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ORIGINAL ARTICLE

Enhanced DVT Prevention in Non-ICU Medical Patients: a Cohort Study of IPC Plus LMWH vs. LMWH Alone

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SUMMARY

Background: **This study aimed to evaluate whether intermittent pneumatic compression (IPC) combined with low molecular weight heparin (LMWH) is more effective than LMWH alone in preventing lower extremity deep vein thrombosis (DVT) among high-risk, non-ICU medical patients.**
Methods: **This prospective cohort study included non-critically ill medical patients admitted to the Department of Internal Medicine at our hospital from March 2023 to December 2023. Patients with Padua scores ≥ 4 were randomized into two groups: IPC combined with LMWH (experimental group, n = 302) and LMWH alone (control group, n = 213). The primary outcome was the incidence of lower extremity DVT assessed weekly via duplex ultrasound and upon clinical suspicion of venous thromboembolism (VTE) or at discharge.**
Results: **Baseline characteristics were comparable between the groups, except for higher white blood cell and platelet counts in the IPC+LMWH group. The incidence of lower extremity DVT was significantly lower in the IPC+LMWH group compared to the LMWH-only group (6.6 vs. 12.2%, p = 0.029). Multivariate logistic regression analysis, adjusted for confounders such as age, BMI, coagulation parameters, and other clinical factors, indicated that IPC combined with LMWH significantly reduced the risk of DVT (RR = 0.392, 95% CI: 0.193 - 0.800, p = 0.010).**
Conclusions: **IPC combined with LMWH is more effective than LMWH alone in reducing the incidence of lower extremity DVT in high-risk, non-ICU medical patients. Further large-scale, rigorously designed studies are warranted to validate these findings.**
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KEYWORDS

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INTRODUCTION

Deep vein thrombosis (DVT) is a common clinical condition characterized by the formation of thrombi within the deep veins of the lower extremities and is frequently complicated by pulmonary thromboembolism (PTE) [1]. Both DVT and PTE are manifestations of venous thromboembolism (VTE), a serious condition associated with considerable morbidity and mortality among hospitalized patients and critically ill individuals [2].

The management and prevention of hospital-acquired VTE remain challenging for healthcare providers and hospital administrators due to the clinical complexity and substantial resource demands [3].

It is estimated that VTE causes approximately 100,000 deaths annually [4]. Evidence from randomized controlled trials indicates that pharmacological thromboprophylaxis, such as low molecular weight heparin (LMWH), can reduce the incidence of lower-extremity DVT by approximately 50% [5]. However, despite routine pharmacologic prophylaxis, approximately 5 – 20% of high-risk hospitalized patients still develop VTE [6-9]. Consequently, there is an ongoing need to explore adjunctive or alternative strategies to further reduce VTE risk.

Mechanical thromboprophylaxis, including IPC, graduated compression stockings, foot vein pump therapies, and neuromuscular electrical stimulation, represents an alternative or complementary approach [10,11]. Among these methods, IPC is particularly suited for patients with restricted mobility and is widely utilized as an alternative prophylaxis measure for patients with contraindications to pharmacological prophylaxis [12]. Nevertheless, whether IPC provides additional benefits when combined routinely with pharmacological prophylaxis remains uncertain.

Previous studies conducted in surgical populations have demonstrated that combining mechanical and pharmacological prophylaxis can significantly reduce VTE incidence compared with pharmacological prophylaxis alone [13,14]. However, a randomized controlled trial in ICU patients revealed no additional benefit when IPC was added to standard pharmacological prophylaxis [15]. Moreover, a meta-analysis indicated that IPC combined with pharmacological prophylaxis did not significantly reduce the incidence of lower extremity DVT compared to pharmacological prophylaxis alone [16]. To date, few high-quality studies have assessed the efficacy of combining IPC and pharmacological prophylaxis, specifically among non-ICU medical patients at high risk of VTE. Therefore, we conducted this prospective cohort study to evaluate whether IPC combined with LMWH could effectively reduce the incidence of lower extremity DVT compared to LMWH alone among hospitalized medical patients with high VTE risk (Padua score ≥ 4).

MATERIALS AND METHODS

Study design and participants

This prospective cohort study was conducted in the Department of Internal Medicine at the Third Affiliated Hospital of Wenzhou Medical University from March 2023 to December 2023. Eligible participants included adult patients ($\geq$ 18 years) admitted to general medical wards and identified as being at high risk for VTE, defined by a Padua prediction score of ≥ 4. Patients were randomly assigned to one of two groups: the experimental group, which received IPC combined with LMWH, and the control group, which received LMWH alone. LMWH was administered as a once-daily subcutaneous injection of 5,000 IU in both groups. In the experimental group, IPC was applied using calf compression sleeves for at least 18 hr per day, according to previously established protocols [17].

Exclusion criteria were as follows: 1) admission to the intensive care unit (ICU); 2) diagnosis of lower extremity DVT by ultrasonography within 24 hours of hospital admission; 3) history of VTE; 4) acute myocardial infarction or ischemic stroke; 5) acute heart failure; 6) recent trauma or surgery within one month; 7) contraindications to LMWH or mechanical prophylaxis; 8) refusal to participate by the patient or their family; and 9) incomplete clinical data. The study protocol was approved by the Ethics Committee of the Third Affiliated Hospital of Wenzhou Medical University (approval number: YJ2022035), and informed consent was obtained from all participants or their authorized representatives.

Data collection

Baseline demographic, clinical, and laboratory data were collected within the first 24 hr following admission. Collected variables included age, gender, BMI, Padua prediction score, presence of active malignancy, mobility limitation, respiratory failure, infection status, blood pressure, alanine aminotransferase (ALT), aspartate aminotransferase (AST), fasting blood glucose, low-density lipoprotein cholesterol (LDL-C), activated partial thromboplastin time (APTT), D-dimer levels, international normalized ratio (INR), prothrombin time (PT), prothrombin activity, fibrinogen levels, estimated glomerular filtration rate (eGFR), white blood cell count (WBC), hemoglobin concentration, platelet count, and C-reactive protein (CRP) levels. Additionally, all participants underwent bilateral lower extremity duplex ultrasound to exclude pre-existing DVT.

For outcome assessment, duplex ultrasound examinations were performed at the following time points: 1) weekly intervals following enrollment, 2) whenever clinical suspicion of VTE arose during hospitalization, and 3) at the time of discharge from the hospital. All ultrasound assessments were conducted by trained ultrasonographers blinded to group assignment.

Statistical analysis

Participants were stratified into two groups for analysis: IPC combined with LMWH and LMWH alone. Continuous variables not normally distributed were summarized as medians with interquartile ranges (IQRs) and compared using the Mann-Whitney U test. Categorical variables were reported as frequencies and percentages and compared using the chi-squared test or Fisher's exact test, as appropriate. Multivariate logistic regression analysis was performed to identify independent risk factors associated with lower extremity DVT, adjusting for potential confounding variables. Statistical analyses were conducted using SPSS statistical software (version

Table 1. Comparison of baseline characteristics between LMWH alone and IPC combined with LMWH groups.

Variable	LMWH alone group (n = 213)	IPC + LMWH group (n = 302)	p-value
Age (years)	74.00 (70.00 - 80.00)	75.00 (70.00 - 80.00)	0.398
BMI (kg/m²)	22.07 (19.49 - 24.22)	21.80 (19.53 - 23.83)	0.406
Systolic BP (mmHg)	130.00 (115.50 - 145.00)	131.00 (116.75 - 148.00)	0.738
Diastolic BP (mmHg)	73.00 (65.00 - 80.50)	74.00 (65.00 - 82.00)	0.420
APTT (s)	33.15 (28.65 - 36.10)	33.20 (29.28 - 36.82)	0.831
D-dimer (μg/mL)	1.96 (0.81 - 2.75)	1.45 (0.79 - 2.62)	0.200
INR	1.09 (1.01 - 1.12)	1.09 (1.02 - 1.13)	0.152
PT (second)	16.74 (15.35 - 17.19)	16.60 (15.40 - 17.15)	0.563
Prothrombin activity (%)	89.00 (80.35 - 95.00)	87.48 (76.60 - 93.00)	0.085
Fibrinogen (g/L)	4.69 (3.82 - 5.32)	4.78 (4.16 - 5.57)	0.107
eGFR (mL/minute)	50.67 (41.40 - 60.46)	50.29 (42.24 - 60.35)	0.847
Fasting blood glucose (mmol/L)	6.93 (5.45 - 8.21)	7.06 (5.32 - 8.21)	0.916
LDL cholesterol (mmol/L)	2.85 (2.45 - 3.17)	2.82 (2.11 - 3.14)	0.391
WBC (× 10⁹/L)	7.00 (4.70 - 8.48)	7.98 (5.60 - 10.00)	0.002
Hemoglobin (g/L)	113.85 (101.00 - 121.00)	113.67 (103.00 - 124.25)	0.336
Platelet count (× 10⁹/L)	196.00 (128.00 - 223.50)	204.00 (152.75 - 258.00)	0.007
CRP (mg/L)	90.49 (63.62 - 94.46)	90.50 (60.14 - 94.59)	0.829
ALT (U/L)	20.00 (12.00 - 30.00)	21.50 (12.00 - 31.36)	0.208
AST (U/L)	26.00 (19.00 - 36.00)	28.00 (18.00 - 37.83)	0.702
Gender, n (%)			
Female	78 (36.6%)	99 (32.8%)	0.366
Male	135 (63.4%)	203 (67.2%)	
Active malignancy, n (%)			
No	82 (38.5%)	142 (47.4%)	0.055
Yes	131 (61.5%)	160 (53.0%)	
Mobility limitation, n (%)			
No	207 (97.2%)	292 (96.7%)	0.750
Yes	6 (2.8%)	10 (3.3%)	
Heart or respiratory failure, n (%)			
No	191 (89.7%)	265 (87.7%)	0.500
Yes	22 (10.3%)	37 (12.3%)	
Infection status, n (%)			
No	158 (74.2%)	214 (70.9%)	0.408
Yes	55 (25.8%)	88 (29.1%)	

Data are expressed as median (interquartile range) or number (%).
BMI body mass index, BP blood pressure, APTT activated partial thromboplastin time, INR international normalized ratio, eGFR estimated glomerular filtration rate, LDL low-density lipoprotein, IPC intermittent pneumatic compression, LMWH low molecular weight heparin, ALT alanine aminotransferase, AST aspartate aminotransferase.

25.0; IBM SPSS Statistics for Windows; IBM Corp., Armonk, NY, USA), and a two-sided p-value of < 0.05 was considered statistically significant.

RESULTS

Patient characteristics

A total of 515 patients with Padua scores ≥ 4 were included in this study. Among them, 302 were assigned to the IPC combined with the LMWH group (experimental

Table 2. Comparison of lower extremity DVT incidence between IPC combined with LMWH and LMWH-alone groups.

Outcome	LMWH alone (n = 213)	IPC + LMWH (n = 302)	χ^2	p-value
Lower extremity DVT, n (%)				
No	187 (87.8%)	282 (93.4%)	4.788	0.029
Yes	26 (12.2%)	20 (6.6%)		

DVT deep vein thrombosis, IPC intermittent pneumatic compression, LMWH low molecular weight heparin.

Table 3. Multivariate logistic regression analysis of the relationship between IPC use and incidence of lower extremity DVT.

Variable	Adjusted RR	95% CI	p-value
Age	1.001 - 1.140	1.073	0.021
BMI	0.813 - 1.057	0.927	0.255
Systolic BP	0.989 - 1.026	1.007	0.447
Diastolic BP	0.991 - 1.065	1.028	0.139
APTT	0.924 - 1.057	0.988	0.726
D-dimer	1.042 - 1.230	1.132	0.003
INR	0 - 68.701	0.087	0.473
PT	0.896 - 1.116	1.000	0.996
Prothrombin activity	0.953 - 1.030	0.991	0.633
Fibrinogen	0.853 - 1.416	1.099	0.467
eGFR	0.975 - 1.079	1.026	0.321
Fasting blood glucose	0.937 - 1.080	1.006	0.863
LDL cholesterol	0.920 - 1.721	1.259	0.150
WBC	0.990 - 1.209	1.094	0.079
Hemoglobin	0.979 - 1.020	0.999	0.940
Platelet count	0.999 - 1.007	1.003	0.120
CRP	0.981 - 1.000	0.991	0.058
ALT	0.966 - 1.007	0.986	0.186
AST	0.988 - 1.017	1.003	0.723
Gender	0.104 - 0.851	0.298	0.024
Active malignancy	0.225 - 1.402	0.561	0.216
Mobility limitation	0.144 - 12.808	1.358	0.790
Heart or respiratory failure	0.307 - 2.516	0.879	0.810
Infection status	0.415 - 2.163	0.948	0.899
Collaboration with IPC	0.193 - 0.800	0.392	0.010

Adjusted for age, body mass index (BMI), systolic blood pressure, diastolic blood pressure, APTT, D-dimer, international normalized ratio (INR), prothrombin time (PT), prothrombin activity, fibrinogen, estimated glomerular filtration rate (eGFR), fasting blood glucose, low-density lipoprotein cholesterol (LDL-C), white blood cell count, hemoglobin, platelet count, CRP, alanine aminotransferase (ALT), aspartate aminotransferase (AST), gender, active malignancy, mobility limitation, heart or respiratory failure, and infection status.
CI confidence interval, DVT deep vein thrombosis, IPC intermittent pneumatic compression, RR relative risk.

group) and 213 to the LMWH-alone group (control group). Baseline demographic and clinical characteristics, including age, gender distribution, BMI, presence of active malignancy, mobility limitation, respiratory failure, infection status, systolic and diastolic blood pressures, ALT, AST, fasting blood glucose, LDL-C, APTT, D-dimer, INR, PT, prothrombin activity, fibrinogen, eGFR, hemoglobin, and CRP levels showed no sig-

nificant differences between groups (all $p > 0.05$). However, patients in the IPC+LMWH group had significantly higher WBC counts ($p = 0.002$) and platelet counts ($p = 0.007$) compared to those in the LMWH-alone group (Table 1).

Incidence of lower extremity deep vein thrombosis

During the follow-up period, the incidence of lower extremity DVT was significantly lower in the IPC combined with LMWH group compared to the LMWH-alone group (6.6% [20/302] vs. 12.2% [26/213], $\chi^2 = 4.788$, $p = 0.029$; Table 2).

Multivariate logistic regression analysis

Multivariate logistic regression analysis was performed after adjusting for potential confounding variables, including age, gender, BMI, systolic and diastolic blood pressures, APTT, D-dimer, INR, PT, prothrombin activity, fibrinogen, eGFR, fasting blood glucose, LDL-C, WBC count, hemoglobin, platelet count, CRP, ALT, AST, presence of active malignancy, mobility limitation, respiratory failure, and infection. The adjusted model revealed that patients receiving IPC combined with LMWH had a significantly lower risk of developing lower extremity DVT compared to those receiving LMWH alone (adjusted OR = 0.392, 95% CI: 0.193 - 0.800, $p = 0.010$; Table 3).

DISCUSSION

In this prospective cohort study, we demonstrated that combining IPC with low LMWH significantly reduced the incidence of lower extremity DVT compared to LMWH alone among non-ICU medical patients at high risk of VTE. These findings suggest a clear benefit of adjunctive mechanical prophylaxis in this patient population, potentially improving clinical outcomes by reducing thrombotic events.

Previous studies evaluating the efficacy of IPC primarily focused on surgical populations. A recent clinical trial demonstrated that IPC combined with LMWH significantly reduced the incidence of lower extremity DVT after femoral neck fracture surgery compared to LMWH alone (2.53 vs. 12.68%, $p = 0.017$) [18]. Consistent with these findings, a meta-analysis involving 17 randomized trials with 6,151 surgical and trauma patients revealed a significantly lower incidence of DVT in patients receiving combined IPC and pharmacological prophylaxis compared to pharmacological prophylaxis alone (5.48 vs. 9.28% OR: 0.38, 95% CI: 0.21 - 0.70) [12]. However, evidence from critical care units appears less consistent. A randomized controlled trial published in the New England Journal of Medicine indicated that adjunctive IPC did not significantly reduce the incidence of VTE among ICU patients already receiving pharmacological prophylaxis [6]. The high prevalence of VTE in ICU patients, reportedly ranging from 27 to 33% [19-21], contrasts markedly with rates observed in general medical wards. Indeed, extensive international studies estimate the prevalence of VTE in hospitalized medical patients without prophylaxis between 4.96 and 14.90%, with associated mortality rates as high as 5% [22,23].

The detailed mechanisms by which IPC enhances thromboprophylaxis remain incompletely understood. In addition to improving venous return through mechanical compression, IPC may benefit endothelial function by reducing inflammatory responses and thrombin generation. IPC has been shown to stimulate endothelial nitric oxide synthase, thereby promoting nitric oxide release and subsequent vasodilation. This, in turn, inhibits platelet aggregation and enhances endogenous fibrinolytic activity by reducing plasminogen activator inhibitor-1 (PAI-1) levels. Further biochemical studies focusing on inflammatory and coagulation markers may offer deeper insights into the synergistic mechanisms between IPC and pharmacological prophylaxis [24].

Few high-quality studies have investigated the combined use of IPC and pharmacologic prophylaxis in non-ICU medical populations. The prospective cohort study addresses this gap by demonstrating that combining IPC with LMWH significantly reduces the incidence of lower extremity DVT compared to LMWH alone (6.6 vs. 12.2%, $p = 0.029$). This difference remained statistically significant after adjusting for multiple clinical and laboratory confounding factors (adjusted OR = 0.382, 95% CI: 0.186 - 0.783). These findings suggest that IPC, when used adjunctively with pharmacologic prophylaxis, may provide additional protection against DVT and potentially reduce the risk of pulmonary embolism and associated mortality in high-risk medical patients outside the ICU setting.

Despite its strengths, this study has several limitations. First, as a single-center prospective cohort study, it is subject to potential selection bias and limited generalizability. In addition, the follow-up duration may have been insufficient to fully capture all clinically relevant thrombotic events. Although duplex ultrasonography is reliable for detecting proximal DVT, it has recognized limitations in identifying calf vein and iliac vein thromboses, which may have led to an underestimation of the true incidence of VTE. Multicenter randomized controlled trials with larger sample sizes and longer follow-up periods are needed to provide more robust evidence and allow for a comprehensive assessment of additional outcomes, including pulmonary embolism, mortality rates, quality of life, and cost-effectiveness.

This study suggests that IPC combined with LMWH is more effective than LMWH alone in preventing lower extremity DVT among high-risk, non-ICU medical patients. These findings support the consideration of IPC as an adjunctive prophylactic intervention in clinical practice. However, further research is necessary to validate its broader implementation and to thoroughly evaluate its safety profile.

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Data Availability Statement:
The datasets analyzed during the current study are available from the corresponding author upon reasonable request.

Ethics Approval and Consent to Participate:
The study protocol was approved by the Ethics Committee of the Third Affiliated Hospital of Wenzhou Medical University (approval number: YJ2022035), and informed consent was obtained from all participants or their authorized representatives.

Declaration of Interest:
The authors declare that they have no competing interests.

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