

One-year treatment outcomes in patients with lower extremity deep vein thrombosis

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Lower extremity deep vein thrombosis remains one of the leading causes of venous thromboembolism and is associated with the risk of pulmonary embolism, post-thrombotic syndrome, and disease recurrence. In contemporary clinical practice, direct oral anticoagulants (DOACs) are considered an alternative to traditional anticoagulant therapy using low-molecular-weight heparin and warfarin. However, the outcomes of their use in real-world clinical practice require further investigation.

OBJECTIVE – to evaluate the treatment outcomes of acute deep vein thrombosis of the lower extremities in patients receiving conventional anticoagulant therapy with low-molecular-weight heparin and Warfarin, compared with those treated with direct oral anticoagulants, focusing on recanalization, recurrence of venous thromboembolism, and treatment safety in real-world clinical practice.

MATERIALS AND METHODS. A single-center retrospective comparative cohort study was conducted involving 217 patients with acute lower extremity deep vein thrombosis treated between 2020 and 2025. The traditional therapy group included 82 patients who received low-molecular-weight heparin followed by transition to warfarin, whereas the DOAC group included 135 patients treated with rivaroxaban, dabigatran, or apixaban. The primary endpoints were venous segment recanalization and recurrence of venous thromboembolism during the 12-month follow-up period.

RESULTS. At 3 months after treatment initiation, complete venous segment recanalization was achieved in 18.0% of patients, partial recanalization in 71.0% of patients, while no recanalization was observed in 11.1% of patients. There was no statistically significant difference between the groups in the degree of recanalization ($p=0.839$). The one-year recurrence rate of venous thromboembolism was 8.8%: 7.3% in the traditional therapy group and 9.6% in the DOAC group ($p=0.557$). No significant difference in recurrence rates was identified among the different agents within the DOAC group. No major hemorrhagic complications or anticoagulant therapy-related deaths were recorded in this study.

CONCLUSIONS. Traditional anticoagulant therapy with low-molecular-weight heparin followed by warfarin and direct oral anticoagulants demonstrated comparable clinical efficacy in the treatment of acute lower extremity deep vein thrombosis: after 3 months, complete or partial venous segment recanalization was achieved in 89.0% of patients, with no statistically significant difference between the groups ($p=0.839$). The absence of major hemorrhagic complications and anticoagulant therapy-related mortality indicates a satisfactory safety profile for both traditional anticoagulant therapy and direct oral anticoagulants in the treatment of acute lower extremity deep vein thrombosis in real-world clinical practice.

KEYWORDS

deep vein thrombosis, venous thromboembolism, direct oral anticoagulants, warfarin, rivaroxaban, apixaban, dabigatran, recanalization, recurrent deep vein thrombosis.

ARTICLE • Received 2026-03-21 • Received in revised form 2026-04-23 • Published 2026-05-31

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Deep vein thrombosis of the lower extremities remains a significant challenge in modern angiology and vascular surgery due to its high prevalence, the risk of pulmonary embolism, the development of post-thrombotic syndrome, and significant socioeconomic impact [3, 5, 8, 43]. Venous

thromboembolism (VTE), which includes both deep vein thrombosis and pulmonary embolism, ranks among the most prevalent cardiovascular diseases worldwide and is associated with substantial short-term and long-term mortality [13, 17, 19, 23, 27, 28].

The incidence of VTE in the general population is estimated at 1–2 cases per 1,000 individuals annually, with the risk progressively increasing with age and the presence of concomitant risk factors [13, 25, 34]. The American Heart Association reports that over 1 million VTE cases occur annually in the United States, with approximately 70–80% attributable to lower extremity deep vein thrombosis [39, 42]. First-year mortality after a VTE episode can reach 15–20%, particularly among elderly patients and those with comorbidities [36, 37].

Anticoagulant therapy remains the primary treatment for deep vein thrombosis, aiming to prevent thrombus progression, pulmonary embolism, and recurrent venous thromboembolism. Traditionally, treatment included unfractionated or low-molecular-weight heparin, followed by vitamin K antagonists (VKAs), primarily Warfarin [35, 40]. However, over the past decade, clinical practice has changed substantially due to the widespread introduction of direct oral anticoagulants (DOACs), which have demonstrated comparable efficacy and a more favorable safety profile [9, 11].

DOACs offer a number of advantages, including fixed dosing regimens, rapid onset of action, no need for routine laboratory monitoring, fewer drug and dietary interactions, and the possibility of outpatient treatment for a substantial proportion of patients [12]. Current international guidelines, including those of the American Society of Hematology and the European Society of Cardiology, recommend DOACs as first-line therapy in most patients with deep vein thrombosis, provided no contraindications are present [31].

The Cochrane systematic review by X. Wang et al. [41], which included more than 30,000 patients, found that DOAC administration did not increase the rate of recurrent venous thromboembolism compared with conventional therapy and was associated with a statistically significant reduction in the risk of major bleeding. Similarly, the meta-analysis by Z. Y. Liu et al. [24], which was based on real-world clinical practice and included more than 63,000 patients, reported comparable efficacy among different DOACs in preventing recurrent venous thromboembolism. Notably, the risk of hemorrhagic complications was lower in the Apixaban group compared with the Rivaroxaban group.

Particular interest has been focused on the optimal duration of anticoagulant therapy and strategies for the secondary prevention of recurrent venous thromboembolism. The risk of recurrence remains elevated for many years after discontinuation of anticoagulation, especially in patients with unprovoked deep vein thrombosis or persistent risk

factors [13, 14, 18]. The RENOVE study by F. Coutraud et al., which investigated extended anticoagulation in high-risk patients, demonstrated a low recurrence rate of venous thromboembolism with both full-dose and reduced-dose DOAC regimens, while dose reduction was associated with a lower incidence of clinically significant bleeding [10].

Despite numerous randomized trials and meta-analyses, the choice of an optimal anticoagulant strategy in real-world clinical practice remains controversial. This issue is especially pertinent for patients with different localizations of deep vein thrombosis, variable time to clinical presentation, comorbidities, and limitations regarding the long-term use of specific medications. In addition, there is a paucity of data on the outcomes of deep vein thrombosis treatment in real-world clinical settings in Ukraine.

OBJECTIVE – to evaluate the treatment outcomes of acute deep vein thrombosis of the lower extremities in patients receiving conventional anticoagulant therapy with low-molecular-weight heparin and Warfarin, compared with those treated with direct oral anticoagulants, focusing on recanalization, recurrence of venous thromboembolism, and treatment safety in real-world clinical practice.

Materials and methods

A single-center retrospective comparative cohort study was conducted to evaluate the treatment outcomes in 217 patients with acute deep vein thrombosis of the lower extremities treated at the Central City Clinical Hospital of Kyiv between 2020 and 2025.

Among the examined patients, 96 (44.2%) were men and 121 (55.8%) were women. The patients' age ranged from 35 to 76 years, with a mean age of 50.9 ± 8.5 years.

The inclusion criteria were:

- acute symptomatic deep vein thrombosis of the lower extremities;
- age over 18 years;
- diagnosis confirmed by duplex ultrasonography;
- administration of anticoagulant therapy according to accepted clinical approaches;
- availability for one-year clinical follow-up.

The exclusion criteria were:

- active malignant neoplasms;
- antiphospholipid syndrome;
- congenital or acquired high-risk thrombophilia;
- antithrombin III deficiency;
- hemophilia and other coagulopathies;
- idiopathic thrombosis with a high suspicion of occult malignancy;
- inability to undergo follow-up evaluation.

All patients underwent standard clinical and laboratory examinations. Duplex ultrasonography of the lower extremity veins was the primary method for confirming the diagnosis of deep vein thrombosis. According to clinical indications, contrast venography was performed in 5 (2.3 %) patients, and contrast-enhanced spiral computed tomography in 14 (6.5 %) patients.

According to the localization of the thrombotic process, the following segments were identified:

- calf-popliteal segment – 57 (26.3 %) patients;
- popliteal-femoral segment – 88 (40.6 %);
- femoral-iliac segment – 72 (33.2 %).

The duration of the disease before hospitalization was:

- 1–7 days – in 80 (36.9 %) patients;
- 8–14 days – in 54 (24.9 %);
- 15–21 days – in 47 (21.7 %);
- 22–28 days – in 36 (16.6 %) patients.

Depending on the anticoagulant therapy used, the patients were divided into two groups.

The conventional therapy group included 82 patients who, during the acute phase, received low-molecular-weight heparin – Enoxaparin sodium at a dose of 1 mg/kg administered subcutaneously twice daily, followed by transition to Warfarin. Warfarin therapy was dose-adjusted under the control of the international normalized ratio (INR), maintaining a therapeutic range of 2.0–3.0. Parenteral anticoagulation was continued for at least 5 days and until a stable therapeutic INR had been achieved.

The DOAC group consisted of 135 patients. Depending on the clinical situation, comorbidities, drug availability, and individual patient characteristics, the following agents were administered:

- Rivaroxaban – 72 (53.3 %);
- Dabigatran – 38 (28.1 %);
- Apixaban – 25 (18.5 %).

Rivaroxaban was prescribed at a dose of 15 mg twice daily for the first 21 days, followed by 20 mg once daily.

Apixaban was administered at a dose of 10 mg twice daily for the first 7 days, followed by 5 mg twice daily.

Dabigatran was prescribed after preliminary parenteral anticoagulation with low-molecular-weight heparin for at least 5 days at a dose of 150 mg twice daily.

The duration of the primary anticoagulant therapy in most patients was approximately 5 months, depending on the clinical situation and the individual risk of recurrence.

Background therapy in both groups included:

- compression therapy using class II–III compression garments;
- nonsteroidal anti-inflammatory drugs as needed;

- analgesics;
- venoactive agents.

Patients were followed for 12 months. Follow-up clinical and ultrasound examinations were performed at 3, 6, and 12 months after treatment initiation.

The primary study endpoints were:

- recurrence of deep vein thrombosis or other manifestations of venous thromboembolism within one year;
- the degree of venous segment recanalization after 3 months of treatment.

Recanalization was assessed by duplex ultrasonography as:

- complete;
- partial;
- absent.

Additionally, hemorrhagic complications, clinical tolerability of treatment, and mortality were evaluated.

Statistical analysis was performed using IBM SPSS Statistics 22.0. The normality of data distribution was assessed using the Shapiro–Wilk test. Quantitative variables were presented as mean ± standard deviation (M ± SD). Depending on the distribution pattern, comparisons of quantitative variables were performed using Student's t-test or the Mann–Whitney U test. Categorical variables were compared using Pearson's χ^2 test or Fisher's exact test. Differences were considered statistically significant at $p < 0.05$.

Results

The study groups were statistically comparable with respect to the main clinical and demographic characteristics (Table 1). No significant differences were identified between the conventional anticoagulant therapy group and the DOAC group regarding age, sex, duration of disease before hospitalization, localization of the thrombotic process, or stage of chronic venous disease (all $p > 0.05$).

After 3 months of treatment, partial recanalization of the venous segment predominated in both groups, whereas complete recanalization was observed in less than one-fifth of patients. The frequencies of complete, partial, and absent recanalization did not differ significantly between the conventional therapy and DOAC groups ($p = 0.839$) (Table 2).

Thus, in the majority of patients, complete or partial recanalization of the venous bed was observed after 3 months of treatment, regardless of the anticoagulant strategy selected.

During the 12-month follow-up period, recurrent venous thromboembolism occurred in 19 (8.8 %) patients. In the conventional therapy

Table 1. **Baseline characteristics of the study groups**

Parameter	Conventional therapy group (n = 82)	DOAC group (n = 135)
Men	37 (45.1 %)	59 (43.7 %)
Women	45 (54.9 %)	76 (56.3 %)
Age, years (M ± SD)	51.7 ± 9.1	50.4 ± 8.1
Duration of DVT before hospitalization, days		
1–7	29 (35.4 %)	51 (37.8 %)
8–14	22 (26.8 %)	32 (23.7 %)
15–21	19 (23.2 %)	28 (20.7 %)
22–28	12 (14.6 %)	24 (17.8 %)
Localization of DVT		
Calf-popliteal segment	21 (25.6 %)	36 (26.7 %)
Popliteal-femoral segment	33 (40.2 %)	55 (40.7 %)
Femoral-iliac segment	28 (34.1 %)	44 (32.6 %)
Chronic venous disease		
C0	6 (7.3 %)	4 (3.0 %)
C1	10 (12.2 %)	10 (7.4 %)
C2	17 (20.7 %)	35 (25.9 %)
C3	16 (19.5 %)	41 (30.4 %)
C4	13 (15.9 %)	15 (11.1 %)
C5	10 (12.2 %)	10 (7.4 %)
C6	10 (12.2 %)	20 (14.8 %)

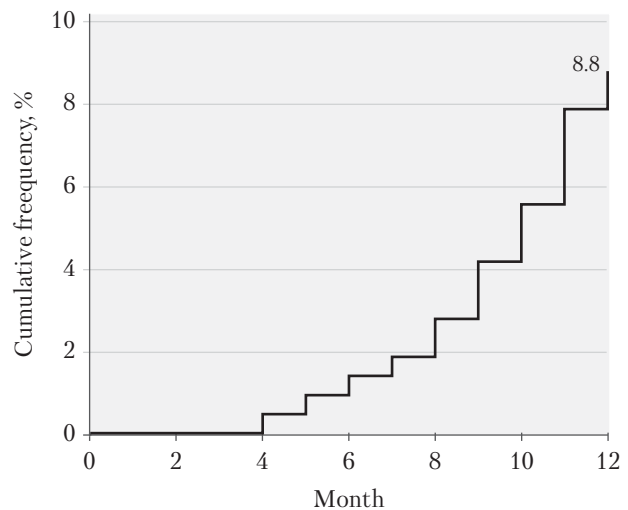
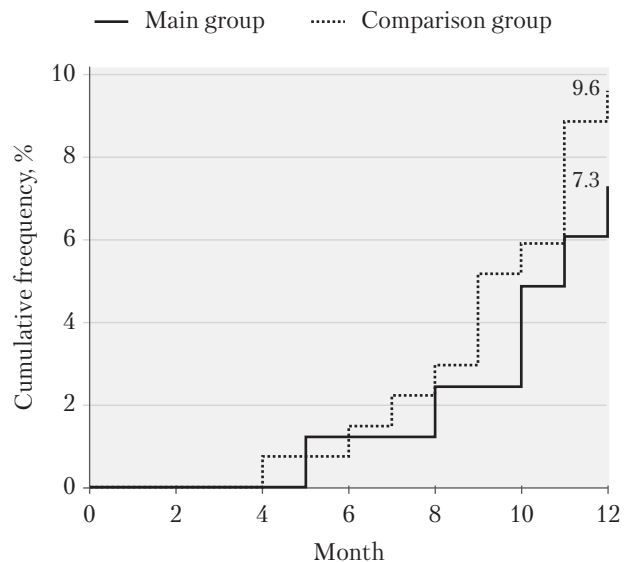
All p > 0.05.

Table 2. **Degree of venous segment recanalization after 3 months of treatment**

Recanalization	Main group (n = 82)	Comparison group (n = 135)	Total (n = 217)
Complete	14 (17.1 %)	25 (18.5 %)	39 (18.0 %)
Partial	60 (73.2 %)	94 (69.6 %)	154 (71.0 %)
Absent	8 (9.8 %)	16 (11.9 %)	24 (11.1 %)

group, recurrent deep vein thrombosis was registered in 6 (7.3 %) patients, whereas in the DOAC group, recurrence was observed in 13 (9.6 %) patients. The differences between the groups were not statistically significant ($p = 0.557$).

The cumulative incidence of recurrent deep vein thrombosis during the one-year follow-up period is presented in Fig. 1. Most recurrences were noted during the second half of the follow-up period, predominantly after the completion of the main course of anticoagulant therapy.

Figure 1. **Cumulative incidence of recurrent deep vein thrombosis during the 12-month follow-up period**Figure 2. **Cumulative incidence of recurrent deep vein thrombosis in the conventional therapy group and the DOAC group during the 12-month follow-up period**

Comparison of the cumulative recurrence rates between the study groups revealed no statistically significant differences (Fig. 2).

Analysis of the recurrence pattern within the DOAC group also demonstrated no significant association between recurrence rate and the specific anticoagulant agent used ($p = 0.945$) (Table 3).

It should be noted that this analysis was descriptive in nature due to the relatively small sample sizes of the individual DOAC subgroups.

Table 3. Frequency of recurrent DVT depending on the type of DOAC therapy

Drug	Recurrent DVT	No recurrence	Total
Rivaroxaban	7 (9.7%)	65 (90.3%)	72
Dabigatran	4 (10.5%)	34 (89.5%)	38
Apixaban	2 (8.0%)	23 (92.0%)	25
Total	13 (9.6%)	122 (90.4%)	135

During treatment and follow-up, no major hemorrhagic complications, fatal bleeding events, or deaths directly associated with anticoagulant therapy were registered. No clinically significant differences in treatment tolerability were identified between the groups.

The findings indicate that both conventional anticoagulant therapy and DOACs demonstrated comparable clinical efficacy in the treatment of acute deep vein thrombosis of the lower extremities in real-world clinical practice. Specifically, the rates of venous recanalization and recurrent venous thromboembolism did not differ significantly between the study groups.

Discussion

The results indicate that conventional anticoagulant therapy with low-molecular-weight heparin and Warfarin demonstrates clinical efficacy comparable to that of modern DOACs in treating acute deep vein thrombosis of the lower extremities. The majority of patients exhibited complete or partial recanalization of the affected venous segment after 3 months of treatment, while the rate of recurrent venous thromboembolism during the one-year follow-up period did not differ significantly between the study groups.

The modern concept of venous thromboembolism management is based on three main phases of anticoagulant therapy: the initial phase, the primary treatment phase, and secondary prevention [30]. Treatment goals include preventing thrombus progression and pulmonary embolism, as well as reducing the risk of recurrent venous thromboembolism and post-thrombotic syndrome. At the same time, prolongation of anticoagulant therapy is inevitably associated with an increased risk of hemorrhagic complications, which necessitates a continuous search for the optimal balance between treatment efficacy and safety [7, 15, 16].

In this study, the overall recurrence rate of venous thromboembolism during the one-year follow-up

period was 8.8 %, which is somewhat higher than the rates reported in large randomized trials and meta-analyses. In particular, M. R. Aryal et al. reported recurrence rates of 1.14 % in the Apixaban group and 1.35 % in the Rivaroxaban group over 6 months in a meta-analysis of more than 24,000 patients [2]. Similarly, X. Wang et al. found that DOAC administration was not associated with an increased risk of recurrent venous thromboembolism compared with conventional therapy [41].

The higher recurrence rate observed in this study may be explained by several factors. First, the study reflects real-world clinical practice, in which patients exhibit substantial clinical heterogeneity, variable time to hospitalization, and multiple comorbidities. Second, over 60 % of patients were hospitalized more than 7 days after disease onset, which may potentially be associated with a greater thrombotic burden and a lower potential for early recanalization. Third, the duration of primary anticoagulant therapy in most cases was approximately 5 months, whereas some contemporary recommendations support extended anticoagulant treatment in patients at high risk of recurrence.

Recent research has increasingly focused on extended anticoagulant therapy. In the RENOVE study by F. Couturaud et al., which included patients at high risk of recurrent venous thromboembolism, a low rate of recurrent thrombotic events was demonstrated with both full-dose and reduced-dose DOAC regimens [10]. At the same time, dose reduction was associated with a significant decrease in the incidence of clinically relevant bleeding [12, 29]. These findings support the current trend toward individualized anticoagulant therapy duration and intensity, balancing the risks of recurrence and hemorrhagic complications.

An equally important issue is the selection of a specific agent within the DOAC class. In our study, no statistically significant differences in the recurrence rate of venous thromboembolism were identified among Rivaroxaban, Dabigatran, and Apixaban. Similar results were demonstrated in the meta-analysis by Liu et al., which showed comparable efficacy of different DOACs in preventing recurrent venous thromboembolism [24]. Nevertheless, several studies suggest a potentially more favorable safety profile of apixaban. In particular, M. R. Aryal et al. reported a significantly lower incidence of major and clinically relevant non-major bleeding in patients treated with apixaban compared with rivaroxaban [2]. Similar conclusions were also presented in the meta-analysis by D. Fredman et al. [15].

No major hemorrhagic complications were recorded in this study. This outcome may be related

to careful patient selection, exclusion of patients at high risk of bleeding, the relatively small sample size, and the specific features of the retrospective study design. Nevertheless, the results are generally consistent with current recommendations, which indicate that DOACs have a more favorable safety profile than VKAs [1, 6, 26, 33, 38, 44].

The contemporary literature continues to debate optimal management strategies for distal deep vein thrombosis. Historically, some authors have advocated for serial imaging surveillance without anticoagulation in patients with isolated distal thrombosis [4, 14, 22]. However, current systematic reviews and clinical guidelines demonstrate the benefits of anticoagulant therapy in these patients, particularly when symptomatic disease or risk factors for thrombus progression are present [20, 21, 32]. Therefore, patients with calf-popliteal deep vein thrombosis were included in this study and received standard anticoagulant therapy.

The study results reflect real-world clinical practice, where the choice of anticoagulant agent often depends not only on clinical guidelines but also on comorbidities, renal function, bleeding risk, patient adherence, drug availability, and economic factors. In this context, the findings have important practical implications, demonstrating the effective use of both conventional therapy and DOACs across a broad spectrum of clinical situations.

This study has several limitations. First, the retrospective single-center design and absence of randomization may introduce selection bias. In addition, the choice of a specific DOAC was not standardized and depended on clinical circumstances and drug availability. The relatively small number of patients in individual DOAC subgroups limits the statistical power of intragroup comparisons. Furthermore, the study did not include a systematic assessment of post-thrombotic syndrome, quality of life, or treatment adherence, which could have provided additional information regarding long-term therapy outcomes.

Despite these limitations, the results of this study confirm the contemporary literature data on the comparable efficacy of conventional anticoagulant therapy and DOACs in the treatment of acute deep vein thrombosis of the lower extremities. The absence of statistically significant differences in venous thromboembolism recurrence rates between the study groups supports the consideration of DOACs as an effective and safe alternative to Warfarin in routine clinical practice.

Conclusions

Conventional anticoagulant therapy using low-molecular-weight heparin and Warfarin, as well as direct oral anticoagulants, demonstrated comparable clinical efficacy in the treatment of acute deep vein thrombosis of the lower extremities: complete or partial venous recanalization after 3 months was achieved in 89.0% of patients, with no statistically significant difference between the groups ($p = 0.839$).

The recurrence rate of venous thromboembolism during the 12-month follow-up period was 8.8% and did not differ significantly between the conventional therapy group (7.3%) and the DOAC group (9.6%) ($p = 0.557$). No significant differences in recurrence rates were identified among individual DOAC agents.

The absence of major hemorrhagic complications and deaths directly associated with anticoagulant therapy indicates a satisfactory safety profile of both conventional anticoagulant therapy and direct oral anticoagulants in the treatment of acute deep vein thrombosis of the lower extremities in real-world clinical practice.

DECLARATION OF INTERESTS

The authors declare no conflict of interest.

Funding. This study was conducted in accordance with the research work plan of the Department of Surgery with a Course of Emergency and Vascular Surgery at Bogomolets National Medical University.

AUTHORS CONTRIBUTIONS

D. S. Myrhorodskyyi: concept and design of the study, data collection and analysis, statistical analysis, manuscript drafting; A. O. Burka: critical review.

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Однорічні результати лікування гострих венозних тромбозів нижніх кінцівок

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Тромбоз глибоких вен нижніх кінцівок залишається однією з провідних причин венозної тромбоемболії та асоціюється з ризиком тромбоемболії легеневої артерії, посттромботичного синдрому й рецидиву захворювання. У сучасній клінічній практиці прямі пероральні антикоагулянти (ППАК) розглядають як альтернативу традиційній антикоагулянтній терапії із застосуванням низькомолекулярного гепарину та варфарину. Однак результати їхнього використання в умовах реальної клінічної практики потребують подальшого вивчення.

Мета — оцінити результати лікування гострого тромбозу глибоких вен нижніх кінцівок у пацієнтів, які отримували традиційну антикоагулянтну терапію із застосуванням низькомолекулярного гепарину та варфарину, порівняно з пацієнтами, які отримували прямі пероральні антикоагулянти, за показниками реканалізації, частоти рецидиву венозної тромбоемболії та безпечності лікування в умовах реальної клінічної практики.

Матеріали та методи. Проведено ретроспективне одноцентрове порівняльне когортне дослідження результатів лікування 217 пацієнтів із гострим тромбозом глибоких вен нижніх кінцівок, які перебували на лікуванні в 2020—2025 рр. У групі традиційної терапії було 82 пацієнти, які отримували низькомолекулярний гепарин із подальшим переходом на варфарин, у групі ППАК — 135 пацієнтів, які отримували ривароксабан, дабігатран або апіксабан. Основними кінцевими точками були частота реканалізації венозного сегмента та рецидив венозної тромбоемболії протягом 12 міс спостереження.

Результати. Через 3 міс лікування повна реканалізація венозного сегмента досягнута в 18,0 % пацієнтів, часткова — у 71,0 %, відсутність реканалізації спостерігалась у 11,1 % хворих. Статистично значущої різниці між групами за ступенем реканалізації не виявлено ($p=0,839$). Частота рецидиву венозної тромбоемболії протягом року становила 8,8%: 7,3 % у групі традиційної терапії та 9,6 % у групі ППАК ($p=0,557$). Не встановлено вірогідної різниці між препаратами в групі ППАК за частотою рецидиву. Великих геморагічних ускладнень або летальних наслідків, пов'язаних з антикоагулянтною терапією, не зареєстровано.

Висновки. Традиційна антикоагулянтна терапія із застосуванням низькомолекулярного гепарину та варфарину й прямі пероральні антикоагулянти продемонстрували порівнянну клінічну ефективність у лікуванні гострого тромбозу глибоких вен нижніх кінцівок: через 3 міс повна або часткова реканалізація венозного сегмента досягнута в 89,0 % пацієнтів без статистично значущої різниці між групами ($p=0,839$). Відсутність великих геморагічних ускладнень і летальних наслідків, пов'язаних з антикоагулянтною терапією, свідчить про задовільний профіль безпечності як традиційної антикоагулянтної терапії, так і прямих пероральних антикоагулянтів у лікуванні гострого тромбозу глибоких вен нижніх кінцівок в умовах реальної клінічної практики.

Ключові слова: тромбоз глибоких вен, венозна тромбоемболія, прямі пероральні антикоагулянти, варфарин, ривароксабан, апіксабан, дабігатран, реканалізація, рецидив тромбозу глибоких вен.

FOR CITATION

Myrhorodskyyi DS, Burka AO. One-year treatment outcomes in patients with lower extremity deep vein thrombosis. *General Surgery (Ukraine)*. 2026;(2):22-29. <http://doi.org/10.30978/GS-2026-2-22>.