Chapter

Advances of Thrombectomy in Venous Thromboembolism

Jia-Ling Lin, Po-Sheng Chen, Po-Kai Yang and Chih-Hsin Hsu

Abstract

Venous thromboembolism (VTE) presenting as deep vein thrombosis and pulmonary embolism clinically is a potentially fatal cardiovascular diseases with short-term and long-term sequelae. Furthermore, there is high recurrent rate in VTE patients during follow-up. Anticoagulation with traditional anticoagulants or new generation of oral anticoagulants is the gold standard treatment in patients with VTE. On the other hand, there is remarkable progression in device-based or surgical thrombectomy in managements of VTE in recent years. Current evidence also demonstrates the efficacy and safety of these invasive procedures in selective VTE patients. The present article will illustrate recent advances of device-based or surgical thrombectomy in VTE treatment.

Keywords: deep vein thrombosis, pulmonary embolism, catheter-directed thrombolysis, (mechanical thrombectomy), rheolytic embolectomy, aspiration thrombectomy, rotational thrombectomy

1. Introduction

Venous thromboembolism (VTE) is a set of diseases in which blood clot forms and occludes venous circulation and regard as the third frequent acute cardiovascular disease [1]. Clinically, VTE presents as deep vein thrombosis (DVT) and pulmonary embolism (PE) which account for two-third and one-third of VTE, respectively [2]. The estimated annual rate of incidence of VTE is 80 to 260 per 100000 population [3]. In general, the incidence of VTE increases with age. One epidemiologic study in United States showed that the incidence of VTE was 143 per 100000 in papulation at age 45–49 years and 1134 per 100000 in those at age > 80 years [4]. There is difference of incidence between ethnicities and black and white have higher incidence than other races [2]. Although patients with VTE might be asymptomatic, VTE is a potentially fatal disease. One study reported that the estimated annual VTE-related death was around 300000 in U.S [5] and nearly 30% of VTE patients died within 30 days after diagnosis. Compared to DVT, PE accounts for majority of early-stage mortality of VTE [6, 7]. In addition to VTE-related mortality and cardiovascular sequelae, such as post-thrombotic syndrome, chronic venous insufficiency and chronic thromboembolic pulmonary hypertension, etc., patients with VTE have high risk of other atherosclerotic diseases and acute cardiovascular events, such as acute myocardial infarction and ischemic stroke, in the short-term and long-term follow-up [8–10]. With a brief review of pathogenesis and risk factors of VTE, the following of this chapter focuses on percutaneous interventions for VTE.

2. Pathogenesis and risk factors of venous thromboembolism

Virchow's triad composed of stasis, vascular damage and hypercoagulable status describes the essential components contributing to the thrombus formation [11]. In most cases of VTE, stasis plays a major role triggering the formation of venous thrombosis [12]. However, the exact pathogenesis of VTE seems to be more complex and is not fully understood [2, 13]. Only one existing contributing factor is hard to result in the development of clot formation [14]. Nonetheless, the interaction between multiple concurrent contributing factors increases the risk of formation of venous thrombosis which progresses to significant VTE clinically thereafter.

In clinical aspect, many diseases and circumstances regarded as risk factors are identified to predispose to the development of VTE. In general, these risk factors are classified into genetic and acquired risk [15–18]. Genetic risk factors including protein C and S deficiency, antithrombin deficiency, the factor V Leiden gene mutation, antiphospholipid syndrome, etc. Acquired risk factors are further divided into concurrent diseases (elderly, chronic diseases, active cancer, obesity) and transient states (surgery, trauma, hospitalization, immobility, central venous catheter or device indwelling, oral contraceptives, etc.) [2]. Of note, hospitalization is an important period that multiple risk factors encounter concurrently and increase the risk of VTE greatly [2, 19]. Although predisposing factors are identified in most cases of VTE, there are still almost 20% of case having no obvious etiology. The result suggests the significance of unknown genetic or acquired risk factors to the development of VTE [2, 3].

3. Thrombectomy in management of VTE

To date, anticoagulation is still the principal treatment in VTE. In addition to traditional anticoagulation, including heparin, low molecular weight heparin and vitamin K antagonists, as well as direct thrombin inhibitors, non-vitamin K oral anticoagulants (NOACs), known as direct oral-anticoagulant (DOACs) change the strategy in medical treatment of VTE. The update of principles and strategies of medical treatment of VTM will be illustrated in another chapter. On the other hand, endovascular or surgical thrombectomy and embolectomy have role in treatment of VTE. Historically, Läwen conducted the first thrombectomy for venous thrombosis of upper extremity in 1938 [20]. After evolution in nearly 90 years, there are great advances in techniques and modalities in performing thrombectomy and embolectomy. However, thrombectomy or embolectomy is still indicated in limited population in modern treatment of VTE, especially in patients with massive or submassive thrombus burden accompanied by unstable hemodynamic status or critical complications [21–23]. Theoretically, endovascular or surgical thrombectomy removes majority of thrombus load more completely and recanalization of occluded vessels earlier [24, 25]. Moreover, some previous studies even reported that thrombectomy may have potential benefits comparing to anticoagulation alone in long-term complications and quality of life in certain VTE patients [22, 26]. The aim of this chapter will focus on the advances of modalities of endovascular and surgical thrombectomy.

4. Catheter-based therapy

Percutaneous management, also known as catheter-based therapy (CBT), for VTE can be divided into two mechanisms: thrombolysis-based and mechanical thrombectomy. There are also devices combining these two mechanisms. For certain conditions, percutaneous approaches also include balloon angioplasty and stenting. We describe different types of CBT in the following sections.

4.1 Catheter-directed thrombolysis

Compared to systemic thrombolysis, catheter-based thrombolysis is, by concept, more likely a local therapy. The advantage of this approach is a reduced-dose thrombolysis. Therefore, there is less risk of bleeding [27, 28]. Although with lower dosage needed, absolute contraindications for catheter-directed thrombolysis are the same as for systemic thrombolysis, including history of any intracranial hemorrhage, ischemic stroke within three months, structural intracranial lesion, active bleeding, recent head, eye or spinal surgery, and recent head trauma [29, 30].

This approach is done by placing an infusion catheter with multiple side holes and a tip occluding wire or a dedicated catheter specifically for a certain device, preferentially into the thrombus. It may sometimes require two catheters to be placed in each of the main pulmonary arteries. If there is no specialized catheter, a standard pig-tail or pulmonary artery catheter may also serve to deliver thrombolytic agent locally. When performing intervention for pulmonary embolism (PE), power injection may be necessary to take clear angiography to localizes the emboli. For each main pulmonary artery, perform contrast injection at 15–20 m/s for a total volume of 30 ml [28]. For intervention of deep venous thrombosis (DVT), careful hand injection with low-volume contrast is preferred to avoid disruption of thrombi with progression to PE [30].

Thrombolytic agent is administered via the carefully placed catheter. There is no standard for the agent and dosage used. It varies according to accompanied device, patients' bleeding tendency, and physicians' preferences. A commonly used regimen is tissue plasminogen activator (tPA) 0.5–1.0 mg/hr for 6–24 hours, with total dosage usually between 12 and 24 mg. Fibrinogen should be monitored during infusion of fibrinolytic agent. Dose reduction or discontinuation should be considered if level of fibrinogen falls below 150 mg/dL. During t-PA infusion, a low-dose heparin infusion is usually kept, with a partial thromboplastin time (PTT) just around the lower limit of therapeutic range, usually PTT 40–50 seconds [28, 30].

Catheter-directed thrombolysis applies for both DVT and PE. A key factor to success of lytic-based approach is that whether the thrombolytic agent is delivered into the thrombus with good penetration. A resolution to this problem is combining other method to enhance efficacy of drug delivery, such as the EkoSonic system.

EkoSonic™ Endovascular System (EKOS) is a device for ultrasound-assisted catheter-directed thrombolysis. It includes a control unit and a uniquely designed catheter to achieve better penetration of thrombolytics by so-called acoustic pulse thrombolysis. The catheter is composed of an ultrasonic core in central lumen, central coolant lumen, and drug delivery lumen. The ultrasonic core generates an acoustic field to enhance drug delivery into the clot and to unwind the fibrin for better exposure to thrombolytic agents. This system is indicated for both DVT and PE [31].

There were also devices designed for a true localized therapy. Trellis™ Peripheral Infusion System is a specialized device for isolated thrombolysis. It consists of two occlusive balloons to isolate the treatment area, an infusion zone to deliver thrombolytic agents, an oscillation drive unit to better disperse the drug to thrombi, and an aspiration window to remove the dissolved clot. Although with a unique design to ensure localized thrombolysis and thrombi removal, the devices were recalled due to incorrectly labelling of proximal and distal balloons [32].

Of note, catheter-directed thrombolysis alone may not be sufficient to clear all blood clots, although it is true that the goal of catheter-directed thrombolysis for PE is not to remove emboli completely, but to reduce the risk from high to intermediate [29]. Further intervention to remove emboli and thrombi may be needed and there are devices combining local thrombolysis and sequential blood clot removal, which would be described later.

4.2 Mechanical thrombectomy

Mechanical thrombectomy is achieved by physical disruption of thrombus via different methods, with various devices designed for this purpose. These devices have different benefits, adverse effects, and special concerns while manipulation. Overall, they are less invasive compared with traditional surgical thrombectomy. Some devices achieve thrombus removal in a single session, sparing the use of thrombolytic agents. The following section describes devices with approval. Devices still under development are not covered.

4.2.1 Thrombus fragmentation

Mechanical thrombectomy without a device has long been described in both treatment for DVT and PE. It is usually done by a pigtail with manual rotation or by balloon angioplasty [28]. An important issue of fragmentation is that it might create distal emboli, causing worse distal obstruction; and fragmentation alone may not be enough to resolve obstruction. It may be followed by systemic thrombolysis, catheter-directed thrombolysis, or thrombi removal by manual aspiration. Due to lack of clinical evidence, there is no recommendation for how to combine other strategy after manual thrombus fragmentation.

4.2.2 Aspiration thrombectomy

Besides manual thrombus aspiration with a regular guide catheter or specialized catheters with greater power of suction, there are devices designed to remove thrombus by suction via negative pressure. The advantages are the ability to remove large thrombi or even chronic thrombi, avoidance of thrombolytic agents, and possible less risk of bleeding.

The AngioVac® system works in an extracorporeal circuit and needs two large venous access sites for AngioVac inflow cannula (22Fr) and reinfusion outflow cannula (16–20 Fr). The third generation uses funnel-shaped and different-angled tip (20 degree or 180 degree) to facilitate navigation. Besides the need of two large-bore accesses, another disadvantage of this device is that perfusionist is required. It is indicated for removal of fresh, soft thrombi or emboli in right atrium, right ventricle, superior vena cava, inferior vena cava, and iliofemoral veins during extracorporeal bypass. It is not indicated in pulmonary vasculature although there are case series [33].

The FlowTriever® system includes an Triever Aspiration Catheter, a FlowTriever catheter, and a retraction aspiration device. Thrombus removal is done by manual aspiration with a syringe via the large-lumen aspiration catheter. There are nitinol mesh disks on the tip of FlowTriever catheter to disrupt and drag residual clots into the aspiration catheter for extraction. This system is indicated for PE [34]. A similar system dedicated for DVT is the ClotTriever® system. It includes a ClotTriever sheath and a ClotTriever catheter. The procedure steps are somewhat different. The ClotTriever catheter is position beyond the thrombus. A mesh collection bag on the tip of ClotTriever catheter retracts thrombi into the ClotTriever sheath with a self-expanding funnel tip, providing embolic protection. Manual aspiration is applied if there are residual thrombi in the sheath. Since treatment is completed in a single session and there is no need for thrombolysis, care in intensive care unit (ICU) after procedure may not be necessary. However, a large-bore vascular access (20 Fr) is needed [35].

Penumbra's Indigo® Aspiration System operates in a more "automatic" way, with less need of manual control. The main components of the system are a catheter, a Penumbra ENGINE to generate vacuum for aspiration, and a tubing system. When the catheter is in position, the system performs automatic aspiration. With different catheters, there are corresponding Separator wires to remove clot in the lumen of aspiration catheters. Compared to AngioVac® and FlowTriever®, the Indigo® system does not require large-bore vascular access but may therefore unable to remove larger thrombi. It is indicated for removal of fresh, soft thrombi or emboli in both peripheral arterial and venous system and for treatment of PE [36].

Syringed-based thrombectomy offers limited force and aspirated volume, and operators could not further manipulate. Pump systems with specific devices provide increased force and volume but usually with increased complexity of the procedure and increased cost. Control Mechanical Thrombectomy™ system (Aspire) works in a different way. The system includes a thrombectomy catheter and a control mechanical aspirator which is like a handle. Through the handle, the operator can adjust strength of the aspirated force, and switch between continuous and pulsed force. It is indicated for removal of fresh, soft thrombi in peripheral vasculature, but not PE [37].

4.2.3 Rotational thrombectomy

The concept of rotational thrombectomy is thrombus disruption by a catheter with rotating head. Most devices also have the ability to remove thrombus via active suction.

Aspirex® mechanical thrombectomy device consists of a catheter with a handle and a drive system. At the tip of the catheter, there is aspiration port to suck in thrombi; and inside the catheter, there is rotational coil to break down thrombi. The fragmented thrombi are then aspirated out. The device is indicated for both arterial and venous thrombi. With limited case studies, it is not approved for treatment of PE [38].

CLEANER™ Rotational Thrombectomy System is a one-piece device. Rotating action of its sinusoidal wire breaks down thrombi. The sinusoidal shape provides atraumatic action on thrombi adhered to vessel wall. The device also enables infusion of thrombolytic agents via a distal side hole. It is indicated for removal of thrombus in peripheral vasculature, but not for PE [39].

4.2.4 Rheolytic thrombectomy

Rheolytic thrombectomy is based on Bernoulli effect. A high-velocity saline jet creates a low-pressure, drawing thrombi into the catheter. To eliminate thrombi better, it may be accompanied with thrombolysis or other mechanical method such as aspiration.

Among this category, the mostly studied device is AngioJet™ Rheolytic Thrombectomy System, consisting of a console and a thrombectomy catheter. The system works in both pharmacological and mechanical ways. Operators can deliver thrombolytic agents directly into the clot to facilitate removal of thrombus. The console generates pressurized saline to draw thrombi into the catheter via an inflow window near the tip of the catheter, and then evacuates the thrombi.

Notable adverse events include pain, cardiac arrythmia (mainly bradyarrhythmia), hypotension, transient hemolysis, bleeding, and acute kidney injury. Hydration before, during, and after the procedure may be considered. AngioJet™ system is indicated in removal of thrombi in peripheral vasculature. When used in PE, there were severe adverse events, including death; so, there is a "black box" warning for AngioJet™ in treating PE [40].

4.3 Combined thrombolytic and mechanical approaches

The concept of combination works in at least two modes. One is to combine multiple mechanisms at the same time, usually by devices, like EKOS or AngioJet™. The other way is to use different methods sequentially. For instance, physicians may perform balloon angioplasty first to disrupt the thrombi; and then leave an infusion catheter for thrombolysis. This concept also works in a reverse way. Physicians may place an infusion catheter for thrombolysis first, usually for 24 hours; and then break the loosen thrombi with balloon angioplasty. Theoretically, combing thrombolysis and mechanical thrombectomy improves efficacy of thrombus removal, but there is no standard for how to combine multiple strategies due to limited studies. This so-called pharmacomechanical approach is therefore, largely based on clinicians' experience.

4.4 Angioplasty and stenting

Besides thrombolysis and mechanical thrombectomy, some adjuvant procedures may be needed, mainly for DVT. Balloon angioplasty plays a role in chronic thromboembolic pulmonary hypertension, but not for acute PE. For DVT, placement of inferior vena cava filter before procedure may be considered to prevent PE, especially for patients with poor cardiopulmonary function and deemed unable to tolerate PE [30]. The results of studies regarding stenting for DVT were inconsistent, although some showed reduced severity in post-thrombotic syndrome and improved quality of life in some aspects [41–43]. This approach is therefore largely based on clinicians' experience.

Stenting is considered if there is residual thrombi or residual venous outflow obstruction. It may also be considered when there is non-thrombotic cause of stenosis, such as in May-Thurner syndrome. Therefore, careful assessment of the lesion is important. It is helpful to combine other image modality such as computed tomography or intravascular ultrasound. Besides anatomical nature, clinicians should put patients' life expectancy, bleeding risk, and likelihood of symptom improvement into consideration. When a stent is placed, there is always risk of in-stent restenosis or occlusion. Risk factors include poor inflow, external compression, inappropriate stent design, stent misplacement or migration, stent fracture, and bleeding. Patients should be notified about the possibility of reintervention [44].

4.5 Summary of catheter-based therapy

The purpose of CBT is to relieve obstruction quicker, compared with traditional medical therapy. However, there is no strong evidence that CBT is better than traditional systemic thrombolysis since randomized trial assessing hard outcomes, such as mortality, is lacking. Also, among CBT, there is no trial comparing catheter-directed thrombolysis and mechanical thrombectomy or comparing different devices. It is also important to remember that published studies for CBT with devices are of small patient numbers. There are many trials still going on. Hopefully, these trials will provide evidences for more specific guidance.

For any intervention, there are always complications. Possible complications of CBT include access site bleeding, vascular injury, major bleeding (including intracranial hemorrhage), distal emboli (especially of concern with PE when performing intervention for DVT), cardiac tamponade (intervention for PE), hemodynamic deterioration, and deterioration in renal function. Some studies did not demonstrate the presumed benefit of less major bleedings (including intracranial hemorrhage) in percutaneous methods, compared with systemic thrombolysis [28, 29]. The balance between risk and benefit of these interventions should be personalized.

Generally speaking, CBT may be considered in patients with iliofemoral DVT who have severe symptoms and a low risk of bleeding [45]. For PE, CBT is an alternative to systemic thrombolysis and surgical embolectomy, considered when these approaches are contraindicated or fail [46]. For now, the choice of CBT largely remains on physicians' experience and local availability.

5. Surgical embolectomy

Surgical intervention is an old skill compared with percutaneous intervention. Surgical embolectomy of PE requires cardiopulmonary bypass. After thoracotomy, emboli are removed manually with forceps. Balloon catheter and suction may be used for residual emboli. Although surgical embolectomy is a class I indication for massive pulmonary embolism, it is usually reserved as a salvage therapy when other therapies fail or are contraindicated, due to its invasive nature. If there is thrombus in right heart or thrombus across patent foramen ovale, surgical embolectomy would be considered the first-line therapy [27].

On the other hand, surgical thrombectomy for DVT is usually done with a special balloon catheter to pull out thrombi in the direction of venous flow, called Fogarty maneuvers [47]. Unlike for PE, surgical thrombectomy for DVT is not recommended by clinical guidelines. Although there are studies showing good patency rates after surgery, it is usually considered only in certain conditions when rapid reduction of venous obstruction is needed, such as in patients with phlegmasia cerulea dolens [48].

6. Conclusions

Although rapid evolution of modalities and relatively high successful rate in experienced center, routine use of endovascular or surgical thrombectomy and thrombolysis in patient with VTE is not recommended. To date, large-scale clinical trial assessing the efficacy and safety of invasive thrombolysis or thrombectomy is still lack. The application of endovascular or surgical strategies should be considered in selective VTE patients with unstable hemodynamic status or critical VTE-associated complications or having contraindications or high risk of bleeding while receiving systemic thrombolysis. In addition, future studies focusing on cost-effectiveness are needed to integrate these invasive procedures with medical strategies in the protocol of VTE treatment.

Author details

Jia-Ling Lin[1,2], Po-Sheng Chen[1,3], Po-Kai Yang[2] and Chih-Hsin Hsu[1,3]*

1 Division of Cardiology, Department of Internal Medicine, National Cheng Kung University Hospital, Tainan, Taiwan

2 Division of Cardiology, Department of Internal Medicine, National Cheng Kung University Hospital, Dou-Liou Branch, College of Medicine, National Cheng Kung University, Yunlin, Taiwan

3 Division of Critical Care, Department of Internal Medicine, National Cheng Kung University Hospital, College of Medicine, National Cheng Kung University, Tainan, Taiwan

*Address all correspondence to: chihhsinhsu@gmail.com

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