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Long-term outcomes of ventriculoperitoneal shunt therapy in idiopathic normal pressure hydrocephalus

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Abstract

Background Limited data are available regarding the long-term functional outcomes and associated factors in patients with idiopathic normal pressure hydrocephalus (iNPH) undergoing ventriculoperitoneal shunt (VPS) placement. This study aimed to retrospectively evaluate the long-term outcomes of iNPH patients treated with VPS.

Methods Functional outcomes were assessed preoperatively and at 1-year, 2-year, and 3-year intervals postoperatively using the modified Rankin Scale (mRS), the iNPH grading scale (iNPHGS), and the Mini-Mental State Examination (MMSE).

Results Significant improvements were observed in mRS and iNPHGS scores at 1, 2, and 3 years post-surgery compared to the baseline level. MMSE scores showed significant improvement at 1-year and 3-year follow-ups. Multivariate regression analysis identified key factors influencing changes in mRS scores: postoperative complications and education level at 1 year, postoperative complications at 2 years, and sex, education level, postoperative complications at 2 years, and sex, education level, postoperative complications at 1 and 2 years. For iNPHGS scores, significant factors included sex, age at surgery, and smoking at 1 and 2 years. Changes in MMSE scores were associated with sex and the duration of preoperative symptoms at 1 year, and postoperative complications, education level, and smoking at 3 years.

Conclusion This study affirmed the efficacy and safety of VPS in managing iNPH. Factors influencing postoperative outcomes predominantly included education level, smoking, duration of preoperative symptoms, and postoperative complications. However, further research is required to validate these findings.

Keywords Follow-up, Functional outcome, Idiopathic normal pressure hydrocephalus, Ventriculoperitoneal shunt

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Background

Idiopathic normal pressure hydrocephalus (iNPH) is a progressive yet potentially treatable neurological disorder predominantly affecting the elderly, with an estimated prevalence of 3.7% among individuals aged 65 years and older [1]. The prevalence markedly increases in those aged 80 years and above [1, 2]. Clinically, iNPH is defined by a triad of hallmark symptoms: gait disturbance, cognitive decline, and urinary dysfunction, typically accompanied by ventricular enlargement and normal cerebrospinal fluid (CSF) pressure as evidenced by brain imaging [3–5].

CSF shunting is the cornerstone of iNPH management, offering significant improvements in symptoms and prognosis. Among the surgical options, ventriculoperitoneal shunt (VPS) is the most commonly employed, while ventriculoatrial shunt (VAS) and lumboperitoneal shunt (LPS) are less frequently utilized [6-12]. Despite its efficacy, shunt surgery carries a risk of complications, including mechanical malfunctions, infections, and overdrainage [13–17]. VPS remains the preferred treatment modality for iNPH in Western countries [18, 19]. However, complication rates associated with VPS vary widely, with common issues including intracerebral hemorrhage, seizures, infections, over-drainage, and shunt obstruction [8, 13, 17, 20, 21]. Notably, limited studies have specifically investigated VPS-related complications in the Chinese population, highlighting a gap in the literature [20, 21].

Regular clinical follow-up after shunt surgery serves a dual purpose: managing potential complications and assessing the efficacy of treatment. However, studies investigating the outcomes and prognostic factors of shunt surgery have produced inconsistent findings. These discrepancies are attributed to differences in outcome measures, diagnostic criteria, follow-up durations, postoperative management strategies, and the types of shunt systems employed [14]. For example, Israelsson H et al. [22] and Petersen J et al. [23] have reported enhanced quality of life within 6 to 45 months post-surgery. In contrast, Junkkari A et al. [24] have observed a decline in long-term quality of life due to disease progression and comorbid conditions. Similarly, Yamada S et al. [25] have noted that symptoms can worsen several years after surgery, despite initial improvements achieved through optimal valve pressure adjustments following VPS.

Research on the long-term prognosis of iNPH patients post-VPS remains limited, with most studies restricted to follow-up periods of approximately 1 year. Furthermore, evaluations of long-term cognitive outcomes are even scarcer. This study sought to address this gap by investigating the extended functional outcomes and associated factors in iNPH patients treated with VPS within the Chinese population.

Methods

Study subjects

This study included patients diagnosed with iNPH who underwent VPS placement. All participants were of Chinese Han ethnicity and were selected from Southwest Hospital. The diagnosis of iNPH was established based on clinical manifestations, physical examinations, brain imaging findings, and the results of experimental diagnostic tests, following the Japanese guidelines (Guidelines for Management of Idiopathic Normal Pressure Hydrocephalus: Second Edition) [3]. Patients underwent VPS using an identical programmable valve system with uniform settings. Surgical procedures were performed by the same medical team, utilizing Codman Johnson CSF shunts and accessories (826653). The initial intraoperative pressure was set at 10-mm H₂O lower than the preoperative lumbar puncture pressure and subsequently adjusted during follow-up visits based on clinical improvements.

The inclusion criteria for the study required participants to meet the clinical diagnosis of iNPH, which was defined by the presence of at least one of the three cardinal iNPH symptoms, ventriculomegaly with an Evans index > 0.3, and an intracranial pressure (ICP) \leq 200 mm H₂O as determined by a spinal tap test (STT) with normal CSF analysis (routine and biochemical). Additionally, participants needed to demonstrate symptom improvement in at least one of the following scenarios: after a CSF drainage test, following continuous CSF drainage, or post-shunting surgery. The exclusion criteria ruled out individuals with secondary causes of ventricular enlargement or other neurological disorders such as Parkinson's disease, Alzheimer's disease, and cerebrovascular conditions.

Study design

This study employed an observational, retrospective, long-term follow-up design, leveraging 13 years of comprehensive follow-up data collected at our hospital. Based on the predefined inclusion and exclusion criteria, a total of 44 patients were enrolled between March 2012 and May 2022. Each participant underwent standardized clinical evaluations conducted by the same team of trained physicians both preoperatively and at 12, 24, and 36 months postoperatively. During follow-up visits, valve pressure settings were monitored and adjusted as necessary to address any deviations. The study was approved by the institutional ethics committee, and informed consent was obtained from all participants. This study was performed in line with the principles of the Declaration of Helsinki.

Clinical assessment

Patient outcomes were evaluated using three standardized scales throughout the follow-up period. The modified Rankin Scale (mRS) assessed daily living abilities, the iNPH Grading Scale (iNPHGS) measured symptom severity [26], and the Mini-Mental State Examination (MMSE) evaluated overall cognitive function. Preoperative assessments served as baseline benchmarks for monitoring postoperative improvements and progression over time.

Data collection

Data collection spanned from the preoperative period to June 2023. For each participant, demographic characteristics and clinical assessment outcomes were systematically recorded. Demographic data included sex, age at the time of surgery, education level (categorized as illiterate, primary school, secondary school, and university or above), duration of preoperative disease, history of comorbidities (hypertension, coronary heart disease, diabetes), and unhealthy lifestyle habits (smoking and alcohol consumption history). Clinical assessment outcomes were determined by calculating the difference between postoperative and preoperative scores across the three assessment scales. The primary outcome measures were defined as the difference in scores between the baseline and each follow-up period, reflecting clinical improvement. Secondary outcomes included the incidence of complications and mortality.

Statistical analysis

The Shapiro–Wilk test was utilized to assess the distribution of continuous variables. Measurement data were expressed as mean \pm standard deviation (mean \pm SD) or median with interquartile range [M (IQR)], depending

Table 1 Baseline characteristics of study subject

Characteristics	$\stackrel{-}{X}$ ±S/ M (IQR), or %
Total	44
Sex (Male)	54.5
Age at the time of surgery (years)	64.73±7.12
Level of education	
Illiterate	13.6
Primary	36.4
Secondary	29.5
University and above	20.0
Course of preoperative disease (months)	24 (12,24)
History of other diseases	
Hypertension (Yes)	38.6
Coronary heart disease (Yes)	18.2
Diabetes (Yes)	18.2
Poor lifestyle habits	
Smoking (Yes)	34.1
Drinking (Yes)	43.2

on the distribution. Categorical data were summarized as rates [n (%)]. Differences between two dependent samples were analyzed using the paired sample t-test or Wilcoxon signed-rank test, as appropriate. Friedman ANOVA was employed to measure repeated outcomes across the follow-up period. Multivariate regression analysis was conducted to examine the impact of variables, including sex, age at the time of surgery, education level, duration of preoperative disease, comorbidities (hypertension, coronary heart disease, diabetes), and lifestyle factors (smoking and alcohol consumption), on clinical outcomes. Statistical analyses were performed using IBM SPSS Statistics version 20, with a significance threshold set at P < 0.05.

Results

Baseline characteristics

Between March 2012 and May 2022, 44 patients diagnosed with iNPH underwent VPS treatment. The cohort included 24 men (54.55%) and 20 women (45.45%), with a mean age at admission of 64.73 ± 7.12 years. The median duration of preoperative disease was 24 months (IQR: 12–24 months). Table 1 provides an overview of the base-line characteristics of the study population.

As of June 2023, all 44 patients completed both preoperative assessments and clinical evaluations at the 12-month postoperative mark. A total of 31 patients (70.45%) completed follow-up assessments at 24 months, while 25 patients (56.82%) completed assessments at 36 months. The follow-up trajectory of the participants is depicted in Fig. 1.

Clinical outcomes

Complications: Postoperative complications were observed in seven patients (15.91%). Five patients experienced overdrainage, while two cases of infection and shunt blockage were reported, respectively.

Mortality

By the study endpoint, five patients had died during follow-up periods of 19, 25, 38, 40, and 62 months, resulting in an overall mortality rate of 11.40%. The causes of death included pneumonia, kidney failure, and Alzheimer's disease in three patients, and cardiovascular disease in two patients. The median follow-up duration for surviving patients was 49 months (IQR: 20.5–77.0 months).

Abilities of daily living

Measured by the mRS, the proportion of patients achieving a favorable outcome, defined as an improvement of at least 1 point in mRS score, was 61.40% (95% CI: 46.40–76.30%) at 1 year, 48.39% (95% CI: 23.10–64.90%) at 2 years, and 44.00% (95% CI: 23.10–64.90%) at 3 years postoperatively.



Fig. 1 Flowchart of the study subjects

Symptom severity

Based on the iNPHGS, the proportion of patients demonstrating a favorable outcome, defined as an improvement of at least 1 point in iNPHGS score, was 95.45% (95% CI: 89.00–101.90%) at 1 year, 80.65% (95% CI: 65.90–95.40%) at 2 years, and 76.00% (95% CI: 58.00–94.00%) at 3 years postoperatively.

Overall cognitive function

Using the MMSE, the rate of improvement in overall cognitive function, defined as an increase of at least 1 point in MMSE score, was 52.30% (95% CI: 36.90–67.60%) at 1 year, 35.48% (95% CI: 17.60–53.30%) at 2 years, and 16.00% (95% CI: 0.60–31.40%) at 3 years postoperatively. Clinical outcomes are detailed in Table 2.

Comparison of functional improvement

At 12 months postoperatively, patients demonstrated a significant improvement in their abilities of daily living compared to preoperative scores (P < 0.001). This improvement persisted at 24 months (P < 0.05) and 36 months (P < 0.05) postoperatively, reflecting sustained benefits over time. Symptom severity, as measured by the iNPHGS, showed substantial and enduring alleviation across all follow-up periods compared to baseline (all P < 0.001). At the 12-month mark, symptom severity

Table 2 Clinical outcomes of patients

Clinical outcomes	total	%
Complications (Yes)	44	15.90
Mortality (Yes)	44	11.40
Functional improvement		
Abilities of daily living		
12 months after surgery (Yes)	44	61.40
24 months after surgery (Yes)	31	48.39
36 months after surgery (Yes)	25	44.00
Severity of symptoms		
12 months after surgery (Yes)	44	95.45
24 months after surgery (Yes)	31	80.65
36 months after surgery (Yes)	25	76.00
Overall cognitive function		
12 months after surgery (Yes)	44	52.30
24 months after surgery (Yes)	31	35.48
36 months after surgery (Yes)	25	16.00

 Table 3
 Comparison of functional improvement of patients preand postoperatively

Groups	Median (P25,	Ρ
	P75) OR X ±S	value
Abilities of daily living		
Before surgery vs. 12 months after surgery	-1.00 (-1.00, 0.00)	< 0.001
Before surgery vs. 24 months after surgery	0.00 (-1.00, 0.00)	0.009
Before surgery vs. 36 months after surgery	0.00 (-1.00, 0.00)	0.049
Severity of symptoms		
Before surgery vs. 12 months after surgery	-2.50 (-30, -1.25)	< 0.001
Before surgery vs. 24 months after surgery	-1.58 ± 1.34	< 0.001
Before surgery vs. 36 months after surgery	-1.44 ± 1.36	< 0.001
Overall cognitive function		
Before surgery vs. 12 months after surgery	1.00 (-1.00, 2.00)	0.023
Before surgery vs. 24 months after surgery	-1.00 (-2.00, 2.00)	0.877
Before surgery vs. 36 months after surgery	-1.00 (-1.00, 0.00)	0.011

significantly decreased (P < 0.001) relative to preoperative scores. This trend of significant alleviation continued at 24 months (P < 0.001) and 36 months (P < 0.001), indicating consistent symptom relief over the study duration. In terms of cognitive function, as assessed by the MMSE, patients exhibited a notable improvement at 12 months postoperatively (P < 0.05) compared to their preoperative scores. However, a slight decline in cognitive function was observed at 24 months, though it did not reach statistical significance relative to the postoperative status (P > 0.05). By 36 months, a significant reduction in cognitive function was evident compared to preoperative scores (P < 0.05). Table 3 provides a detailed summary of the comparisons in functional improvement before and after surgery.

Over the entire follow-up period, only 25 of the 44 patients completed all three postoperative clinical assessments. Repeated measurement comparisons revealed statistically significant differences across the four clinical evaluation time points (P<0.05). However, not all pairwise comparisons demonstrated statistical significance. The statistically significant differences are provided in Table 4.

Significant improvements were observed in the abilities of daily living when comparing 12 months post-surgery to both pre-surgery scores and 36 months post-surgery.

For symptom severity, pre-surgery scores were significantly worse than those recorded at 12, 24, and 36 months post-surgery. Additionally, outcomes at 12 months post-surgery were significantly better than those at 36 months, reflecting a gradual decline over time.

Regarding overall cognitive function, scores at 12 months post-surgery were significantly better than those at 36 months, indicating a notable decline in cognitive performance over the long term.

Factors influencing clinical outcomes

Postoperative complications were strongly associated with variations in pre- and postoperative mRS scores, indicating reduced responsiveness to shunt treatment. Interestingly, education level exhibited a dual impact on daily living abilities: higher education was positively correlated with reduced daily functioning 12 months postsurgery, yet inversely associated with functional decline at 36 months post-surgery. Additionally, the duration of preoperative illness and smoking emerged as significant negative predictors of daily living abilities 36 months post-surgery, suggesting that a longer disease history corresponded to greater functional impairment. Further details regarding the factors influencing pre- and postoperative differences in daily living abilities are provided in Table 5.

Regarding iNPHGS scores, smoking was identified as a significant negative factor influencing the differences between preoperative and postoperative measurements at both 12 and 24 months (Table 5). Age at the time of surgery was also negatively correlated with symptom severity, indicating that older patients tended to experience more pronounced symptoms at 12 months

Table 4 Comparison of functional improvement of patients over the follow-up period

	pre-surgery	post-surgery 12 months	post-surgery 24 months	post-surgery 36 months	X ²	р
mRS	3(3-3)	2(2–2)	2(2–3)	3(2-3)	51.747	0.000
iNPHG	7(5.5-8)	4(3.5-5)	6(4-6.5)	6(4–7)	47.160	0.000
MMSE	23(21-25.5)	24(21.5–25)	23(21-24.5)	23(18.5–24)	11.430	0.010

Table 5	Factors associated with abilities of daily living of
patients	after surgery

Times after surgery	variables	<i>p</i> -value	β-value (95%Cl)
12	Primary	0.016	0.888 (0.175, 1.601)
months	University and above	0.049	0.830 (0.006, 1.653)
	Post-operative complications	0.021	-0.799 (-1.473, -0.126)
24 months	Post-operative complications	< 0.001	-1.601 (-2.414, -0.789)
36	sex	0.028	-0.872 (-1.638, -0.107)
months	Secondary	0.028	-0.841 (-1.577, -0.105)
	Course of preopera- tive disease	0.029	-0.017 (-0.032, -0.002)
	Post-operative complications	< 0.001	-1.741 (-2.464, -1.018)
	Smoking	0.038	-0.738 (-1.430, -0.047)

Table 6 Factors associated with the severity of symptoms of patients after surgery

Times after surgery	variables	<i>p</i> -value	β-value (95%Cl)
12 months	Sex	0.043	-0.918 (-1.805, -0.032)
	Age at surgery	0.017	-0.060 (-0.108, -0.011)
	Smoking	0.023	-0.952 (-1.767, -0.137)
24 months	Smoking	0.012	-1.339 (-2.361, -0.317)

Table 7 Factors associated with the overall cognitive function of patients after surgery

Times after surgery	variables	<i>p</i> -value	β-value(95%Cl)
12	Sex	0.027	-1.137(-2.139,-0.134)
months	Course of preoperative disease	0.024	0.030 (0.004, 0.055)
36	Primary	0.012	-3.180(-5.564,-0.796)
months	Secondary	0.007	-4.015(-6.753, -1.277)
	Post-operative complications	0.022	2.341(0.381,4.300)
	Smoking	0.014	2.166(0.492,3.841)

post-surgery. Additional factors impacting the severity of symptoms are outlined in Table 6.

The duration of preoperative illness significantly exacerbated the differences in MMSE scores between preand 12-month postoperative assessments, highlighting its detrimental effect on cognitive function. Postoperative complications and smoking were further implicated in accelerating cognitive decline at 36 months post-surgery. Other factors influencing overall cognitive function are summarized in Table 7.

Discussion

A standardized follow-up protocol is critically needed, not only to evaluate the efficacy of shunting but also to gain deeper insights into disease progression and identify strategies to delay its advancement. Despite its importance, no universally accepted follow-up protocol currently exists. In this study, we employed three commonly used and readily accessible clinical scales to assess the outcomes of VPS treatment. These scales, also integral to preoperative evaluations, enhance their utility for continuous follow-up and longitudinal monitoring.

VPS treatment is widely recognized as beneficial for patients with iNPH. For instance, David Krahulik et al. have observed a statistically significant improvement in MMSE scores following VPS treatment within a 6-month follow-up period [8]. Similarly, a 1-year follow-up study has reported favorable outcomes in 69% of patients based on mRS scores and in 77% of patients based on iNPHGS scores [14]. Furthermore, a comprehensive meta-analysis on VPS efficacy has revealed that more than 75% of patients experience overall improvement post-treatment, with notable gains in gait (72%), cognitive function (61%), and urinary control (54%) [27]. Abdul Malik Popal et al. have also demonstrated that 58% of patients have achieved independent living (mRS 0–2) at 2 years postsurgery [28].

In our study, the results aligned closely with those documented in the literature, further corroborating the benefits of VPS. We found that 61.40% of patients exhibited marked improvements in daily living abilities at 1 year post-surgery, decreasing to 48.39% at 2 years and 44.00% at 3 years. Symptom improvement was observed in 95.45% of patients at 1 year, 80.65% at 2 years, and 76.00% at 3 years. Cognitive function improvements were noted in 52.30% of patients at 1 year, 35.48% at 2 years, and 16.00% at 3 years. These findings underscored the enduring, albeit declining, benefits of VPS treatment over time, affirming its role as an effective therapeutic intervention for iNPH.

Using the iNPHGS, symptoms at all three follow-up points demonstrated significant improvement compared to baseline. However, symptoms at the final follow-up showed greater deterioration relative to the first followup. This aligned with a previous study that has reported a statistically significant decline in the 10-meter walk test for VPS patients at the 6-month follow-up [8]. In contrast, a long-term follow-up study spanning at least 10 years has found substantial and sustained improvements across all symptoms compared to baseline, as measured by the Japanese Scale for Idiopathic Normal Pressure Hydrocephalus [9]. These varying outcomes may be attributed to differences in follow-up duration, diagnostic protocols, selection criteria, and the use of diverse outcome measures.

Regarding daily living abilities, the mRS score at 1 year post-surgery was significantly lower than preoperative levels, based on both the 25- and 44-patient samples. Similarly, prior research has demonstrated a significant increase in the proportion of patients able to live independently (mRS scores of 0-2), rising from 53% presurgery to 82% at 12 months post-surgery [29]. However, the mRS score differences between pre-operation and the last two follow-up points were statistically significant only when the preoperative population consisted of 44 patients. When the preoperative sample was limited to 25 patients, the differences were not statistically significant.

In terms of cognitive function, MMSE scores for the 44-patient cohort differed significantly between pre-operation and both 1-year and 3-year follow-ups, although no significant difference was observed at 2 years post-surgery. Conversely, when comparing MMSE scores among four groups within the 25-patient cohort, no significant differences were noted except between the 1-year and 3-year follow-ups. These discrepancies might stem from variations in sample size and characteristics, highlighting the influence of these factors on statistical outcomes.

Notably, both mRS and MMSE scores at the 3-year follow-up were significantly worse than those at the 1-year follow-up, reflecting a decline in daily living abilities and cognitive function over time. This deterioration was likely attributable to aging and the progressive nature of the disease [30-33]. Our findings align with previous research. For instance, one study has reported that 83% of patients show clinical improvement at the 1-year followup, decreasing to 62% at mid-term follow-up and 38% at late follow-up [34]. Another study has observed a moderate decline in gait performance over time, from 91% at 3 months to 75% at 3 years, while memory improvements are sustained at 80% throughout the same period [35]. These results underscore the critical importance of integrating long-term symptom monitoring into postoperative management to enhance patients' quality of life and alleviate the burden on caregivers.

Our study also highlighted several significant negative factors affecting postoperative outcomes, including the duration of preoperative illness, smoking, age at surgery, and postoperative complications. These factors were associated with poorer daily living abilities, increased symptom severity, and diminished cognitive function after surgery. These findings emphasized the value of early surgical intervention, smoking cessation, and strategies to minimize surgical complications in improving overall patient outcomes. Proactive management of these factors may play a pivotal role in enhancing postoperative health and recovery.

In recent years, considerable attention has been devoted to identifying the risk factors influencing shunting outcomes in patients with iNPH. This study primarily focused on the background risk factors associated with VPS in iNPH. Regarding daily living abilities, postoperative complications were identified as a significant negative factor influencing the difference in mRS scores from pre-surgery at all follow-up intervals (1, 2, and 3 years post-surgery). Interestingly, this contrasted with findings by Andren, K. et al., who have reported no adverse impact of complications on long-term mRS outcomes in iNPH patients [36].

For symptom severity, age at the time of surgery emerged as a significant adverse factor influencing iNPHGS score differences at 1 year post-surgery, consistent with previous studies [37, 38]. However, Kimura, T. et al. have found no significant correlation between age and the degree of postoperative improvement following VPS or LPS, highlighting discrepancies in the literature [39].

In terms of cognitive function, our study revealed that the duration of preoperative disease positively impacted MMSE scores at 1 year post-surgery. This finding contrasted with previous research [28, 40, 41], which have demonstrated that a longer duration from iNPH onset to surgery is significantly associated with poorer shunt responsiveness in MMSE outcomes.

The variability in reported risk factors likely stemmed from differences in patient selection criteria and followup intervals among studies. These discrepancies underscored the need for accumulating more long-term clinical data to enable comprehensive analysis and more robust conclusions regarding the risk factors affecting shunting outcomes in iNPH.

Conclusions

This study reaffirmed the efficacy and safety of VPS as a treatment for iNPH. Key factors influencing postoperative outcomes included education level, smoking status, disease duration, and postoperative complications. However, further research is necessary to validate these findings and deepen our understanding of their impact.

Abbreviations

- iNPH Idiopathic normal pressure hydrocephalus
- CSF cerebrospinal fluid
- VPS Ventriculoperitoneal shunt
- VAS ventriculoatrial shunt
- LPS lumboperitoneal shunt
- ICP intracranial pressure
- STT spinal tap test
- mRS modified Rankin Scale INPHGS
- INPH Grading scale MMSE Mini-Mental State Examination
- M (IQR) median with interguartile rang

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Author contributions

As the first author, Jingyu Chen contributed to research design, manuscript drafting, and revisions for important intellectual content and data analysis. Jishu Xian as the co-first author, conducted the work of data collection and analysis and manuscript drafting. Feilong Wang, Chenghai Zuo and Li Wei actively enrolled patients in the study. As corresponding authors, Hua Feng, Rong Hu, and Zhi Chen contributed to initiative concept, research design,

manuscript revisions, and final manuscript approval. All authors had access to the data, significantly contributed to the article, agreed to submit it for publication, and vouched for the integrity, accuracy, and completeness of the data and the fidelity of the trial to the protocol. All authors read and approved the final manuscript.

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Data availability

The data that supports the findings of this study are available on request from the corresponding author.

Declarations

Human Ethics and Consent to Participate

This study was performed in line with the principles of the Declaration of Helsinki. The institutional ethics committee of Southwest Hospital, Army Medical University approved this study (No. (B)KY2023027). Informed consents were signed by each subject.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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