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Влияние сроков стентирования на состояние клапанного аппарата вен нижних конечностей, частоту и тяжесть развития посттромботической болезни

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АННОТАЦИЯ

Актуальность. Острый тромбоз глубоких вен (ТГВ) нижних конечностей (НК) является жизнеугрожающим состоянием, сопровождающимся высокими показателями инвалидизации среди лиц трудоспособного возраста. Несмотря на раннее выявление ТГВ и применение рекомендуемой антитромботической терапии, неизбежно происходит повреждение венозной стенки, развитие клапанного рефлюкса и посттромботической болезни (ПТБ). Клиническая картина ПТБ становится очевидной после появления несостоятельности клапанов, что приводит к возникновению вертикального венозного рефлюкса и хронической венозной гипертензии. Своевременное устранение венозной обструкции может позволить сохранить функциональность клапанных структур, что в последующем будет способствовать снижению частоты и тяжести ПТБ.

Цель. Оценить влияние сроков стентирования на состояние клапанного аппарата, частоту и тяжесть развития ПТБ у пациентов с острым ТГВ НК.

Материалы и методы. В проспективное интервенционное исследование включили 49 пациентов с острым илиофemorальным тромбозом. После селективного тромболитика 25 пациентам выполнили раннее (до 7 дней), 24 — отсроченное (7–30 дней) стентирование. Частоту развития и степень тяжести ПТБ оценивали с помощью шкалы *Villalta* через 3, 6 и 12 месяцев. Влияние лечения на состояние клапанного аппарата НК оценивали через 12 месяцев. При ультразвуковом исследовании оценивали рефлюкс по балльной системе.

Результаты. Через 12 месяцев у 2 (8%), 13 (52%) и 10 (40%) пациентов, перенесших отсроченное стентирование, развилась соответственно тяжелая, средней тяжести и легкая ПТБ. В группе раннего стентирования у 6 (25%) пациентов симптоматика ПТБ отсутствовала, у 15 (62,5%) и 3 (12,5%) развилась ПТБ соответственно легкой и средней степени ($p = 0,0005$). Через 12 месяцев, в группе раннего стентирования отсутствие рефлюкса было зарегистрировано у 6 (25%) пациентов, у 4 (17%) был рефлюкс клапанов в бедренном, у 14 (58%) в подколенном сегменте. В группе отсроченного стентирования у 12 (48%) пациентов выявлена клапанная недостаточность обоих сегментов, у 4 (16%) и 9 (36%) пациентов клапанный аппарат бедренных и подколенной вен был сохранен; пациентов без рефлюкса в обоих сегментах не было. Результаты лечения по этому показателю оказались лучше, если было выполнено раннее стентирование ($p = 0,0005$).

Заключение. Раннее стентирование после селективного тромболитика у пациентов с проксимальным ТГВ НК приводит к снижению частоты развития и выраженности симптоматики ПТБ, позволяет снизить частоту развития рефлюкса в глубоких венах.

Ключевые слова: раннее стентирование; посттромботическая болезнь; шкала *Villalta*; клапанный аппарат

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Influence of Timing of Stenting on Condition of Venous Valves of Lower Extremities, Frequency and Severity of Development of Post-Thrombotic Disease

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ABSTRACT

INTRODUCTION: Acute deep vein thrombosis (DVT) of the lower extremities (LE) is a life-threatening condition, accompanied by high rates of disability among people of working age. Despite early detection of DVT and the use of recommended antithrombotic therapy, damage to the venous wall, development of valvular reflux and post-thrombotic disease (PTD) inevitably occur. The clinical picture of PTD becomes evident after the development of valve incompetence, which leads to vertical venous reflux and chronic venous hypertension. Timely elimination of venous obstruction can preserve the functionality of valve structures, which will subsequently help reduce the frequency and severity of PTD.

AIM: To evaluate the impact of the timing of stenting on the condition of the venous valves, the frequency and severity of the development of PTD in patients with acute DVT of LE.

MATERIALS AND METHODS: A prospective interventional study included 49 patients with acute iliofemoral thrombosis. After selective thrombolysis, 25 patients underwent early (within 7 days) and 24 patients underwent delayed (7–30 days) stenting. The incidence and severity of PTD was assessed on the Villalta scale at 3, 6 and 12 months. The effect of treatment on the condition of the venous valves of the LE was assessed at 12 months. On ultrasound examination, reflux was assessed using a scoring system.

RESULTS: At 12 months, 2 (8%), 13 (52%), and 10 (40%) patients who underwent delayed stenting, developed severe, moderate, or mild PTD, respectively. In the early stenting group, 6 (25%) patients had no symptoms of PTD, 15 (62.5%) and 3 (12.5%) developed mild and moderate PTD, respectively ($p = 0.0005$). At 12 months, in the early stenting group, the absence of reflux was recorded in 6 (25%) patients, 4 (17%) patients had valve reflux in the femoral segment, and 14 (58%) in the popliteal segment. In the delayed stenting group, valvular incompetence of both segments was detected in 12 (48%) patients; in 4 (16%) and 9 (36%) patients, the valves of the femoral and popliteal veins were preserved; there were no patients without reflux in both segments. Treatment results for this indicator were better if early stenting was performed ($p = 0.0005$).

CONCLUSION: Early stenting after selective thrombolysis in patients with proximal DVT of LE leads to a decrease in the incidence and severity of symptoms of PTD, and can reduce the incidence of reflux in the deep veins.

Keywords: *early stenting; post-thrombotic disease; Villalta scale; valve apparatus*

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LIST OF ABBREVIATIONS

DVT — deep vein thrombosis
LE — lower extremities
PTD — post-thrombotic disease
SCDT — selective catheter-directed thrombolysis
US — ultraviolet examination

INTRODUCTION

The main chronic complication of acute deep vein thrombosis (DVT) of the lower extremities (LE) is post-thrombotic disease (PTD) [1]. Even early identified and timely treated DVT of LE almost always leads to the irreversible alterations of the venous wall and of valve structures. PTD is manifested by edema and heaviness in the extremity, trophic disorders alternated with venous claudication. Clinical manifestations of PTD are most pronounced in the development of post-thrombotic valvular incompetence leading to vertical venous reflux and chronic venous hypertension.

The severity of PTD is usually determined on the Villalta scale [2]. The most severe types of PTD develop after iliofemoral thrombosis, which is also an important predictor of recurrent DVT [3–7]. The iliofemoral DVT accounts for about 20% of all DVT of LE with development of symptomatic PTD in 66% of cases and venous trophic ulcers in 10%–15% [8]. Along with life style modification, elastic compression stockings and phlebotropic agents

are widely used in treatment of PTD [9, 10]. A promising surgical direction in the treatment of DVT is catheter-directed thrombolysis, which at different times can be supplemented with stenting of the iliac veins, which reduces the risk of developing severe PTD [11–14].

The **aim** of this study to evaluate the effect of the timing of stenting on the condition of the valve apparatus, the frequency and severity of the development of post-thrombotic disease in patients with acute deep vein thrombosis of the lower extremities.

MATERIALS AND METHODS

The study was of prospective intervention design. For the primary analysis, 65 patients with proximal venous thrombosis were selected. Later, 7 patients refused to participate in the study. During history taking, 9 patients were excluded because of non-correspondence to inclusion criteria. In result, 49 patients were included in the study (Figure 1).

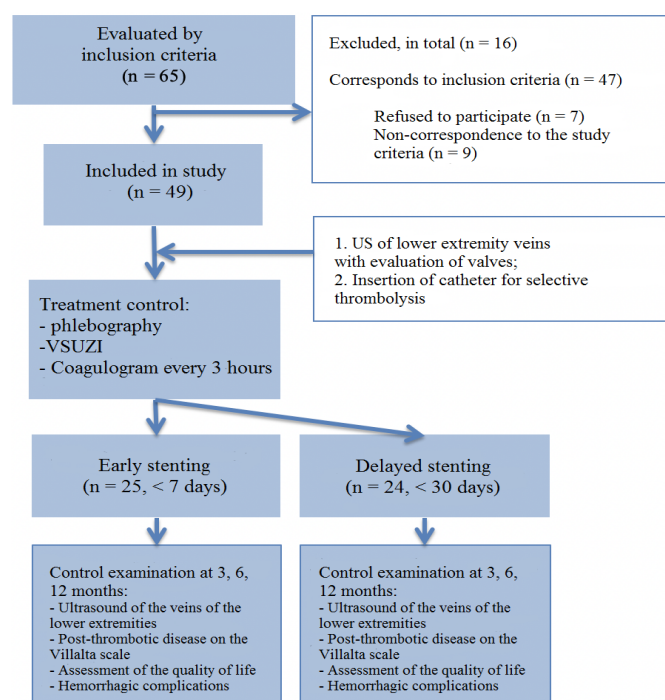


Fig. 1. Block-diagram of the study.

Note: US — ultrasound examination.

Inclusion criteria: acute proximal DVT of LE identified by US, edema and pain in the affected extremity, age of thrombosis up to 14 days, age of patient ≥ 18 years, signing of the informed consent to participate in the study.

Non-inclusion criteria: a history of allergic reaction to an iodine contrast agent, recent surgical interventions, pregnancy, pulmonary embolism, chronic renal failure, past DVT of LE, body mass index ≥ 35 kg/m², trophic venous ulcers, documented cancer process, high risks of bleeding on the HAS-BLED scale, a history of stroke, impossibility to come to follow-up examinations.

Study groups. After inclusion in the study, the patient underwent a selective catheter-directed thrombolysis (SCDT). After completion of the thrombolysis, early (up to 7 days) or delayed stenting (7–30 days) was conducted.

Assessment criteria. The frequency of detection and severity of symptoms of PTD were assessed on the Villalta scale at 3, 6 and 12 months. The condition of the valves of the femoral and popliteal veins was assessed at 12 months. The valves were assessed using a scoring system, in which, in case of absence of reflux in the studied segment, a point was added, and if reflux was detected, no point was added. The maximum score was 2.

Ethics. The study was approved by the Local Ethics Committee at Clinical Hospital No. 1 of Administrative Department of the President of the Russian Federation (Protocol No. 3/d of November 30, 2021).

Statistical analysis. Comparison of shares in the groups was carried out using the chi-square test (χ^2). Comparisons of Villalta scores were assessed using Mann–Whitney test. The severity of PTD depending on the state of the valve apparatus was compared using Kruskal–Wallis test. The influence of the chosen

treatment strategy on the condition of the valvular apparatus was assessed using Mann–Whitney test.

RESULTS

The frequency of development of PTD and severity of its symptoms throughout a year after acute DVT of LE and the conducted treatment are presented in Table 1. The average scores on the Villalta scale are presented in Figure 2.

The analysis of the state of the valves after treatment revealed that in the *early* stenting group, by the end of the observation period (12 months), 18 patients (75%) had intact valves in at least one segment. Differences in the scoring (Me (Q1–Q3)) of the valve conditions showed that it was statistically significantly better in this group 1.0 (1.0–2.0) versus 1.0 (0–1.0), $p = 0.0005$.

Also, in the *early* stenting group, in 6 (25%) patients, the valves of both the femoral and popliteal segments remained intact. In the *delayed* stenting group, reflux was recorded in the valves of the femoral and popliteal segment in 12 (48%) patients, reflux in one of the segments was recorded in 4 (16%) and 9 (36%) patients. There were no patients with intact valves of both segments after *delayed* stenting.

When analyzing the incidence and severity of PTD symptoms at 12 months, in 6 (13%) patients, the valvular apparatus of both segments functioned, PTD symptoms were absent. In 25 (51%) patients, in the absence of reflux in at least one valve segment, mild PTD developed. Sixteen (32%) and 2 (4%) patients developed moderate and severe PTD, which was associated with reflux in both segments. When analyzing the dependence of factors, statistically significant differences were found ($p < 0.001$).

Table 1. Frequency of Development and Severity of Symptoms (n (%)) of Post-Thrombotic Disease at 3 Months, 6 Months and 12 Months

| Assessment Time | Severity of Symptoms on Villalta Scale | Delayed stenting | Early stenting | p |
|-----------------|--|------------------|----------------|--------|
| n | | 24 | 25 | |
| 3 Months | Absent | 5 (20) | 12 (50) | 0.052 |
| | Mild | 19 (76) | 12 (50) | |
| | Moderate | 1 (4) | 0 | |
| | Severe | 0 | 0 | |
| 6 Months | Absent | 0 | 6 (25) | 0.001 |
| | Mild | 12 (48) | 15 (63) | |
| | Moderate | 13 (52) | 3 (13) | |
| | Severe | 0 | 0 | |
| 12 Months | Absent | 0 | 6 (25) | 0.0005 |
| | Mild | 10 (40) | 15 (62.5) | |
| | Moderate | 13 (52) | 3 (12.5) | |
| | Severe | 2 (8) | 0 | |

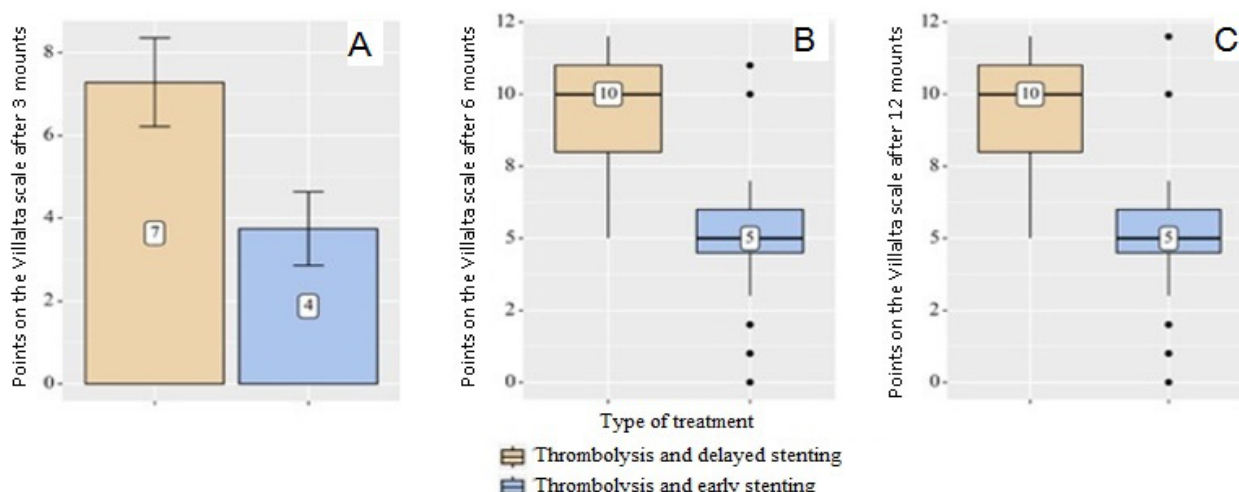


Fig. 2. Average score on the Villalta scale in the groups at 3 months (A), 6 months (B) и 12 (C) months of follow-up.

Table 2. Ultraviolet Examination Results of Lower Extremity Veins at 12 Months Depending on Severity of Post-Thrombotic Disease

| Symptoms of Post-Thrombotic Disease | n | Ultraviolet Examination Results, points | | p |
|-------------------------------------|----|---|---------|---------|
| | | Me | Q1–Q3 | |
| Absent | 6 | 2.0 | 2.0–2.0 | < 0.001 |
| Mild | 25 | 1.0 | 1.0–2.0 | 0.0001 |
| Moderate | 16 | 0.0 | 0.0–1.0 | 0.004 |
| Severe | 2 | 0.0 | 0.0–0.0 | 0.008 |

DISCUSSION

As a result of study, it was found that *early* stenting permits to reduce the rate of occurrence and severity of PTD symptoms, among other things, due to preservation of the valvular apparatus of the lower extremities. *Delayed* stenting was associated with the development of valvular reflux in the femoral and popliteal segments, which, in turn, was associated with increase in the frequency of severe and moderate PTD.

The highest quality evidence base regarding PTD in patients who have suffered acute DVT of LE was obtained in two multicenter randomized controlled trials: CaVenT and ATTRACT.

The CaVenT study showed improvement of the patency of the iliofemoral segment (65.9% vs. 47.4%) and lower frequency of development of PTD (41.1% versus 55.6%) in application of SCDL in comparison with patients who received only conservative therapy. These results persisted for 24 months after treatment and remained

such within 5 years of follow-up [13]. However, SCDT did not improve the quality of life in the long term [14]. On the other hand, in ATTRACT sub analysis of iliofemoral thrombosis, there were no differences in the frequency of development of PTD in the 6–24-month period between the groups with isolated anticoagulant therapy or SCDT. Analysis of the additional evaluation criteria showed the advantages of SCDT: in the SCDT group, fewer cases of moderate and severe PTD were recorded (18% and 28%, $p = 0.021$; 9% and 15%; $p = 0.048$, respectively). Besides, SCDT led to a significant reduction of pain and edema of LE within 30 days, reduction of severity of PTD and significant improvement of the quality of life [15].

CaVenT and ATTRACT studies were criticized for a *low frequency of stent implantation*, which was not an obligatory part of the study protocol. Only 16.7% and 28.0% of patients in the comparison groups (39.0% with proximal DVT) had stents implanted.

Studies on the influence of the state of the valves on the development of PTD were carried out as early as

in 1979 by K C Shull and A N Nicolaidis, and in 1995 B E Johnson demonstrated that the *development of valvular incompetence of the LE in a severe form observed in most cases, contributes to the development of PTD* [16, 17]. Despite a relatively long time of studying the problem, the influence of endovascular treatment methods and the timing of their implementation on the condition of the valves has not yet been assessed. We have shown that the early stenting has undoubted advantages over delayed stenting in patients after catheter-directed thrombolysis for proximal venous thrombosis [18, 19].

Limitations. The study has a non-randomized design and a small sample size.

CONCLUSION

Early stenting after selective catheter-directed thrombolysis in patients with iliofemoral deep vein thrombosis permits to reduce the frequency of development and severity of manifestations of post-thrombotic disease. Selective catheter-directed thrombolysis with early elimination of residual obstruction helps preserve the valvular apparatus of the lower extremities in at least one segment, which contributes to reduction of the frequency and severity of the post-thrombotic disease.

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