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Dose-dependent effects of heparin sodium injection in preventing peripherally inserted central catheter-related venous thrombosis during postoperative chemotherapy in non-small cell lung carcinoma patients

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Abstract

Objective To evaluate the preventive effects of varying doses of heparin sodium injection on peripherally inserted central catheter (PICC)-related venous thrombosis during postoperative chemotherapy in patients with non-small cell lung carcinoma (NSCLC), and to analyze potential risk factors for the occurrence of venous thrombosis.

Methods This study was a single-center, single-blind, randomized controlled trial involving 425 NSCLC patients who underwent PICC placement at the Cancer Hospital Chinese Academy of Medical Sciences, Shenzhen Hospital from July 2019 to July 2021. All patients received chemotherapy regimens of pemetrexed plus cisplatin or paclitaxel plus cisplatin. The patients were randomly divided into three groups: the control group (using 10 mL of 0.9% saline for catheter sealing), Group I (using 2 mL of 10 IU/mL heparin sodium injection for catheter sealing), and Group II (using 5 mL of 10 IU/mL heparin sodium injection for catheter sealing). The baseline characteristics of the three groups were compared using statistical methods, and Doppler ultrasound was performed on the 7th day after catheter placement to assess the occurrence of venous thrombosis. Further correlation analysis and multivariate logistic regression analysis were conducted to explore the risk factors for thrombosis.

Results The incidence rates of thrombosis in the three groups were 20.00% in the control group, 7.75% in Group I, and 2.10% in Group II, with statistically significant differences among the groups ($P < 0.001$). Additionally, correlation analysis of baseline characteristics and thrombosis occurrence revealed a significant association between different doses of heparin sodium injection and thrombosis ($P < 0.001$), while other baseline characteristics (such as age, sex, and weight) showed no significant differences in relation to thrombosis ($P > 0.05$). Multivariate logistic regression analysis indicated that heparin sodium injection was a protective factor against thrombosis, with Group I: OR = 0.312 ($P = 0.003$) and Group II: OR = 0.081 ($P < 0.001$), suggesting that the preventive effect was more pronounced in Group II. Safety evaluation did not reveal any severe adverse reactions.

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Conclusion This study demonstrates that the use of heparin sodium injection is associated with a reduced incidence of PICC-related venous thrombosis in NSCLC patients during postoperative chemotherapy. At appropriate doses, heparin sodium injection exhibits favorable safety and may provide a potential clinical option for PICC patients at high risk of thrombosis.

Keywords Heparin sodium injection, NSCLC, PICC, Venous thrombosis, Prevention

Introduction

Primary bronchial lung cancer is one of the malignancies with high morbidity and mortality in China and the world [1]. With the rising incidence of lung cancer, an increasing number of patients are diagnosed, most of whom are in advanced stages of the disease, with chemotherapy as the primary treatment method [2]. Peripherally inserted central catheter (PICC) is a catheterization that sends the catheter tip to the bottom third of the superior vena cava, or junction of the superior vena cava and right atrium, by puncturing the peripheral vein with the catheter. This method allows for longer indwelling time, fewer puncture times, and less drug-caused irritation to the veins. It offers patients who require long-term intravenous infusions, tumor treatment, and the injection of irritant medications an efficient long-term route in their veins [3, 4]. Additionally, because of facile indwelling and lengthy indwelling time [5, 6], PICC is frequently utilized in clinical practice, especially in patients with malignancies receiving chemotherapy [7]. However, preventing complications associated with catheter use is the next step.

PICC-related complications mainly include venous thrombosis, phlebitis, catheter-related bloodstream infection (CRBSI), and catheter ectopy (including abnormal course and abnormal position of blocked catheter tip) [8–12]. Among them, PICC-related venous thromboembolism (VTE) refers to the process in which blood clots are formed on the inner wall of the vessel where the catheter is located and the adherent wall of the catheter after the placement of PICC, due to factors such as direct damage to the vascular intima by puncturing or catheter and the state of patients themselves. PICC-related venous thrombosis is a usual complication of PICC, which is mainly manifested as pain at the involved site, increased body surface temperature, superficial vein exposure, erythema, numbness in the extremities, and impaired neck and limb movements [13]. Multiple publications have shown that the incidence of symptomatic PICC-related venous thrombosis is 2-75% [14, 15], while that of asymptomatic one is as high as 50% [16, 17]. PICC-related venous thrombotic events are also common in patients with lung cancer receiving chemotherapy. Domestic researchers have reported that PICC-related venous thrombosis incidence in lung cancer patients undergoing chemotherapy is 5-20%, seriously affecting the therapeutic effect [18]. Another work indicated that PICC-related venous thrombosis incidence ranged from 3 to 30% in lung cancer patients undergoing chemotherapy [19]. Accordingly, preventing the development of PICC-related venous thrombosis and improving the quality of life of patients are urgent. Preventative anticoagulants are clinically applied as a key method to prevent PICC-associated thrombosis in cancer patients [20]. Low molecular weight heparin (LMWH), unfractionated heparin (UFH), and warfarin are anticoagulants currently applied in clinical practice, among which, saline-diluted UFH or heparin sodium injection-sealed catheters under positive pressure can effectively prevent microthrombus formation in indwelling catheter [21].

Effective sealing can effectively prevent blockage, exudation, and catheter-related thrombosis, with heparin sodium being one of the conventional sealing solutions [22]. Heparin sodium binds to antithrombin III, enhancing the inhibitory effect of antithrombin III on the activation of coagulation factors II, IX, X, XI, and XII, and suppressing the functions of coagulation substances such as thrombin and fibrin, thus exerting an anticoagulant effect. Recent studies have revealed that heparin sodium injection can lower the incidence of venous thrombosis and is both safe and effective [23, 24]. However, consensus has yet to be reached regarding the patient population, timing, and dosage of the medication.

This study employed statistical methods to systematically compare the baseline characteristics and the incidence of venous thrombosis among patients receiving different doses of heparin sodium injection for lock flush. Furthermore, the correlation between baseline characteristics and the occurrence of thrombosis was explored. Subsequently, multivariate logistic regression analysis was conducted to evaluate potential risk factors influencing thrombosis formation. In addition, the incidence of adverse reactions associated with heparin sodium injection was statistically analyzed to comprehensively assess the safety profile of this catheter locking treatment approach.

Data and methods

Trial design

The trial was designed as a single-center, single-blind, randomized controlled trial (RCT). It aimed to compare the differences in the incidence of venous thrombosis among NSCLC patients after PICC placement using normal saline, 2 mL of 10 IU/mL heparin sodium injection,

and 5 mL of 10 IU/mL heparin sodium injection for catheter locking.

Sample size calculation: The primary outcome measure of this study is the comparison of PICC-related thrombosis incidence among three groups of NSCLC patients, which is a categorical variable. According to previous literature [23], the thrombosis incidence was 12.4% in the control group without anticoagulation therapy and 3.03% in cancer patients receiving LMWH lock therapy. Based on this, we assumed thrombosis incidences of 12%, 5%, and 2% for the three groups, respectively. We performed a priori sample size calculation using the "Goodness-of-fit test: Contingency tables" module in G*Power 3.1 software, based on the chi-square test. With a significance level of $\alpha = 0.05$ (two-tailed), power $(1-\beta) = 0.80$, and effect size $w = 0.15$ (representing a small-to-medium effect), the calculated total sample size was 429 (for all three groups combined). Considering a 10% rate of loss to follow-up or invalid data, the final estimated total sample size was 472.

Selection of study participants

From July 2019 to July 2021, a total of 477 patients diagnosed with NSCLC at the Cancer Hospital Chinese Academy of Medical Sciences, Shenzhen Hospital were considered for the study. Patients were selected based on predefined inclusion and exclusion criteria. Inclusion criteria: NSCLC patients requiring PICC placement for chemotherapy; normal blood biochemistry and coagulation tests prior to catheter placement; patients in relatively good physical condition with an ECOG score of 0–2; patients with cognitive ability to actively cooperate with the study; and patients who provided signed informed consent. Exclusion criteria: patients with preoperative coagulation disorders, heparin allergy, or active bleeding ($n = 11$); patients who had used anticoagulants preoperatively or had a history of thrombosis ($n = 32$); and patients with concurrent heart failure ($n = 9$). Ultimately, 425 NSCLC patients who underwent PICC placement were enrolled (Fig. 1). All enrolled patients were NSCLC postoperative cases receiving platinum-based adjuvant

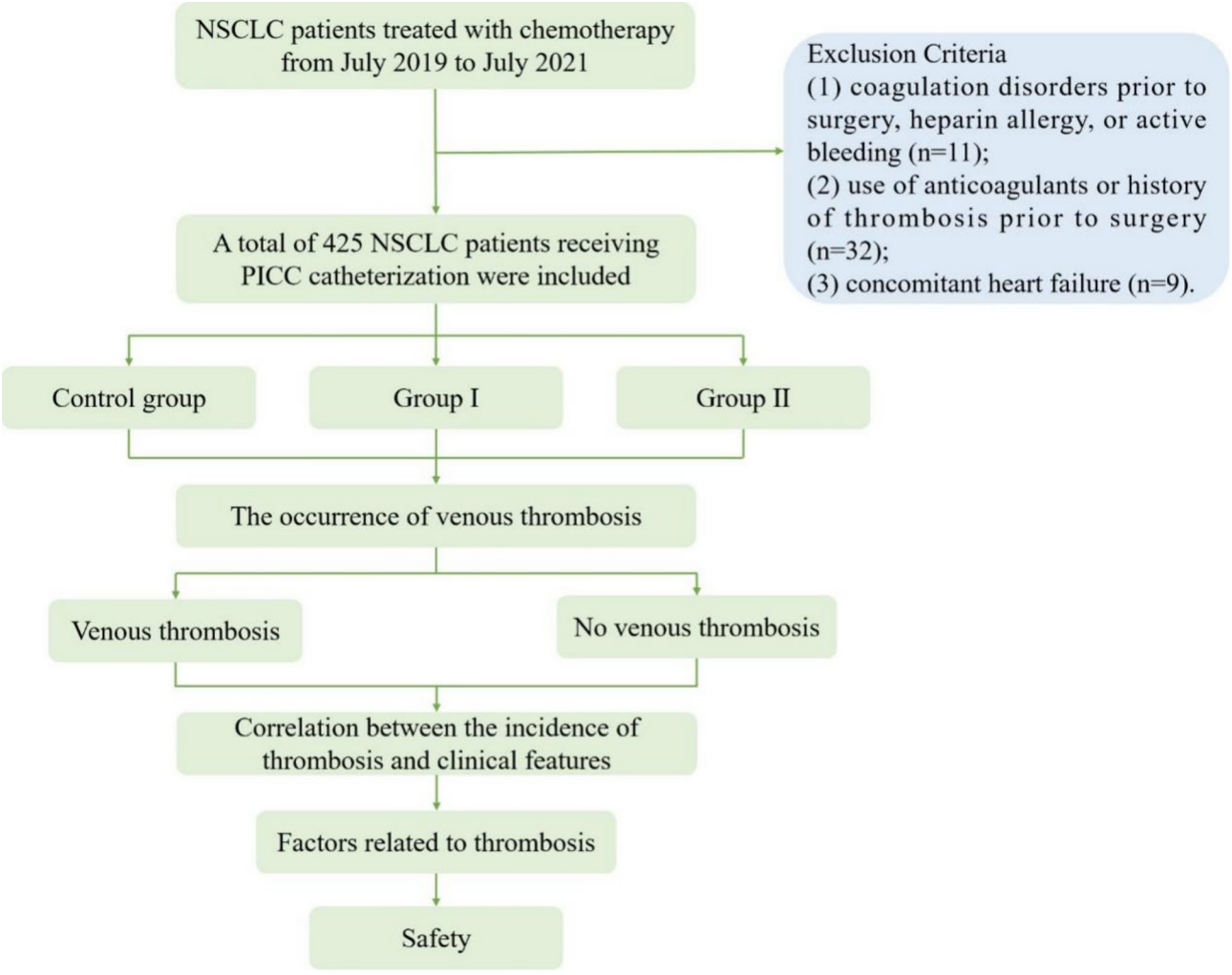

Fig. 1 Flowchart

chemotherapy. The specific regimens were divided into two types based on pathological classification: pemetrexed plus cisplatin (for adenocarcinoma) and paclitaxel plus carboplatin (for squamous cell carcinoma).

Randomization method: A computer-generated random sequence was used to allocate patients into three groups. Control group: 10 mL of 0.9% normal saline was used for catheter locking ($n = 140$). Group I: In addition to routine maintenance with normal saline, 2 mL of 10 IU/mL heparin sodium injection was used for positive-pressure catheter locking after each placement ($n = 142$). Group II: In addition to routine maintenance with normal saline, 5 mL of 10 IU/mL heparin sodium injection was used for positive-pressure catheter locking after each placement ($n = 143$).

Catheter locking method

All three groups of patients received routine maintenance with normal saline. The specific catheter locking methods were as follows: In control group, after catheter placement, a positive-pressure flush with 10 mL of normal saline was performed once daily for 1–7 days. In Group I, after catheter placement, a positive-pressure flush with 2 mL of heparin sodium injection (Heparin Sodium Injection for Lock Flush, Huabicheng; Specification: 5 mL, 50 units) was performed once daily for 1–7 days. In Group II, after catheter placement, a positive-pressure flush with 5 mL of heparin sodium injection was performed once daily for 1–7 days.

Randomization, allocation concealment, and blinding

A dedicated nurse was responsible for patient screening in this study. For each patient who provided informed consent, the study nurse conducted training for the patient and their family to ensure a comprehensive understanding of the study protocol. The study nurse then contacted the trial's randomization personnel to assign the patient a random number, determining their study group. The randomization scheme was generated using the randomization module of statistical analysis software, and the random numbers were stored in sealed envelopes to ensure allocation concealment. Patients were randomly assigned to one of three groups: (1) Normal saline group; (2) 2 mL of 10 U/mL heparin sodium injection group; (3) 5 mL of 10 U/mL heparin sodium injection group. This study employed a single-blind design, meaning that patients were unaware of the concentration of the locking solution used, reducing bias.

Indicators for observation

All patients included in the study underwent color Doppler ultrasound examination within 6 days, 2w ± 6d, 5w ± 6d, 8w ± 6d since PICC catheterization. Color Doppler ultrasound diagnostic apparatus (German PHILIPS ie3.3, L11- 3 probe, 12 MHz) was utilized to observe whether there were substances attached to the vein that gave out solid mass echo and to record venous thrombosis at the catheterization site after the catheterization, so as to compare the thrombosis incidence in each group. Thrombosis incidence refers to the proportion of patients who developed catheter-related thrombosis within the specified time frame among all PICC catheterized patients.

Thrombosis rate = the number of PICC-related thrombosis within a specified time/ total number of patients with PICC catheterization within a specified time×100% [25]. Patients were monitored for any adverse reactions, including hemorrhage, partial bleeding, PICC infections, and other local adverse reactions [26].

Statistical analysis

Data analysis was performed using SPSS 26.0 statistical software. Continuous variables with a normal distribution were presented as Mean ± Standard Deviation (Mean ± SD). Group comparisons were conducted using one-way analysis of variance (ANOVA), with post hoc tests performed using the Least Significant Difference (LSD) method. Continuous variables with a non-normal distribution were expressed as Median (Interquartile Range) [M (IQR)], and group comparisons were conducted using the Kruskal-Wallis rank sum test. Categorical variables were presented as n (%), and group comparisons were performed using the Chi-square test (χ^2 test). Additionally, the relationship between baseline characteristics and thrombosis occurrence was analyzed. The grouping methods for baseline characteristics were as follows: Continuous variables (e.g., age and weight) were categorized based on their median values, which were 63 years and 62 kg, respectively. Categorical variables were grouped accordingly: Surgical approach was classified into lobectomy group and sublobar resection group (including segmentectomy or wedge resection). A multivariate logistic regression analysis was conducted to evaluate the relationship between medication dosage and thrombosis risk. The results were expressed as the Odds Ratio (OR) and the corresponding 95% Confidence Interval (95% CI). A two-sided P-value < 0.05 was considered statistically significant.

Results

Baseline characteristics

The baseline characteristics of the three groups of NSCLC patients were compared (Table 1). There were 140 patients in the control group, 142 patients in Group I, and 143 patients in Group II. Except for sex distribution, which showed a statistically significant difference ($P = 0.047$), there were no significant differences among the three groups in terms of age, weight, smoking history,

Table 1 Baseline data for patients with non-small cell lung carcinoma (NSCLC)

Baseline characteristics	Control group ($n=140$)	Group I ($n=142$)	Group II ($n=143$)	*P* value	SMD
Age (years)	61.88 ± 10.37	61.30 ± 9.10	59.94 ± 10.25	0.243	0.022
Sex				0.047	0.013
Male	95 (67.86)	114 (80.28)	101 (70.63)		
Female	45 (32.14)	28 (19.72)	42 (29.37)		
Weight (kg)	61.85 ± 7.65	60.63 ± 8.10	60.81 ± 7.68	0.370	0.012
Smoking				0.810	0.026
Yes	70 (50.00)	66 (46.48)	67 (46.85)		
No	70 (50.00)	76 (53.52)	76 (53.15)		
ECOG score				0.999	0.013
0	38 (27.14)	40 (28.17)	38 (26.57)		
1	56 (40.00)	56 (39.44)	58 (40.56)		
2	46 (32.86)	46 (32.39)	47 (32.87)		
Pathology type				0.575	0.030
Squamous carcinoma	69 (49.29)	68 (47.89)	77 (53.85)		
Adenocarcinoma	71 (50.71)	74 (52.11)	66 (46.15)		
Disease staging				1.000	0.026
I	12 (8.57)	12 (8.45)	12 (8.39)		
II	20 (14.29)	23 (16.20)	22 (15.38)		
III	40 (28.57)	41 (28.87)	40 (27.97)		
IV	68 (48.57)	66 (46.48)	69 (48.25)		
Operation type				0.993	0.025
Sublobar resection	72 (51.43)	72 (50.70)	73 (51.05)		
Lobectomy	68 (48.57)	70 (49.30)	70 (48.95)		
Hematological parameters					
PT (s)	14.20 (12.70, 14.70)	14.05 (12.70, 14.80)	14.20 (12.60, 15.20)	0.797	0.010
APTT (s)	37.25 (34.23, 40.60)	35.75 (34.20, 42.03)	37.40 (33.90, 41.90)	0.976	0.009
BPC (*10^9/L)	237.50 (169.25, 265.00)	242.50 (185.75, 242.50)	238.00 (178.00, 264.00)	0.687	0.016
D-dimer (μg/mL)	0.49 (0.34, 0.73)	0.47 (0.34, 0.65)	0.46 (0.28, 0.64)	0.339	0.004
FIB (g/L)	3.38 (3.04, 4.24)	3.48 (3.18, 4.29)	3.35 (3.04, 4.28)	0.303	0.024

Note: SMD, Standardized mean difference; PT, prothrombin time; APTT, Activated partial thrombin time; BPC, blood platelet count; FIB, fibrinogen

Table 2 Incidence of thrombus under different catheter locking protocols

	Control group ($n=140$)	Group I ($n=142$)	Group II ($n=143$)	*P* value
Incidence of venous thrombosis	28 (20.00)	11 (7.75)	3 (2.10)	**< 0.001**

ECOG score, pathological type, disease stage, surgical type, or hematological indicators ($P>0.05$, Table 1).

Thrombosis incidence under different catheter locking protocols

Compared with the control group that used normal saline flushing (Table 2), the use of heparin sodium injection (Group I and Group II) significantly reduced the incidence of PICC-related venous thrombosis ($P<0.001$).

Univariate analysis of baseline characteristics and thrombosis outcomes

A comparison was performed between baseline characteristics (including group assignment, age, sex, weight, smoking history, ECOG score, etc.) and venous thrombosis occurrence (Table 3). Except for the catheter locking method, no other baseline characteristic was significantly associated with venous thrombosis occurrence ($P>0.05$).

Multivariate analysis of thrombosis risk factors

A multivariate logistic regression analysis was conducted to identify risk or protective factors associated with thrombosis (Table 4). The results indicated that, compared with the control group, the ORs for thrombosis formation in each heparin sodium injection group suggested that heparin sodium injection was a protective factor against thrombosis. Furthermore, Group II demonstrated a more pronounced protective effect (OR = 0.081, 95% CI: 0.024–0.277, $P<0.001$).

Safety evaluation

During the observation period, no cases of deep vein thromboembolic disease, purpura, skin or systemic allergic reactions, or severe adverse events such as thrombocytopenia were reported among the three groups.

Table 3 Incidence of venous thrombosis in patients with various baseline characteristics

Baseline characteristics	Venous thrombosis ($n=42$)	No venous thrombosis($n=383$)	*P* value
Group			< 0.001
Control group	28 (66.67)	112 (29.24)	
Group I	11 (26.19)	131 (34.20)	
Group II	3 (7.14)	140 (36.55)	
Age (years)			0.373
≤ 63	20 (47.62)	210 (54.83)	
> 63	22 (52.38)	173 (45.17)	
Sex			0.218
Male	34 (80.95)	276 (72.06)	
Female	8 (19.05)	107 (27.94)	
Weight (kg)			0.356
≤ 62 kg	20 (47.62)	211 (55.09)	
> 62 kg	22 (52.38)	172 (44.91)	
Smoking			0.528
Yes	22 (52.38)	181 (47.26)	
No	20 (47.62)	202 (52.74)	
ECOG score			0.752
0	10 (23.81)	106 (27.68)	
1	19 (45.24)	151 (39.43)	
2	13 (30.95)	126 (32.90)	
Pathology type			0.354
Squamous carcinoma	24 (57.14)	190 (49.61)	
Adenocarcinoma	18 (42.86)	193 (50.39)	
Disease staging			0.389
I	1 (2.38)	35 (9.14)	
II	6 (14.29)	59 (15.40)	
III	11 (26.19)	110 (28.72)	
IV	24 (57.14)	179 (46.74)	
Operation type			0.613
Sublobar resection	23 (54.76)	194 (50.65)	
Lobectomy	19 (45.24)	189 (49.35)	

Discussion

In recent years, the age of onset of lung cancer in China has gradually trended younger, with over 1.6 million new cases of lung cancer diagnosed annually. VTE, including pulmonary embolism (PE) and deep vein thrombosis (DVT), is one of the common complications in lung cancer patients [27]. Connolly et al. [28] demonstrated that the incidence of VTE in outpatient lung cancer patients is as high as 14%. The mechanism of thrombosis proposed by the renowned German pathologist Rudolf Virchow highlights three core elements: vascular wall injury, slow blood flow, and hypercoagulability [29]. The pathophysiological mechanisms of VTE in lung cancer patients are primarily associated with the direct activation of the coagulation system by tissue factor (TF), cancer procoagulant (CP), cytokines, and inflammatory factors produced by malignant tumor cells [30]. Additionally, tumor cells can activate local coagulation responses by interacting with endothelial cells, platelets, and leukocytes, promoting platelet activation and aggregation, and stimulating the release of cytokines by leukocytes [27]. The risk of VTE in lung cancer patients is closely related to factors such as lung cancer type, stage, patient-specific factors (e.g., history of VTE, elevated platelet count, and comorbidities such as infection or heart failure), and tumor treatment measures (e.g., chemotherapy, radiotherapy, surgery, and PICC placement) [27].

Among these, PICC is widely used in the treatment of malignant tumors and critically ill patients due to its ability to reduce the risk of drug extravasation and phlebitis, avoid the pain associated with repeated punctures, and improve patients' quality of life. It is also suitable for home care patients, making it favored by healthcare providers and patients alike [31, 32]. However, recent studies have shown that PICC placement significantly increases the risk of catheter-related venous thrombosis [33, 34]. The reasons for PICC-related venous thrombosis may include: (1) the diameter of the PICC catheter affecting central blood flow, thereby increasing turbulence and the risk of thrombosis; (2) the stiffness of the PICC catheter and the insertion process potentially causing direct damage to the venous wall, triggering an inflammatory

Table 4 Multivariate logistic regression analysis of the occurrence of venous thrombosis

Variate	OR	95% CI		*P* value
		Lower	Upper	
Group				< 0.001
Control group	Ref.	-	-	
Group I	0.312	0.146	0.668	**0.003**
Group II	0.081	0.024	0.274	**< 0.001**
Age (> 63 vs. ≤63)	1.106	0.539	2.268	0.784
Sex (female vs. male)	0.541	0.228	1.283	0.163
Weight (> 62 vs. ≤62)	1.352	0.690	2.649	0.380
Smoking history (yes vs. no)	0.988	0.494	1.975	0.972
Pathological types (adenocarcinoma vs. squamous carcinoma)	0.680	0.341	1.354	0.272
Disease staging				0.477
I	Ref.			
II	3.963	0.437	35.906	0.221
III	3.958	0.472	33.207	0.205
IV	5.121	0.626	41.873	0.128
ECOGS				0.853
0	Ref.			
1	1.026	0.411	2.560	0.957
2	1.228	0.559	2.699	0.609
Operation type (sublobar resection vs. lobectomy)	0.860	0.435	1.702	0.666

response and promoting thrombosis; and (3) the formation of a biofilm around the PICC catheter after insertion, combined with low flow and venous stasis, further increasing the risk of thrombosis [10]. Therefore, not only is the material selection of the PICC crucial, but postoperative antithrombotic therapy is equally important.

In clinical nursing, heparin is commonly used for the effective prevention and treatment of thrombosis [35]. An earlier study has demonstrated the safety and efficacy of intravenous heparin in preventing recurrent VTE [36]. The administration methods of heparin mainly include continuous intravenous infusion and subcutaneous injection [37]. Previous randomized trials have shown a correlation between heparin dosage and efficacy and safety, although the anticoagulant effect intensity and duration exhibit a nonlinear relationship with dosage [37]. Additionally, increasing heparin dosage may also raise the risk of bleeding, so clinical practice often involves monitoring the anticoagulant effect of heparin through activated partial thromboplastin time (APTT) to adjust intravenous dosing [37]. However, there is no consensus on the optimal dosage of heparin sodium for PICC locking. This study compared the incidence of venous thrombosis in NSCLC patients after PICC placement across three groups and found that using heparin sodium injection for flush lock significantly reduced the incidence of venous thrombosis (2.10 – 7.75%). Previous research indicated that the incidence of venous thrombosis in cancer patients using low molecular weight heparin sodium for PICC locking was 3.03%, compared to 12.4% in the control group without anticoagulation therapy; however, the study included various cancer types, making it unclear which specific patient population benefited [23]. Furthermore, multivariate logistic regression analysis revealed that heparin sodium injection is a protective factor against thrombosis. Although some studies suggest that advanced age, obesity, and lung resection surgery are independent predictors of VTE [38], this study found through OR value analysis that age > 63 years, weight > 62 kg, disease stage, and ECOG score might be potential risk factors for PICC-related thrombosis, though these did not reach statistical significance.

In summary, the use of heparin sodium injection is associated with improved coagulation function and a reduced incidence of venous thrombosis in patients. This association may help maintain normal blood flow, positively impact surgical treatment, and potentially enhance patient survival benefits.

Limitations

Although this study adopted a randomized trial design, certain limitations remain. First, the relatively small and single-source sample size may limit the generalizability of the results, potentially introducing bias in their applicability to different populations. Second, the study did not include genetic susceptibility data for thrombosis formation, which somewhat restricts the in-depth exploration of thrombosis mechanisms and personalized treatment strategies. Additionally, missing data on preoperative comorbidities and early postoperative activity in some patients may affect the comprehensive evaluation of surgical outcomes. Future research should validate the

current findings through multicenter, large-sample clinical trials and expand sample diversity to improve external validity. Furthermore, incorporating genetic susceptibility data related to thrombosis formation and combining genomic analysis could provide deeper insights into the molecular mechanisms of thrombosis, offering a theoretical basis for personalized treatment.

Supplementary Information

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Supplementary Material 1

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Author contributions
All authors contributed to data analysis, drafting and revising the article, gave final approval of the version to be published, and agreed to be accountable for all aspects of the work.

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Data availability
The data used to support the findings of this study are included within the article. The data and materials in the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
The study was approved by the ethics committee of Cancer Hospital Chinese Academy of Medical Sciences, Shenzhen Hospital. The methods were carried out in accordance with the approved guidelines. informed consent was obtained from all subjects and/or their legal guardian(s).

Consent for publication
Not applicable.

Conflict of interest
The authors declare that they have no potential conflicts of interest.

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