Catheter-Directed Embolectomy, Fragmentation, and Thrombolysis for the Treatment of Massive Pulmonary Embolism After Failure of Systemic Thrombolysis*

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Purpose: **The standard medical management for patients *in extremis* from massive pulmonary embolism (PE) is systemic thrombolysis, but the utility of this treatment relative to catheter-directed intervention (CDI) is unknown. We evaluated the effectiveness of CDI as part of a treatment algorithm for life-threatening PE.**

Methods: **A retrospective review was performed on 70 consecutive patients with suspected acute PE over a 10-year period (from 1997 to 2006) who had been referred for pulmonary angiography and/or intervention. The criteria for study inclusion were patients who received CDI due to angiographically confirmed massive PE and hemodynamic shock (shock index, ≥ 0.9). CDI involved suction embolectomy and fragmentation with or without catheter thrombolysis.**

Results: **Twelve patients were treated with CDI. There were seven men and five women (mean age, 56 years; age range, 21 to 80 years). Seven patients (58%) were referred for CDI after failing systemic infusion with 100 mg of tissue plasminogen activator, and five patients (42%) had contraindications to systemic thrombolysis. Catheter-directed fragmentation and embolectomy were performed in all patients (100%). Additionally, catheter-guided thrombolysis was performed in eight patients (67%). Technical success was achieved in 12 of 12 cases (100%). There were no major procedural complications (0%). Significant hemodynamic improvement (shock index, < 0.9) was observed in 10 of 12 cases (83%). The remaining two patients (17%) died secondary to cardiac arrest within 24 h. Ten of 12 patients (83%) survived and remained stable until hospital discharge (mean duration, 20 days; range, 3 to 51 days).**

Conclusion: **In the setting of hemodynamic shock from massive PE, CDI is potentially a life-saving treatment for patients who have not responded to or cannot tolerate systemic thrombolysis.**

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Key words: pulmonary embolism; radiology intervention; shock; thrombolysis; thrombolytic therapy

Abbreviations: CDI = catheter-directed intervention; PE = pulmonary embolism; TNK = tenecteplase; tPA = tissue plasminogen activator

Massive pulmonary embolism (PE) is a common life-threatening condition. Although the true incidence is unknown, an estimated 530,000 cases of symptomatic PE[1] and 150,000 cases of acute massive PE occur annually in the United States.[2] The 30-day mortality rate for massive PE approaches 30%,[3] and the presence of shock in these patients defines a threefold to sevenfold increase in mortality, with a majority of deaths occurring within 1 h of presentation.[4] The standard medical management for patients *in extremis* from massive PE is systemic thrombolysis,[5] but this treatment is associated with hemorrhagic risks, and some patients cannot receive systemic lysis due to contraindications. Furthermore, the safety and efficacy of systemic tissue plasminogen activator (tPA) [alteplase; Genentech; South San Fran-

cisco, CA] relative to catheter-guided intervention has not been firmly established. When the initial infusion of systemic thrombolysis fails to resolve hemodynamic shock, it is also unclear whether additional IV tPA should be administered vs treatment with alternative methods. If patients in extremis are not candidates for systemic thrombolysis, the remaining options are catheter-directed intervention (CDI) or open surgical embolectomy. CDI is considered to be much less invasive than open surgery; and for patients who are deemed to be poor surgical candidates, CDI is the only alternative treatment option. In this retrospective study, we evaluated the effectiveness of CDI (embolectomy, fragmentation, with or without local thrombolysis) as part of a treatment algorithm in our institution for the management of life-threatening PE.

Materials and Methods

This study was performed following institutional review board approval. A retrospective review was performed of 70 consecutive patients with suspected acute PE over a 10-year period (from 1997 to 2006) who had been referred to our department for pulmonary angiography and potential catheter intervention. The criteria for study inclusion were patients who received emergency CDI due to angiographically confirmed massive PE (Miller index score, > 0.6), with involvement of the central pulmonary arteries, and hemodynamic shock defined as a shock index (*ie*, heart rate/systolic BP) score of ≥ 0.9. CDI was performed, as part of an algorithm for treating massive PE, after the failure of therapy with systemic tPA (100 mg IV over 2 h) or as a first-line treatment in patients with contraindications to systemic tPA infusion.

CDI involved suction embolectomy and fragmentation (with a rotating pigtail or rheolytic catheter) with or without local thrombolysis with tPA or tenecteplase (TNK) [Genentech], at the operator's discretion. Suction embolectomy was performed through an 8F or 9F guiding catheter, and fragmentation was achieved with either a 5F or 6F rotating pigtail catheter or a rheolytic thrombectomy device (AngioJet; Possis Medical; Minneapolis, MN). The insertion of an angioplasty balloon (diameter, 9 to 14 mm) was used adjunctively in some cases to achieve further clot disruption. Following fragmentation, catheter thrombolysis was accomplished by injecting the drug into and around the angiographically visible clot using either a pigtail catheter or an infusion catheter (Unifuse; Angiodynamics; Queensbury, NY).

The degree of pulmonary involvement was assessed before and after CDI, based on a consensus interpretation by two radiologists, using the scoring system of Miller et al.[6] The Miller score ranges from 0 to 34 with higher scores reflecting greater pulmonary involvement. The Miller index (*ie*, Miller score divided by 34) ranges from 0 to 1.0, with massive PE defined as a Miller index of > 0.6. Technical success was defined as a reduction in the baseline Miller index following treatment. Hemodynamic status was assessed by calculating the shock index (*ie*, heart rate/systolic BP) before and after CDI, with severe impairment defined as a shock index of ≥ 0.9, which is an indicator and value previously described[7,8] as useful in identifying and assessing critically ill patients. Significant hemodynamic improvement was defined as achieving a shock index < 0.9. Clinical success was defined as the stabilization of hemodynamic parameters, the resolution of shock, complete weaning off ventilatory and inotropic support, and survival until discharge from the hospital.

Major procedural complications from CDI were defined as follows: hemorrhage requiring transfusion; perforation of cardiopulmonary structures; anaphylaxis from contrast injection; induction of right heart block; further increase in pulmonary hypertension; worsening hypoxia; exacerbation of shock; and/or death during the procedure. Minor procedural complications were defined as follows: transient catheter-induced arrhythmia; mild contrast reactions; catheter-related infection; and small hematomas not requiring transfusion. The data were analyzed using the Student *t* test for the comparison of paired samples. A p value of < 0.05 was considered to be statistically significant.

Results

Twelve patients with massive PE were referred for treatment. There were seven men and five women with a mean age of 56 years (age range, 21 to 80 years). Risk factors for PE included preexisting deep venous thrombosis, right atrial thrombus, or both. Prior to CDI, pulmonary hypertension was documented in 11 of 12 patients (92%). Right ventricular strain was documented in 10 of 12 patients (83%). Nine of 12 patients (75%) were managed with ventilatory support, and 6 of 12 (50%) patients required inotropic/pressor support in addition to intubation. All patients (100%) were in hemodynamic shock.

Seven of 12 patients (58%) were referred for CDI after no response (*ie*, no resolution of shock) to the administration of 100 mg of IV tPA. A large retroperitoneal hemorrhage requiring transfusion developed in one of seven patients (14%) who were being treated with systemic thrombolysis. Five of 12 patients (42%) had contraindications to systemic thrombolytic therapy and were referred directly for CDI without receiving IV tPA.

Catheter-directed fragmentation and suction embolectomy were emergently performed in all cases (100%). In 2 of 12 patients (17%), the insertion of an

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We would like to disclose that one case from our retrospective series was previously published as a "Letter to the Editor" in the *Journal of Vascular and Interventional Radiology* (Sze DS, Carey MBL, Razavi MK. Treatment of massive pulmonary embolus with catheter-directed tenecteplase. *J Vasc Interv Radiol* 2001; 12:1456–1457). Figure 1 from this article is reproduced with permission from the publisher.

The authors have reported to the ACCP that no significant conflicts of interest exist with any companies/organizations whose products or services may be discussed in this article.

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