Chapter 34
In Patients with Iliofemoral Deep Vein Thrombosis Does Clot Removal Improve Functional Outcome When Compared to Traditional Anticoagulation?

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Abstract Iliofemoral deep vein thrombosis is a common clinical condition which often results in post-thrombotic syndrome, a cause of long-term morbidity due to diminished function. The mainstays of treatment for deep vein thrombosis include anticoagulation and compression therapy but these only prevent propagation of the venous clot. Therapeutic options which actively remove clot decrease the risk of post-thrombotic syndrome when compared to conventional anticoagulation alone, an effect attributed to alleviated obstruction and decreased damage to venous valves. Removal of venous clot with catheter-directed thrombolysis is a safe, effective treatment option which can improve functional outcomes in iliofemoral deep vein thrombosis. In patients with contraindication to thrombolytic therapy, surgical thrombectomy is an alternative which also improves functional outcomes in iliofemoral deep vein thrombosis.

Keywords Iliofemoral DVT • Post-thrombotic syndrome • Catheter directed thrombolysis • Surgical thrombectomy

Introduction

Deep vein thrombosis (DVT) is a very common disorder with an estimated lifetime incidence of 2.5–5 % [1]. One out of every two to three patients with DVT develop post-thrombotic syndrome (PTS) which manifests as chronic pain, intractable edema, or leg ulceration and results in significant morbidity [2–6]. PTS has been

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shown to carry considerable negative socioeconomic consequences to both individual patients and the healthcare system [7–9]. Proximal venous thromboses are associated with poorer functional outcomes [6], so optimal treatment of iliofemoral DVT is imperative.

Current clinical guidelines strongly recommend treatment of DVT with anticoagulation to prevent propagation of clot and decrease the risk of acute complications such as pulmonary embolus or recurrent DVT [10, 11]. Studies have evaluated compression stockings to reduce the incidence of PTS and guidelines strongly support their use, yet PTS still affects nearly 25 % of patients despite anticoagulation and compression stocking therapy [3, 11, 12]. Additionally, more recent placebo-controlled studies have suggested that compression stockings may actually have no effect on the incidence of PTS [13].

PTS is generally accepted to be a consequence of sustained venous hypertension from obstruction and insufficient venous valves which are damaged by the inflammatory reaction in the presence of acute thrombus. Therefore, prevailing theory supports the prompt removal of venous clot to prevent development of PTS. Multiple interventions have been developed to remove venous clot including catheter-directed pharmacologic or pharmacomechanical thrombolysis (CDT), percutaneous aspiration thrombectomy (PAT), and surgical thrombectomy [14, 15].

Measuring the efficacy of interventions for DVT can be somewhat challenging but often begins with biomarkers and venous patency on imaging. Ultimately, the goal of clot removal is to prevent PTS and improve functional outcome so a number of scoring systems, including the commonly used Villalta score, have been developed to incorporate both patient symptoms and clinical signs [16]. This chapter reviews the evidence to identify whether clot removal strategies lead to better functional outcomes than conventional anticoagulation for patients with iliofemoral DVT.

Search Strategy

A literature search of English language publications from 1995 to 2015 was used to identity published data on treatment of iliofemoral DVT with clot removal or conventional anticoagulation using the PICO outline (Table 34.1). PubMed, Cochrane Evidence Based Medicine, and Embase databases were queried. Terms used in the search were “iliofemoral/thrombectomy,” “iliofemoral/thrombolysis,” “deep vein thrombosis/thrombolysis/anticoagulation,” and “deep vein thrombosis/thrombectomy/anticoagulation.” Articles were excluded if they did not specifically address iliofemoral DVTs. Five randomized-controlled trials, seven cohort studies, and two meta-analyses were included and compared thrombolysis or thrombectomy treatment with conventional anticoagulation therapy alone. The data was classified using the GRADE system. Additional studies and articles were cited and, although they did not directly compare thrombus removal with conventional anticoagulation, provided historical and background information.

Table 34.1 PICO table for clot removal of iliofemoral DVT

P (Patients)	I (Intervention)	C (Comparator group)	O (Outcomes measured)
Patients with iliofemoral deep vein thrombosis	Thrombus removal strategies (pharmacologic or pharmacomechanical catheter directed thrombolysis, percutaneous aspiration thrombectomy, or surgical thrombectomy)	Conventional anticoagulation and compression stockings	Development of post-thrombotic syndrome and functional outcomes

Results

Catheter Directed Thrombolysis

Background

Catheter-directed thrombolysis for iliofemoral DVT, first described in 1991, involves placement of a catheter into the venous thrombus and infusing thrombolytic agents directly into the clot so the drug can be given in high local concentrations and is protected from neutralization by circulating inhibitors [17]. CDT has been well established as an effective means of thrombus removal in acute iliofemoral DVT with multiple cohort and observational studies demonstrating an approximately 90 % success rate for restoring venous patency with a rate of significant bleeding at less than 10 % [18–22]. The largest of these studies, a multicenter prospective registry study which included 221 patients with iliofemoral DVT, found an 83 % rate of successful (>50 %) lysis of the clot with a primary patency rate of 60 % at 1 year [23]. The major complication of CDT is bleeding which was reported to occur in 11 % of patients in this study, 39 % of which represented hematoma at the venous insertion site. This study is somewhat limited by inclusion of femoropopliteal DVTs which may confound results of CDT for iliofemoral DVTs.

The safety and efficacy of CDT for iliofemoral DVT is generalizable to diverse patient populations. Smaller series and case studies have demonstrated efficacy and safety in cancer patients [24], pregnant patients [25], those with congenital venous anomalies [26, 27]. Current guidelines support CDT as a secondary treatment option for acute proximal DVT but limits this recommendation to patients with iliofemoral DVT, symptoms for <14 days, good functional status, life expectancy over 1 year, and low risk of bleeding [11, 28]. Ultimately, the body of literature supports CDT as an effective, safe treatment option for iliofemoral DVT and guidelines have been established to improve treatment quality [29].

Choice of Pharmacologic Agent for Thrombolysis

The choice of pharmacologic agent for thrombolysis in each study varies by availability and institutional preference. Historically, Urokinase (Abbokinase, Abbott

Laboratories, Chicago, IL) was the dominant thrombolytic agent for treatment of venous occlusion. After it was removed from the market in 1999, recombinant plasminogen activators including tissue plasminogen activator (tPA) (Activase, Genentech, San Francisco, CA) and reteplase (rPA) (Retavase, Centocor, Malvern, PA) became the prevailing thrombolytic agents for use in CDT. Fortunately, studies have investigated the difference between the various agents and have found no significant difference in terms of efficacy or safety [21, 22, 30]. Therefore, the thrombolytic agents will be considered equivalent for the purposes of this review.

Pharmacomechanical Thrombolysis

Traditional pharmacologic CDT offers potential benefits to conventional anticoagulation but also involves greater risk of bleeding and incurs costs including longer hospital stays. The use of pharmacomechanical thrombectomy devices are thought to augment venous clot removal and allow for shorter treatment duration. A variety of these devices are available on the market including the Amplatz thrombectomy device (Microvena, White Bear Lake, MN), AngioJet thrombectomy device (Possis Medical, Minneapolis, MN), Trellis infusion system (Covidien, Minneapolis, MN), and EkoSonic endovascular system (EKOS Corporation, Bothell, WA). Each one of these devices aims to mechanically fragment and extract venous clot by using rotational, rheolytic, or ultrasound-assisted mechanisms [31].

Several studies have compared pharmacomechanical thrombectomy devices to standard CDT with infusion catheters and the results suggest that they can decrease length of hospital stay and overall cost while maintaining similar rates of safety and efficacy [32, 33]. Current guidelines advocate the use of pharmacomechanical thrombectomy when expertise is available [28], however no study directly compares the development of PTS or functional outcomes between patients receiving treatment with pharmacologic CDT and those receiving pharmacomechanical CDT. Many of the cohort studies evaluating CDT did not stratify results based on the use of pharmacomechanical thrombolysis so, for the purposes of this review, "CDT" will refer to both pharmacologic and pharmacomechanical catheter directed thrombolysis unless specified.

Functional Outcomes with CDT Versus Conventional Treatment Only

A number of studies directly compare functional outcomes when CDT is added to conventional anticoagulation and compression stocking therapy versus conventional therapy only for iliofemoral DVT. These studies vary widely in terms of the patient populations, thrombolytic agent used, use of pharmacomechanical thrombolysis, and outcomes measured. Nevertheless, a meta-analysis including five studies found that, compared to anticoagulation, CDT was associated with a statistically significant reduction in risk of PTS (RR 0.19; 95 % CI 0.07–0.48) with follow-up periods ranging from 16 to 90 months [34]. A second meta-analysis

including four studies which reported incidence of PTS at 6 to 24 months also found a significant risk reduction in patients receiving thrombolysis (RR 0.64; 95 % CI 0.52–0.79) [35]. These meta-analyses included a number of cohort studies and small randomized control trials which, overall, support CDT in addition to conventional anticoagulation therapy to reduce the incidence of PTS and improve functional outcomes [36–40].

The largest randomized controlled trial evaluating the use of CDT in treatment of iliofemoral DVT to date is the Catheter-directed Venous Thrombolysis (CaVenT) study. This multicenter study evaluated adult patients with first-time iliofemoral DVT presenting within 21 days of symptom onset and randomized 209 patients with 108 receiving only conventional anticoagulation therapy and 101 receiving CDT in addition. The CDT treatment group was given pharmacologic CDT with tPA for up to 4 days followed by the guideline-recommended dose of oral anticoagulation and compression stocking therapy. 90 % of patients completed 24 month follow up. The rate of iliofemoral patency as measured by ultrasonography and air plethysmography was higher in the CDT group at 6 months (65.9 % vs. 47.4 %, $p = 0.012$) and only 5 (4.9 %) clinically relevant bleeding complications were reported [41]. Moreover, the rate of PTS as measured by the Villalta scoring system was 41.1 % in the CDT group compared with 55.6 % in the control group ($p = 0.047$). Further subgroup analysis, however, found that quality of life (QOL) as reported by patients through the generic EQ-5D and the 26-item disease-specific VEINES-QOL/Sym questionnaires did not differ between CDT and control groups at 24 months [42]. The CaVenT study found a somewhat weakly significant difference in PTS between CDT and control groups with follow up analysis of patient-reported QOL showing no different between treatment groups. One potential explanation for the lack of a more robust effect may, in part, be due to only approximately half of the randomized patients having thrombus extending to the iliac level [43].

The ATTRACT trial is an ongoing randomized controlled clinical trial which has enrolled approximately 692 patients and will be comparing the effect of pharmacomechanical CDT in addition to conventional therapy versus conventional therapy alone on risk of PTS and QOL measures at 2 years [44]. This study excludes patients with active cancer diagnoses or pregnancy, but stratifies the patient population by exact venous segment involved and allows treating physicians the discretion to use mechanical thrombectomy devices. The results from this study should provide high-quality evidence about functional outcomes in iliofemoral DVT when CDT is added to conventional treatment.

Percutaneous Aspiration Thrombectomy

Despite the popularity of and support for CDT in treatment of iliofemoral DVT, it is associated with an increase in risk of bleeding. Potential disadvantages of CDT include relatively long durations of treatment, cost of devices, and potential damage to the venous valves [45, 46]. In response, PAT has been proposed as an alternative

treatment strategy to consider as an alternative adjunct therapy to conventional anticoagulation.

A single randomized controlled trial including 42 patients found a significant improvement in a 6-point clinical symptom score used to evaluate patients at 12 month follow up (0.81 for PAT group vs. 2.43 for control group, $p < 0.001$) [47]. This study was limited, however, and did not evaluate development of PTS as follow-up data were available only to 12 months post-treatment.

Surgical Thrombectomy

Surgical thrombectomy was developed before the advent of CDT and, while early studies reported relatively poor results, contemporary technique (including operative fluoroscopy, correction of underlying venous lesions, creation of an adjunctive arteriovenous fistula, and use of anticoagulation to avoid re-thrombosis) has likely improved the safety and efficacy of surgical thrombectomy [14]. Nevertheless, the procedure is more invasive than CDT and requires general anesthesia so guidelines reserve surgical thrombectomy only for patients who may benefit from clot removal but have contraindications to thrombolytic therapy [11, 28].

Data supporting surgical thrombectomy is somewhat limited due to indirect comparison with conventional CDT and discordant time intervals during which the studies were performed. A meta-analysis including 10 studies, one of which was a randomized controlled trial, did find that surgical thrombectomy was associated with a statistically significant reduction in risk of developing PTS (RR 0.67; 95% CI 0.52–0.87) [34]. The randomized controlled trial evaluated 30 patients and found that, at 10-year follow-up, there was a trend towards higher rate of symptom-free survival and decreased rates of leg swelling, varicose veins, venous claudication, and leg ulcers in patients who had undergone surgical thrombectomy versus those who had received only anticoagulation therapy [48].

Recommendations

Patients with iliofemoral DVT benefit from venous clot removal, specifically by a reduction in rates of PTS. Prompt removal of clot resolves venous obstruction and reduces the damage to venous valves from the acute inflammatory reaction. Moderate-grade evidence supports CDT in reducing the risk of PTS and improving function outcomes, findings that have been demonstrated by multiple randomized controlled trials and large cohort studies. Although risk of PTS was decreased by the use of CDT in the CaVenT trial, subgroup analysis did not show any difference in terms of surveyed QOL. The results of the ATTRACT trial will augment the evidence in the current literature and may strengthen the quality of evidence supporting CDT. The addition of CDT to standard anticoagulation is therefore currently

recommended for patients with iliofemoral DVT as long as they have no specific contraindication to thrombolytic therapy.

Moderate-grade evidence supports the use of surgical thrombectomy to improve functional outcomes in iliofemoral DVT. Despite the potential surgical complications and more invasive nature of the procedure, surgical thrombectomy is a viable treatment option and can be considered as long as the benefit of avoiding the morbidity associated with PTS outweighs the risks of surgery. Specifically, surgical thrombectomy should be considered in patients with good baseline functional capacity and life expectancy with contraindications to CDT.

Low-grade evidence supports the use of percutaneous aspiration thrombectomy for clot removal in improving functional outcomes. Only one limited, small study evaluated outcomes in patients receiving PAT in addition to anticoagulation. Until further evidence is available, no specific recommendation can be made regarding PAT for treatment of iliofemoral DVT.

Recommendations

- Catheter directed thrombolysis, whether pharmacologic or pharmacomechanical, is recommended to improve functional outcomes in patients with iliofemoral DVT and without contraindication to thrombolytic therapy (**evidence quality moderate; strong recommendation**).
- For patients with contraindication to thrombolysis, surgical thrombectomy should be offered as a treatment option to patients for whom the benefit in terms of functional outcome outweighs the risk of surgery (**evidence quality moderate; strong recommendation**).

A Personal View of the Data

Iliofemoral DVT is a common problem which commonly results in significant morbidity as PTS manifests long-term. Our experience supports the use of CDT for patients with acute iliofemoral DVT and good baseline functional status and life expectancy. Additionally, we believe that the use of pharmacomechanical CDT can decrease length of hospital stay while offering similar safety and technical efficacy rates to standard pharmacologic CDT. However, we await the results of the ATTRACT trial before making formal recommendations about the use of these devices for effect on functional outcomes. Surgical thrombectomy is a relatively rare procedure and is typically only considered in unusual clinical scenarios. We also believe that the aforementioned clot removal options are used to augment the medical anticoagulation and compression stocking therapies which are still staples in treatment of all patients with iliofemoral DVT. While we encourage clot removal to improve long term functional outcomes, each patient's individual risk and potential benefit must be considered carefully and with astute clinical judgment.

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