with 156 in the ISD cohort and 143 in the suture-securement cohort. During the study period, 28 participants were withdrawn: 26 due to a catheter dwell time of ≤ 2 days, and 2 due to the development of delirium following clinical deterioration. Consequently, 271 participants completed the study and were included in the final analysis (Fig. 1).

Socio-demographic and catheter insertion characteristics

The mean age of the participants was 63.46 ± 14.13 years; males (57.6%) slightly outnumbered females; a history of catheterization was present in 11.1% of the participants; the majority of catheters (84.5%) were placed for surgical patients; double-lumen CICCs constituted the predominant type (93.4%), and the right side was the most common insertion site (97.8%); the mean catheter dwell time was 9.01 ± 4.62 days. Significant differences ($p < 0.05$) were observed between the two groups regarding intended catheter use, number of lumens, inserted catheter length, and catheter dwell time (Table 1).

Primary outcome analysis

During the catheter indwelling period, the rate of complete dislodgement was 1.6% in the suture cohort, with no cases of partial dislodgement. In the ISD cohort, the rates of complete and partial dislodgement were 2.1% and 0.7%, respectively. The Chi-square test results indicated no significant difference between the two cohorts (Table 2).

Secondary outcomes analysis

No CRBSI occurred in either cohort, and no CASI occurred in the suture cohort, while the CASI incidence in the ISD cohort was 1.4%. The Chi-square test results indicated no significant difference in CASI incidence between the cohorts. Comfort scores were 9.22 ± 1.247 for the suture cohort and 9.64 ± 0.662 for the ISD cohort. Average maintenance intervals were 3.53 ± 1.80 days and 5.21 ± 1.99 days, respectively. The Chi-square test revealed significant differences between the two cohorts for both comfort scores and average maintenance intervals (Table 2).

Discussion

ISD demonstrates comparable safety to suture securement, with no increased risk of catheter dislodgement

Catheter dislodgement is a recognized complication associated with CICCs. It not only compromises the security of the line but also subjects patients to the distress of reinsertion and potential further trauma at the insertion site, constituting a secondary injury. Furthermore, it hampers the overall treatment progress and, in severe cases, can lead to life-threatening consequences. Therefore, selecting securement devices requires careful consideration of their efficacy. Current practices for catheter securement exhibit significant global variation. Polyurethane dressings with ISD are more prevalent in high-income countries, while sterile gauze and tape dressings, alongside chlorhexidine-impregnated dressings, are more commonly utilized in middle-income countries[18]. However, comparative research on the effectiveness of suture securement versus ISD is limited. A pilot randomized controlled trial conducted by Marion et al.[15] suggested that suture securement might be more effective than ISD in reducing dislodgement rates. Nevertheless, this study was constrained by a small sample size of only 30

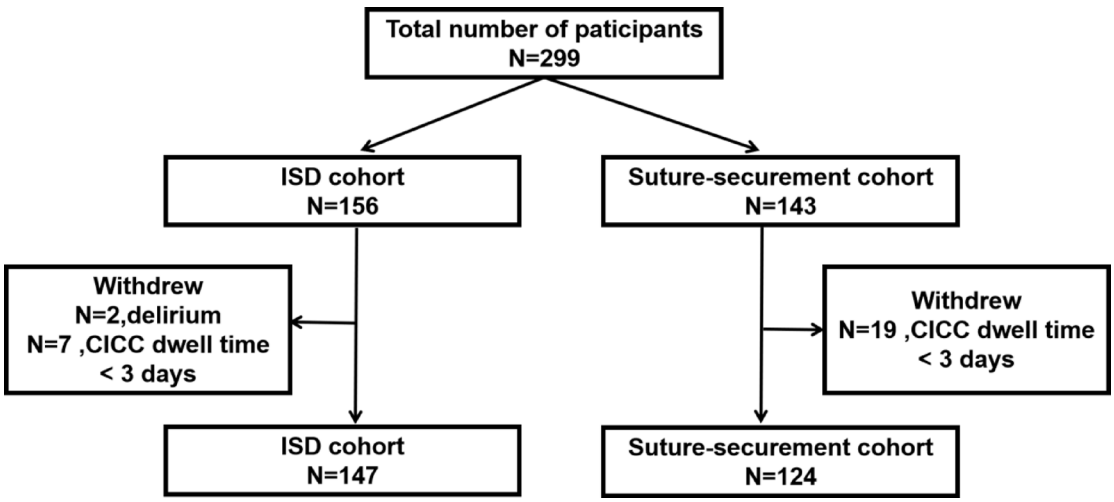

Fig. 1. Flow Chart of Study Participants.

Variable	Suture cohort ($n = 124$)	ISD cohort ($n = 147$)	p-values
Age	61.71 ± 14.53	64.95 ± 13.65	0.072
BMI	22.47 ± 3.65	22.90 ± 3.34	0.326
Gender			0.734
Male	70(56.5%)	86(58.5%)	
Female	54(43.5%)	61(41.5%)	
Education			0.229
Primary school or below	62(50.0%)	58(39.4%)	
Junior middle school	29(23.4%)	49(33.3%)	
High school	17(13.7%)	18(12.2%)	
University or above	16(12.9%)	22(15.1%)	
Marital status			0.915
Married	110(88.7%)	131(89.1%)	
Unmarried/divorced/widowed	14(11.3%)	16(10.9%)	
History of catheterization			0.406
Yes	16(12.9%)	14(9.6%)	
No	108(87.1%)	133(90.5%)	
Intended use of the catheter			<0.001
Surgery	104(83.9%)	125(85.0%)	
Chemotherapy	16(12.9%)	2(1.4%)	
Infusion therapy	4(3.2%)	20(13.6%)	
Insertion site			0.148
Left	1(0.8%)	5(3.4%)	
Right	123(99.2%)	142(96.6%)	
Number of lumens			0.001
1	14(11.3%)	1(0.7%)	
2	109(87.9%)	144(97.9)	
3	1(0.8%)	2(1.4%)	
Inserted catheter length			<0.001
12 cm	78(62.9%)	7(4.8%)	
13 cm	45(36.3%)	60(40.8%)	
14 cm	0(0.0%)	65(44.2%)	
15 cm	1(0.8%)	13(8.8%)	
16 cm	0(0.0%)	2(1.4%)	
Catheter dwell time	8.43 ± 5.13	9.50 ± 4.10	<0.001

Table 1. Socio-demographic characteristics and catheter insertion information.

participants per group, rendering it insufficiently powered to test statistical hypotheses. Suture securement has been regarded as the cornerstone for preventing catheter dislodgement in China due to its physical anchoring effect, and it remains the predominant securement method[19]. Our study, leveraging a substantially larger and adequately powered sample, demonstrates that well-engineered ISD can achieve stability equivalent to that of sutures. This finding holds significant promise for transforming clinical securement practices. Transitioning to sutureless securement methods could eliminate inherent risks associated with sutures, including needlestick injuries, suture-related infections, and patient discomfort or pain. Furthermore, sutureless securement is considerably simpler and faster to perform, saving time for the operator. Therefore, when equivalent securement efficacy is assured, sutureless securement represents a safer and more efficient approach.

ISD enhances patient comfort, extends maintenance intervals

ISD provided significantly greater patient comfort than suture securement in this study, as evidenced by higher comfort scores. Given the high mobility of the neck region, sutures used in traditional securement are prone to tension during movement, causing discomfort (pain and a foreign body sensation) that compromises daily activities and rest. The ISD used in this study mitigated these problems through improved skin conformity, substantially reducing tension-related discomfort. This advantage in comfort was especially pronounced among patients requiring frequent maintenance or prolonged catheterization.

Furthermore, ISD exhibited superior performance in decreasing the necessity for additional dressing changes. This is likely due to its exudate absorption and anti-infection properties, indicating that replacement is only required when blood or fluid seepage reaches a certain level. For nursing staff, ISD reduces the frequency of dressing changes and prolongs catheter maintenance intervals. This decreases the risk of local contamination at the puncture site and potential skin damage associated with frequent manipulation, thereby lowering infection

Outcome	Suture cohort ($n=124$)	ISD cohort ($n=147$)	p-values	OR
Complete dislodgement			0.794	1.271(0.209,7.730)
Yes	2	3		
No	122	144		
Partial dislodgement			0.357	
Yes	0	1		
No	124	146		
CASI			0.192	0.539(0.483,0.602)
Yes	0	2		
No	124	145		
CRBSI			NA	NA
Yes	0	0		
No	124	147		
Comfort score			0.005	5.622(1.564, 20.210)
≤7	13	3		
8–10	111	144		
Average maintenance intervals			<0.001	7.438(2.814, 19.657)
<7 Days	119	112		
7 Days	5	35		

Table 2. Comparison of incidence of complications, comfort score and average maintenance intervals.

risk and further enhancing patient safety[20]. Furthermore, the elimination of suture removal during catheter removal simplifies the removal process, reducing the nursing workload. These improvements in maintenance schedules and procedural workflows allow nursing staff to allocate more time and resources to other critical aspects of patient care. Simultaneously, from an economic perspective, reduced consumable usage and labor costs promote the rational allocation and utilization of healthcare resources. Although our study did not conduct a formal cost analysis and cannot provide specific cost-saving figures, existing evidence supports potential economic benefits. For instance, a cost modeling assessment of Tegaderm™ CHG dressing conducted by the UK National Institute for Health and Care Excellence Medical Technologies Advisory Committee demonstrated savings of £77.26 per patient compared to standard dressings, representing a 98.5% cost reduction[21]. Similarly, a cost-benefit analysis conducted by Maunoury et al.[22], which utilized a health economic model, found that CHG dressings are more cost-effective than transparent dressings. Future research specifically evaluating the costs associated with these devices is warranted to quantify their precise economic contribution and provide robust data to inform optimal healthcare resource allocation.

No significant difference was observed in the rates of CRBSI and CASI between suture securement and ISD securement

CRBSI is a serious complication of CICC. A study conducted across 41 countries in Asia, Africa, Eastern Europe, Latin America, and the Middle East over 24 years reported a pooled Central Line–Associated Blood Stream Infections (CLABSI) rate of 4.82 per 1000 catheter-days[23]. CLABSI associated with CICC not only compromises the utility of the catheter but also increases the healthcare burden and can lead to patient mortality. A multicenter study in Australia found a CLABSI rate of 5.3% for CICCs, identifying it as a primary cause of catheter failure[6]. Singhal et al.[24] revealed that the mortality rate among adult ICU patients with CLABSI in India could be as high as 45%. In China, studies indicate that the average hospitalization cost for patients with CLABSI in the ICU was $67,923, nearly double that of the control group[25]. In non-ICU wards, total healthcare expenditures were 76% higher for CLABSI patients compared to those without CLABSI and after controlling for relevant risk factors, CLABSI was associated with a 2.27-fold increased risk of death[26]. In this study, five catheters from the suture securement cohort and six from the ISD securement cohort were removed due to fever, with all corresponding blood and catheter tip cultures yielded negative results. Our study demonstrated no significant difference in CLABSI rates between suture securement and ISD securement, despite previous studies have suggested that suture securement may increase the risk of CLABSI[27,28]. However, it's worth noting the ISD securement cohort exhibited longer catheter dwell time than the suture securement cohort. The catheter dwelling time is a recognized risk factor for CLABSI[29,30], with a study indicating a 4% increased risk per additional catheter-day[23]. This observation, when considered alongside CLABSI rates, suggests that chlorhexidine gluconate (CHG) dressings may play a beneficial role in reducing infection risk, which is consistent with previous studies[31–33].

While some studies report an association between CHG dressings and an increased risk of skin injury[21], our study observed a low incidence of such events. This discrepancy may be attributable to our limited sample size. Furthermore, chlorhexidine gluconate is an antiseptic agent, and prolonged exposure can lead to dermatitis, meaning long-term use may increase the risk of dermatitis and related skin injuries[34]. Our inclusion criterion, which restricts enrollment to patients with CICCs that have a Limited dwelling time of no more than 1 month, and patients involved in this study only had a mean dwelling time of 9.50 ± 4.10 days, potentially reducing the detection rate for skin injuries. Compared with other central venous access devices, the duration of local skin

exposure in CICCs was relatively short, possibly contributing to the lower observed rate of skin complications. Based on the demonstrated infection prevention benefits and the manageable skin risk profile observed in this cohort with typical CICC dwelling times, CHG dressings could be considered a standard practice for CICC securement.

Study limitations

Naturally, this study has limitations. First, as a single-center investigation, the results should be interpreted with caution regarding generalizability; future multi-center studies with larger samples are warranted for further validation. Second, the influence of individual patient factors (e.g., severe obesity, profuse sweating, poor skin condition) on securement efficacy requires deeper investigation within larger cohorts. Future research should further explore the applicability of ISD in complex clinical scenarios (e.g., agitated ICU patients) and conduct cost-effectiveness analyses comparing ISD with suturing.

Conclusion

As a prospective cohort study conducted in a real-world setting, this research enrolled a diverse patient population—including individuals with varying ages and BMIs—to compare the impact of ISD securement versus conventional suturing on CICCs dislodgement rates. This design enhances the generalizability and external validity of our findings. Our data suggest ISD may be a safer option and that ISD could be suggested as a "safe alternative" to suture. This challenges the traditional paradigm that "sutures are the gold standard for preventing catheter dislodgement," providing crucial evidence-based support for clinical practice.

Data availability

All data and materials are included in this published article.

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Author contributions

Yilin Chen: Designed the experiments and wrote the manuscript; Xianghua Chen: Data collection; Xianghong Jin: Data collection; Xufen Zeng: Analyse the data; Xiuzhu Cao: Quality control; Linfang Zhao: Project management and revised the paper. All authors reviewed the manuscript.

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Declarations

Competing interests

The authors declare no competing interests.

Ethical approval and consent to participate

Prior to commencement, this study received ethical approval (Approval No. 20250401) from the Sir Run Run Shaw Hospital Ethics Committee. Before the study began, all of the participants were informed about the purpose and process of the study, and their participation was voluntary. The guidelines of the Declaration of Helsinki (World Medical Association, 2013) were followed throughout this study. Written informed consent was obtained from all of the included participants.

Additional information

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