CLINICAL STUDY

Comparison of Ultrasound-Accelerated versus Pigtail Catheter–Directed Thrombolysis for the Treatment of Acute Massive and Submassive Pulmonary Embolism

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ABSTRACT

Purpose: To compare the technical and clinical effectiveness of ultrasound-accelerated endovascular thrombolysis (USAT) versus pigtail catheter–directed thrombolysis (PCDT) for the treatment of acute pulmonary embolism (PE).

Materials and Methods: A single-center retrospective study of patients treated with USAT or PCDT for acute massive or submassive PE between January 2010 and December 2016 was performed by reviewing electronic medical records. Sixty treatments were reviewed (mean patient age, 56.7 y ± 14.6), including 52 cases of submassive PE (21 treated with USAT, 31 with PCDT) and 8 cases of massive PE (3 treated with USAT, 5 with PCDT). Endpoints included pulmonary artery pressure (PAP), Miller PE severity index, tissue plasminogen activator (TPA) dose, infusion duration, procedural variables, and complications.

Results: Demographics, PE severity, and right:left ventricular diameter ratios were similar between groups. USAT and PCDT significantly reduced mean PAP (reductions of 7.4 mm Hg [$P = .002$] and 8.2 mm Hg [$P < .001$], respectively) and Miller index scores (reductions of 45.8% [$P < .001$] and 53% [$P < .001$], respectively) with similar effectiveness ($P = .47$ and $P = .15$, respectively). Procedure ($P < .001$) and fluoroscopy ($P = .001$) times were significantly longer in the USAT group. The USAT group underwent fewer sessions (2.2 ± 0.6 vs 2.4 ± 0.6; $P = .17$) with shorter infusion times (23.9 h ± 8.8 vs 30.4 h ± 12.6; $P = .065$) and a lower total dose of TPA (27.1 mg ± 11.3 vs 30.4 mg ± 12.6; $P = .075$) compared with the PCDT group, but the differences were not significant. Complications ($P = .07$) and 30-day mortality rates ($P = .56$) were not significantly different between groups.

Conclusions: USAT and PCDT demonstrated comparable effectiveness and safety in the treatment of patients with acute PE.

ABBREVIATIONS

CDT = catheter-directed thrombolysis, DSA = digital subtraction angiography, LV = left ventricular, PAP = pulmonary artery pressure, PCDT = pigtail catheter–directed thrombolysis, PE = pulmonary embolism, PERFECT = Pulmonary Embolism Response to Fragmentation, Embolectomy, and Catheter Thrombolysis [trial], RV = right ventricular, TPA = tissue plasminogen activator, USAT = ultrasound-accelerated endovascular thrombolysis

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Catheter-directed thrombolysis (CDT) for acute pulmonary embolism (PE) has been shown to be effective in reducing right ventricular (RV) dysfunction, pulmonary artery pressure (PAP), and pulmonary thrombus burden while demonstrating low rates of major hemorrhagic complications (1). CDT is typically administered via multiple–side hole infusion catheters placed into the pulmonary arteries, with or without an integrated endovascular ultrasound (US) component, which is theorized to loosen the fibrin matrix (2) and facilitate more rapid dissolution of thrombus when combined with thrombolytic agents (3). A simpler technique for CDT is to infuse the thrombolytic medication through the diagnostic pigtail catheters used for pulmonary angiography, shortening the procedure duration and avoiding the complexity associated with catheterizing segmental pulmonary arteries.

The efficacy of ultrasound-accelerated endovascular thrombolysis (USAT) is well documented (1,3–13). Although pigtail catheter–directed thrombolysis (PCDT) has been previously described (1,14,15), data regarding its efficacy are lacking, as are studies comparing the two techniques. In the present study, we aim to evaluate the effectiveness and safety of PCDT in comparison with USAT for the treatment of acute massive and submassive PE.

MATERIALS AND METHODS

This Health Insurance Probability and Accountability Act–compliant retrospective cohort study was approved by the institutional review board, and informed consent was waived.

Patient Selection

Consecutive patients who underwent CDT for acute massive or submassive PE between January 2010 and December 2016 were identified by searching the electronic medical records of a single community hospital system. Inclusion criteria for the study included patients who presented with acute submassive or massive PE within 14 days of symptom onset, were diagnosed with PE on computed tomographic (CT) angiography of the pulmonary arteries, and were treated with bilateral pulmonary artery CDT with recombinant tissue plasminogen activator (TPA; Genentech, South San Francisco, California) with USAT or PCDT exclusively. Acute massive PE was defined as acute PE in the setting of sustained hypotension, profound bradycardia, or pulselessness (16). Acute submassive PE was defined as acute PE in the setting of an RV–to–left ventricular (LV) ratio greater than 0.9 or biochemical marker evidence of myocardial necrosis (16). Exclusion criteria included administration of systemic TPA before CDT, evidence of chronic PE as diagnosed on CT angiography of the pulmonary arteries (17), onset of symptoms greater than 14 days before presentation, unilateral CDT, CDT performed with a technique other than PCDT or USAT, enrollment in the SEATTLE II trial (3), and use of different types of thrombolysis catheters in the same patient. The RV:LV ratio before intervention was calculated on Vitrea postprocessing software (Vital Images, Minnetonka, Minnesota) by using a standardized 4-chamber view (18–20) by a fellowship-trained radiologist with 13 years of experience.

A total of 101 patients were treated for acute PE during the study period. Forty-two patients were excluded, and 59 patients were enrolled. The study cohort included 60 treatments, as a single male patient in the USAT group had 2 separate treatments 5 months apart. There were 24 treatments in the USAT group and 36 treatments in the PCDT group. Patient demographic characteristics, risk factors for venous thromboembolism, PE severity parameters, and preinterventional RV:LV ratios are displayed in **Table 1**, and were reported in accordance with the Society of Interventional Radiology Reporting Standards for Endovascular Treatment of Pulmonary Embolism (21).

Procedures

Procedures were performed by 1 of 8 fellowship-trained interventional radiologists, with experience ranging from 1 to 18 years (mean, 10.5 y ± 6.9). All patients received anticoagulation with a weight-based continuous intravenous heparin infusion, which was initiated at the time of diagnosis of PE and continued throughout the course of treatment. Partial thromboplastin time was monitored every 6 hours, with a target of 50–80 seconds. A transfemoral approach via a single dual-lumen 12-F sheath or two 5- or 6-F single-lumen sheaths was used in all patients. Right heart and pulmonary artery catheterization was performed by using a 5-F AP2 infusion angled pigtail catheter (Cook, Bloomington, Indiana) through which systolic, diastolic, and mean PAP measurements were obtained.

Bilateral pulmonary digital subtraction angiography (DSA) was performed in all patients with the use of power injections. Reduced flow rates and injection volumes were used in cases of PAP measurements greater than 55 mm Hg. Angiography was followed by clot fragmentation with use of the rotating pigtail technique (n = 1 patient in each group) (22) or thrombectomy (n = 1 patient in the PCDT group) with the Indigo System CAT 8 (Penumbra, Alameda, California), if deemed necessary by the operating physician, followed by repeat angiography and pressure measurements. The choice between USAT and PCDT was left to physician discretion. USAT was performed by using the EkoSonic Endovascular System (EKOS, Bothell, Washington) with USAT infusion catheters placed into the interlobar or a segmental pulmonary artery of each lung (**Fig 1**) as previously described (11). PCDT was performed by placing an AP2 angled pigtail catheter into each of the main pulmonary arteries (**Fig 2**). An infusion of TPA diluted in normal saline solution was initiated at a rate of 0.25–1 mg/h via each catheter. No standardized protocol was used to determine the rate of TPA infusion. The rate was set based on physician preference after evaluation of the clot burden. All patients were monitored in the intensive care unit during the thrombolytic infusion, with coagulation factors and fibrinogen levels measured every 6 hours.