



Open Thrombectomy in Acute Iliofemoral Venous Thrombosis

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Abstract

Background: To assess the effectiveness of open thrombectomy in acute iliofemoral venous thrombosis.

Methods: Between January 2012 and December 2016, a total of 37 patients underwent transfemoral venous thrombectomy in acute iliofemoral venous thrombosis. Six patients underwent a venous hybrid operation comprising balloon-catheter thrombectomy and stenting of residual stenosis of iliac veins. The control group consists of 24 patients who received standard anticoagulant therapy. The results were evaluated by duplex ultrasound. The assessment of clinical effectiveness was made with Venous Clinical Severity Score (VCSS) and Clinical- Etiologic - Anatomic - Pathophysiologic (CEAP) classification.

Results: Patency of iliofemoral segment at 6 months of monitoring after thrombectomy was reported in 92% of cases. Meanwhile, the recanalization of iliofemoral segment was registered only in 21% (5/24; $X^2=31$, $P=0.00001$) of patients, who had anticoagulant therapy. Recanalization of femoropopliteal veins at 6 months after the thrombectomy was reported in 70% cases (23/33). The median preoperative VCSS was 7, which dropped to 2 at 6 months ($P=0.002$).

The cumulative patency rate of iliofemoral veins at 36 months was 86%; 38% (8/21) of surgical patients had normal venous function of distal popliteal and tibial veins in conformity with the results of duplex scanning at three years. According to CEAP classification, 90% (19/21) of patients had no or mild symptoms of postthrombotic syndrome (PTS) after thrombectomy.

Conclusion: In accordance with selective indications, open thrombectomy in iliofemoral venous thrombosis with using current methods of deep veins patency reconstruction increases the effectiveness of treatment of this severe pathology and prevent from progression of PTS.

Keywords: Acute Iliofemoral Venous Thrombosis; Open Thrombectomy; Stenting; Recanalization; Duplex Ultrasound

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Introduction

Deep venous thrombosis (DVT) of lower extremities is one of the most widespread vascular diseases; from 160 to 300 cases per 100000 of general population occur annually [1,2]. Pulmonary embolism (PE) as a complication of DVT is the reason of high mortality rate that is about 20-30% [3].

The treatment of DVT has two main goals. During an acute period, it is a prevention of complications such as PE and phlegmasia cerulea dolens, in the long-term - minimization of postthrombotic syndrome (PTS), that is 40-60% of patients. One in ten patients has trophic ulcer that results in disability [4,5]. The most complicated disturbances of venous hemodynamics occur when iliofemoral veins are damaged [6,7].

The traditional method of treatment of acute DVT is anticoagulant therapy that is based on unfractionated and low-molecular-weight heparins, vitamin K antagonist and new oral anticoagulants. However, these medications have no thrombolytic effect but they prevent from thrombus prolongation, recurrence of thrombosis and they let the risk of PE development decrease [8,9].

Aggressive methods of DVT treatment have been developed in recent years. This is regional catheter-directed and pharmacomechanical thrombolysis. The advantage of this approach is shown in randomized trials CaVenT (Catheter-directed Venous thrombolysis in acute iliofemoral vein Thrombosis) and in the intermediate results of ATTRACT (Acute venous Thrombosis: Thrombus

Table 1: Characteristics of operated patients (n=37).

Age	55.6±12.3
Sex	Male/female 21/16
Localisation of DVT	Left/right 25/12
Thrombus age (from onset of symptoms of disease)	6.2±3.1 days (<10 days)
Extent of DVT	Iliofemoral segment 100%
	In addition: vena cava 5 %
	In addition: femoropopliteal segment 95%
	In addition: calf veins 61%

Removal with Adjunctive Catheter-directed Thrombolysis), which was finished at the end of 2016 [10,11]. If there are any contraindications to thrombolytic therapy, new possibilities can arise for open thrombectomy from deep veins. When this active strategy of DVT treatment is used, the risk of residual obstruction, venous valves damage with reflux decreases. As a result, it prevents from severe complications of PTS [12,13]. The aim of this study is to assess the effectiveness of open thrombectomy in acute iliofemoral venous thrombosis.

Materials and Methods

Between January 2012 and December 2016, a total of 37 patients underwent transfemoral venous thrombectomy in acute iliofemoral venous thrombosis. 29 patients had occlusive thrombosis, 8 patients had floating thrombosis. Isolated thrombosis was registered in two cases. Iliofemoral thrombosis with total occlusions of deep veins and phlegmasia cerulea dolens was observed in one case.

The characteristics of patients are represented in (Table 1). In the control group there were 24 patients with iliofemoral thrombosis (9 men, 15 women, mean age is 54.1±14.2) that received standard anticoagulant therapy for 6 months. Laboratory methods included the D-dimer level validation, thrombophilia markers evaluation. The diagnostic methods included duplex ultrasound (LOGIQ E9, GE Medical Systems, Wauwatosa, WI, USA), magnetic resonance (GE, Signa Horizont, Hdxt 1.5 T, USA) and multislice computed tomography venography (AQUILION 64, Toshiba, Japan), contrast tomography venography (INNOVA 3100, GE, USA), perfusion lung scintigraphy (single-photon emission tomograph Millenium MPR, GE, USA) under suspicion of PE. The system of examination included computer of chest, abdominal and pelvic organs scans.

The main indications for thrombectomy were symptomatic iliofemoral venous thrombosis (occlusive and floating), isolated thrombosis; extended to deep veins of lower extremity and inferior vena cava; total thrombosis of deep veins with phlegmasia cerulea dolens. Contraindications for thrombolytic therapy that are connected with a high risk of bleeding; impossibility or ineffectiveness of this therapy; no more than 10 days from the onset of the first symptoms; the absence of severe accompanying pathology were also the indications for thrombectomy. General characteristics of surgical thrombectomy types and endovascular procedures are presented in (Table 2). The results were controlled with duplex scanning. The assessment of the clinical effectiveness of operations was made with VCSS and CEAP classification.

Surgery technique

The operations were carried out in standardized fashion under general anesthesia. Proximal common iliac vein (CIV) was approached

Table 2: Types of surgical thrombectomy and endovascular procedures.

Transfemoral thrombectomy	n=37
Transfemoral thrombectomy + thrombectomy from IVC	n=2
Transfemoral thrombectomy + stenting CIV	n=6
Total thrombectomy in phlegmasia cerulea dolens	n=1
Regional catheter – directed thrombolysis	n=32
Retrievable cava-filter placement	n=6



Figure 1(A): Exposure of proximal CIV from retroperitoneal approach. The abbreviations presented in the figures are explained in the text.

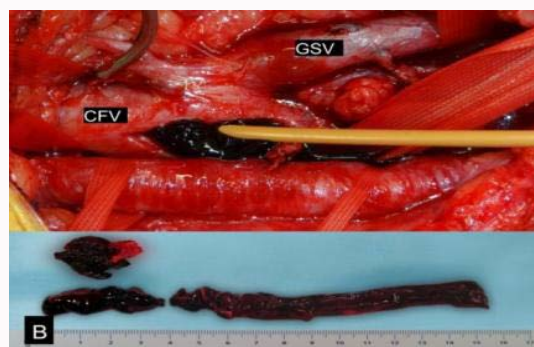


Figure 1(B): Longitudinal venotomy of the CFV, CFV and the iliac veins were then cleared of thrombus with the help of Fogarty catheter; bottom of the figure - fragments of excluded thrombi.



Figure 1(C): CFV lumen after thrombectomy.

through a short incision in pararectal retroperitoneum area (Figure 1A). The common femoral vein (CFV), distal part of external iliac vein (EIV), deep femoral vein (DFV) and femoral vein (FV) were exposed, using a standard longitudinal inguinal incision. After unfractionated heparin intravenously injection (100 IU/kg) CFV with tributaries and CIV near of ilio caval confluence were taken on tourniquets. A longitudinal venotomy was placed on the anterior surface of the CFV and the iliac veins were then cleared of thrombus with the help of a Fogarty venous catheter 8F (Figure 1B). Great attention was paid to opening of orifice(s) DFV and GSV (Figure 1C). The venotomy

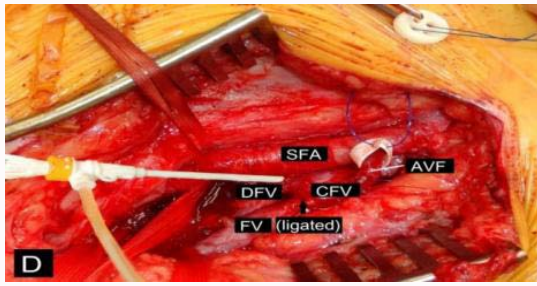


Figure 1(D): AVF between CFV and SFA wrapped in polytetrafluorethylene (PTFE) cuff, that is fixed with 2-0 Prolene suture. The ends of suture were excluded through perforations of sterile button which was placed on skin surface. The femoral vein is ligated by atraumatic absorbable suture 3-0 Vicryl distal to the profunda branches (arrow). The sheath was introduced between the sutures of CFV.

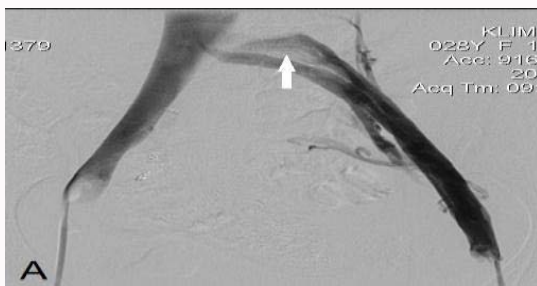


Figure 2(A): Intraoperative venogram of residual compression stenosis of left CIV after thrombectomy. "Bull's-Eye" sign, typical for CIV compression (arrow).



Figure 2(B): Balloon dilatation and stenting of residual stenosis of left CIV by Wallstent® 16x80 mm with complete restoration of its patency.

is closed with continuous suture (7-0 Prolene) and an arteriovenous fistula (AVF) created using the saphenous vein, anastomosing it end-to-side to the superficial femoral artery (SFA) (8-0 Prolene). AVF was wrapped with polytetrafluorethylene (PTFE) cuff, which was fixed with 2-0 Prolene suture. The ends of suture were excluded through perforations of sterile button which was placed either on skin surface or in subcutaneous tissue with marking the place near the wound. The femoral vein was ligated by atraumatic absorbable suture 3-0 Vicryl distal to the profunda branches or plicated with 2-3 longitudinal sutures (6-0 Prolene) (Figure 1D). The patency of iliac veins was verified by intraoperative ascending venography. In cases of residual thrombi or residual stenosis, for example, caused by an iliac spur, the iliac veins underwent angioplasty and stenting (Figure 2A, 2B). When thrombus spreads on IVC, the retroperitoneal approach was prolonged and open thrombectomy was performed from IVC. Postoperatively, all patients received full anticoagulation, first low-molecular-weight heparin (enoxaparin, nadroparin), and then with

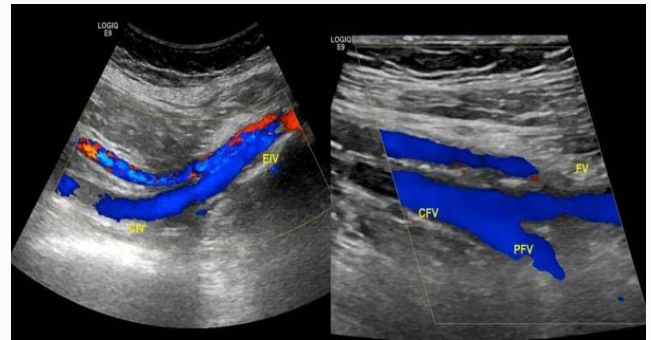


Figure 3: Scanograms of iliofemoral veins at 6 months after thrombectomy. CIV, EIV, CFV, DFV and FV are patent Recanalization of FV.

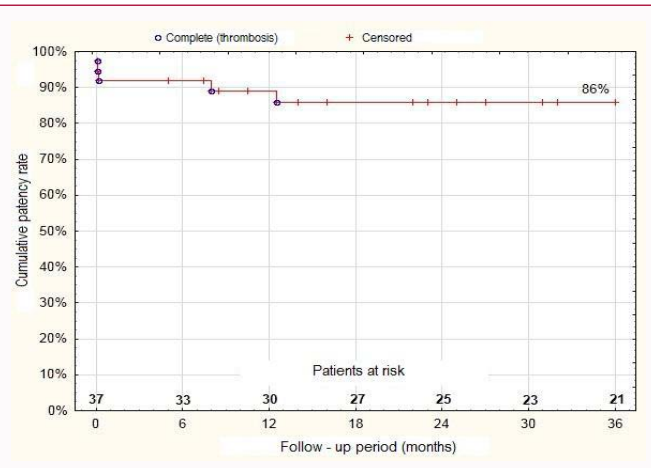


Figure 4: Cumulative patency rate of iliofemoral veins after thrombectomy (%).

rivaroxaban for six months.

Statistical analysis

Statistical analysis was performed using Statistical 10 (StatSoft, Tulsa, OK, USA). The clinical characteristics of patients are presented by methods of descriptive statistics. The data were expressed as mean ± SD values. The VCSS was compared using the Wilcoxon's test. Comparisons of categorical variables were performed with the χ^2 test. The assessment of cumulative patency was performed with Kaplan-Meier curve. A value of $P < 0.05$ was accepted as representing a significant difference.

Results

Thrombosis of the operated segment in early follow-up term was observed in three cases (8%). In two of three cases the reason of thrombosis was non-diagnosed compressive stenosis of left CIV (May-Thurner syndrome). Technical success of stenting amounts to 100%. Wound complications (transient lymphorrhoea) were registered in three cases. There was no pulmonary embolism (PE).

The AVFs were closed after three months under the control of duplex ultrasound. It consists in a distant elimination of fistula under ultrasound control by tightening polypropylene suture till Doppler signal from fistula disappears. This method is simple and reliable, and it doesn't require traumatic redo surgery. In 12 cases AVF has occluded spontaneously.

There was a patency of iliofemoral segment verified by duplex

Table 3: CEAP clinical stage in long-term period after thrombectomy.

C0a	n=9 (asymptomatic, without clinical signs of venous pathology)
C1a	n=6 (asymptomatic telangiectases and reticular veins)
C3a	n=4 (asymptomatic edema)
C3s	n=2 (symptomatic edema with pain syndrome)

ultrasound at 6 months after thrombectomy in 92% cases (Figure 3). Meanwhile, the patients who received a standard anticoagulant therapy, demonstrated the recanalization of iliofemoral veins in 21% of cases (5/24; $\chi^2=31$, $P=0.00001$). The recanalization of femoropopliteal veins at 6 months after the surgery were registered in 23 (70%) of 33 cases. The median preoperative VCSS was 7, which dropped to 2 at 6 months ($P=0.002$). There were two cases of rethromboses at different stages after the operation. The cumulative patency rate of iliofemoral veins at 36 months was 86% (Figure 4). 38% (8/21) of surgical patients had normal venous function of distal popliteal and tibial veins according to the results of duplex scanning at three years. The CEAP clinical stage is shown in (Table 3). Thus, there were no symptoms of PTS or they were mild in 90% of cases (19/21).

Discussion

The issue of surgical thrombectomy remains disputable until now. According to recommendations of medical societies and forums, the quality of evidence remains low [8,14,15]. However, when compared to systemic anticoagulation, which was performed in 10 trials and one of them was randomized, the meta-analysis of the open thrombectomy results in iliofemoral venous thrombosis demonstrated statistically a significant reduction in the risk of PTS development (RR, 0.68; 95% CI, 0.46–0.99) [13].

In Swedish randomized research, published in 1984, it was shown that at 6 months after thrombectomy, the symptoms of PTS were completely absent in 42% of cases, while after the standard anticoagulant therapy, it was only in 7%. Iliac veins patency in the surgical group amounted to 76%, in a group after conservative therapy – to 35%. Valves competence of femoropopliteal segment as compared to above-mentioned groups was 52% and 35% correspondingly. During the control research after 5 and 10 years, the correlation between vein patency and valves competence remained identical [16]. There were similar results in other researches [17–19]. Symptoms of PTS were absent or mild in 95% of patients [2]. Our results also correlated with the literature data.

In 2012, the clinical recommendations of the Society for Vascular Surgery and American Venous Forum were published, in which the experts suggest the strategy of early thrombus removal in selected patients meeting the following criteria: the first episode of acute iliofemoral deep venous thrombosis; symptoms < 14 days in duration; low risk of bleeding, and ambulatory with good capacity and an acceptable life expectancy (Grade 2C) [15]. The main preference is given to the percutaneous methods of treatment: catheter-directed and pharmacomechanical thrombolysis. In contraindications to thrombolysis, it is recommended to perform open venous thrombectomy. However, in some studies, terms for thrombectomy vary from 5–7 to 10 days [20,21]. It confirms the necessity of individual approach in the treatment of DVT.

At the present time, the open thrombectomy from deep veins of lower extremity is performed on selective indications. They are total deep vein thrombosis with the development of phlegmasia cerulea dolens and contraindications to thrombolytic therapy associated

with a high risk of bleeding in various pathologies (active internal bleeding, recent cerebrovascular accidents, malignant tumor, major trauma or surgery within 10 days, the age over 75, coagulopathy, thrombocytopenia or absolute endocarditis, intracardiac thrombosis, severe uncontrolled hypertension, pregnancy, septic thrombosis, allergy to thrombotic agents) [22,23]. According to the randomized trial CaVenT data, about 55% of patients had contraindications for thrombolytic therapy and 30% of them were candidates for surgical thrombectomy [10,22]. In our study, about 1/3 of patients had contraindications for thrombolysis.

A Comerota considers that results of further randomized trials will show that strategies of thrombus removal will be acknowledged as first-line therapy for patients with extensive venous thrombosis [24]. The current approach to technical performance of open thrombectomy from deep veins in iliofemoral thrombosis includes the removal of thrombus with venous Fogarty catheter under the control of balloon catheter, placed with the help of fluoroscopy in the inferior vena cava (IVC) proximal to the thrombus for the prophylaxis of intraoperative PE. It also consists in conduction of regional thrombolytic therapy; thrombectomy effectiveness control with angiography, intravascular ultrasound (IVUS) or ascending phlebography; removal of residual stenosis of iliac veins with angioplasty and stenting; creation of AVF [2,9,10,25,26]. In addition, when thrombectomy is combined with endovascular reconstruction, primary and secondary patency of iliofemoral segment amounts to 80% and 90% correspondingly [9]. Rethrombosis frequency after thrombectomy in patients with residual stenosis of iliac veins or IVC amounts to 72% [27]. It is confirmed by the fact that in our research the reason of early thrombosis in 2 out of 3 cases was undiagnosed May-Thurner syndrome. So, routine performance of intraoperative phlebography is considered as a justified procedure. Also, a key success factor was that the majority of patients were under observation, and it allowed controlling the treatment effectiveness.

We take into consideration some definite moments in choosing a surgical strategy. It is known that the initial development of thrombosis in calf deep veins is widespread and its clinical features are minimal. Manifestation of thrombosis develops in ascending thrombosis propagating to popliteal and femoral vein with maximal clinical indications during the prolongation of thrombus on common femoral and iliac veins. Consequently, sometimes it is difficult to identify the thrombus age localized in the infrainguinal segment. That is why we use total open thrombectomy only in case of phlegmasia cerulea dolens. Such surgery was successfully performed on one patient with complete symptoms relief. We perform thrombectomy from the iliofemoral segment by Fogarty venous catheter with placement of tourniquet on proximal CIV through retroperitoneal approach. We consider this method to be more reliable in prevention of intraoperative PE. At the same time, great attention is paid to the DFV orifice(s) release that supply collateral blood flow. A patent iliac venous outflow plus a competent profunda collateral system will most of the time achieve normal venous function. Creation of AVF between femoral artery and CFV is considered as the essential step of surgery. The femoral vein is then ligated distal to the profunda branches by atraumatic absorbable suture distal to the profunda branches or we perform its plication. In a 13 year follow-up after femoral vein ligation in this setting, Masuda et al. [28]. found excellent clinical and physiological results without PTS.

In the residual stenosis of iliac veins (commonly determined by May-Thurner syndrome) we carry out balloon angioplasty

and stenting. The same tactics is used by B Eklöf et al. [29]. We consider that surgical thrombectomy is also indicated in isolated iliofemoral thrombosis, both floating and occlusive. Moreover, open thrombectomy can be performed when anticoagulant therapy with progressive symptoms of disease is not efficient and when there is a lack of necessary technical conditions for regional thrombolysis during inpatient monitoring.

Conclusion

Thrombectomy in iliofemoral thrombosis according to selective indications and using current methods of patency restoration in deep veins increases the effectiveness of treatment and prevents from the development of PTS.

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