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Systemic Thrombolysis Increases Hemorrhagic Stroke Risk without Survival Benefit Compared to Catheter-Directed Intervention for the Treatment of Acute Pulmonary Embolism

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Abstract

Background—Systemic thrombolysis (ST) and catheter-directed intervention (CDI) are both used in the treatment of acute pulmonary embolism (PE), but the comparative outcomes of these two therapies remain unclear. The objective of this study was to compare short-term mortality and safety outcomes between the two treatments using a large national database.

Methods—Patients presenting with acute PE were identified in the National Inpatient Sample from 2009–2012. Comorbidities, clinical characteristics, and invasive procedures were identified using International Classification of Diseases version 9 (ICD-9) codes and the Elixhauser comorbidity index. To adjust for anticipated baseline differences between the two treatment groups, propensity score matching was used to create a matched ST cohort with clinical and comorbid characteristics similar to the CDI cohort. Subgroups of patients with and without hemodynamic shock were analyzed separately. Primary outcomes were in-hospital mortality, overall bleeding risk, and hemorrhagic stroke risk.

Results—Of 263,955 subjects with acute PE, 1.63% (n=4272) received ST and 0.55% (n=1455) received CDI. ST subjects were older, had more chronic comorbidities, and higher rates of respiratory failure (ST: 27.9%, n=1192; CDI: 21.2%, n=308; P<.001) and shock (ST: 18.2%, n=779; CDI: 12%, n=174; P<.001). CDI subjects had higher rates of concurrent deep venous thrombosis (ST: 35.8%, n=1530; CDI 45.9%, n=668; P<.001) and vena cava filter placement (ST: 31.1%, n=1328; CDI: 57%, n=830; P<.001). In the unmatched cohort, ST subjects had higher inhospital mortality (ST: 16.7%, n=714; CDI: 9.4%, n=136, P<.001) and hemorrhagic stroke rates (ST: 2.2%, n=96; CDI: 1.4%, n=20; P=.041). After propensity matching, 1434 patients remained in each cohort; baseline characteristics of the matched cohorts did not differ significantly using standardized difference comparisons. Analysis of the matched cohorts did not demonstrate a significant effect of CDI on in-hospital mortality or overall bleeding risk but did show a significant protective effect against hemorrhagic stroke compared to ST (OR 0.47, 95% CI 0.27–0.82, P=.01).

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Subgroup analysis showed decreased odds of hemorrhagic stroke for CDI in the non-shock subgroup, and increased procedural bleeding for CDI but no difference in hemorrhagic stroke risk in the shock subgroup.

Conclusions—Systemic thrombolysis for acute pulmonary embolism may not improve inhospital mortality compared to CDI but increases the overall risk of hemorrhagic stroke compared to catheter-directed intervention. Further prospective studies should examine the comparative effectiveness and safety of these two treatments.

INTRODUCTION

Acute pulmonary embolism (PE) is a morbid condition with a wide severity spectrum, ranging from asymptomatic incidentally detected emboli to large PE causing hemodynamic instability and even death. Acute PE is classified into risk categories based on the presence of hemodynamic shock (high-risk or massive PE) or absence of shock but with evidence of myocardial necrosis or right heart strain (intermediate-risk or submassive PE)^{1–3}. Systemic thrombolysis (ST) remains the current standard of care for high-risk PE and has been advocated⁴ as the treatment of choice for select intermediate-risk patients.

Catheter-directed interventions (CDI) have recently become popular for the treatment of acute high and intermediate-risk PE due to the potential for decreased bleeding complications compared to systemic thrombolysis, while providing similar efficacy in mortality and improvement in imaging parameters of heart strain. However a paucity of direct comparative studies of CDI and ST exist. The expectation of lower rates of complications and similar effectiveness are based primarily on mechanistic similarities between CDI and ST but with less thrombolytic exposure with CDI, with supporting data from single-arm studies or comparisons with anticoagulation. Therefore the objective of our study is to compare outcomes of CDI and ST in patients with massive or sub-massive PE using a large national database.

METHODS

This study of deidentified national database data was approved and exempted from informed consent by the university institutional review board prior to data acquisition and analysis (IRB# PRO15060452).

Data for the study were acquired from the National Inpatient Sample (NIS) from 2009– 2012. The NIS is a dataset containing a 20% sample of nationwide inpatient discharges from US hospitals collected and curated by the Agency for Healthcare Research Quality's Healthcare Cost and Utilization Project (AHRQ HCUP⁵). Prior to 2011, this was a collection of all discharges from a 20% sample of hospitals but transitioned to a 20% sample of all discharges with the 2012 dataset, precluding further analysis of center volume data. Diagnoses and procedures were identified using International Classification of Disease, version 9 (ICD-9-CM) coding. Admission and discharge information including in-hospital mortality, length-of-stay, and hospital characteristics are hard-coded in the data. Nationwide population estimates were calculated using sampling weights provided by the AHRQ in order to approximate nationwide hospital prevalence and incidence of these interventions.

Patients with acute PE were identified by ICD-9-CM coding (ICD-9 codes 415.11/13/19): both primary and secondary codes were utilized, increasing sensitivity of identification in order to include patients who may have developed acute PE after admission for another primary diagnosis. Clinical characteristics such as respiratory failure and hemodynamic shock were also identified using ICD-9 diagnosis codes.

Procedures were also identified using ICD-9-CM volume 3 coding. CDI does not have a unique ICD-9 code; the coding for endoluminal intervention (39.79) in the presence of a diagnosis of PE has been previously utilized⁶ and so was incorporated in this study to identify CDI. In addition, procedure codes for invasive pulmonary angiography (88.43) in conjunction with a same-day administration of thrombolytic (99.10), in the absence of coronary or electrophysiology procedures, were used to identify catheter-directed thrombolysis.

Comparative Analysis

The primary outcomes were in-hospital mortality, overall hemorrhagic complications, and hemorrhagic stroke. Secondary outcomes included additional hemorrhagic events such as gastrointestinal bleed and clinically significant hematoma, as well as hospital length of stay and total charges.

Propensity matching was used in order to balance clinical and comorbid conditions^{7,8}. A propensity model was specified using logistic regression on the odds of receiving CDI compared to ST (Supplement Table I). The predicted probability was used as a propensity score in order to match CDI patients to ST patients with the same clinical and comorbid characteristics using 1:1 greedy matching. Validity of the model to create covariate balance between the matched groups was analyzed using significance testing and standardized differences, demonstrating adequate balancing across propensity-matched treatment groups (Supplemental Figure 1). Sensitivity of the propensity model to an unmeasured confounder was assessed using the bounding method described by Rosenbaum^{9,10}.

Exploratory subgroup analyses of high and intermediate-risk patients were performed. Highrisk PE patients were identified using ICD-9 coding of hemodynamic shock. Intermediaterisk patients, however, are more difficult to identify as classification is based on disease and imaging-specific information not present in the NIS. By assuming that those receiving systemic thrombolysis or CDI were either at high or intermediate-risk (i.e, no or very few low-risk patients would receive thrombolysis), removing the high-risk patients, then matching ST patients to those remaining in the lysis cohort, matched subgroups were created approximating those at intermediate-risk.

Statistical Methods

Statistical analyses were performed using Stata SE 13.1 (StataCorp, College Station, TX). Normality was assessed qualitatively. Unadjusted demographic and outcome comparisons ere performed using chi-square, student t-test, Fisher exact, Wilcoxon rank-sum, and Kruskal-Wallis testing where appropriate. Paired t-testing, McNemar test, standardized differences, and binomial-family generalized estimating equation regression with logit link and robust standard errors were used for analysis of matched outcomes.

RESULTS

Using NIS datasets from 2009–2012, we identified 263,955 patient admissions with a diagnosis of acute PE. A minority (n=5727) underwent treatment with ST or CDI: 4272(75%) received ST and 1455(25%) CDI. The average age was 57.1±16.7 years, and 50% were male. A quarter of patients had respiratory failure (n=1500, 26%) and 953 (17%) carried an ICD-9 diagnosis of hemodynamic shock. Compared to patients receiving systemic thrombolysis, patients receiving CDI were significantly younger, were more often male, and had lower rates of respiratory failure, hemodynamic shock, and overall chronic comorbidities including heart failure, hypertension, diabetes, and renal failure (Table I). The median time to initiation of therapy was 1 day for both the CDI (IQR 1–1 days) and ST (IQR 0–2 days; P<.001).

The overall unadjusted in-hospital mortality rate was 15% (n=850), and was significantly higher for the ST group (ST: 17%, n=714; CDI: 9%, n=136; P<.001). Overall unadjusted rates of major hemorrhagic complications did not differ between groups (ST: 7.8%, n=335; CDI: 8.5%, n=123; P=.5), but CDI carried a lower rate of intracranial hemorrhage (CDI: 1.4%, n=20; ST: 2.2%, n=96; P=.04) and higher rates of gastrointestinal bleed (CDI: 4.8%, n=70; ST: 3.5%, n=151; P=.03) and hematoma (CDI: 3.8%, n=55; ST: 2.6%, n=111; P=.02) compared to ST (Table II). CDI patients also had higher unadjusted length of stay (CDI: 8d [5–14]; ST: median 7d, IQR [4–12]; P<.001) and higher total charges (CDI: \$103,919 [\$64,760–\$180,638]; ST: median \$73,757, IQR[\$46,051–\$128,641]; P<.001). CDI subjects had higher rates of concurrent deep venous thrombosis (ST: 35.8%, n=1530; CDI 45.9%, n=668; P<.001) and vena cava filter placement (ST: 31.1%, n=1328; CDI: 57%, n=830; P<.001)

After propensity matching, 1430 patients remained in each group (Table III). Matched mortality did not differ between CDI and ST overall, or in the high-risk or intermediate-risk subgroups (Figure 1). Odds of overall hemorrhagic complication also did not differ between CDI and ST; however, the odds of intracranial hemorrhage were significantly lower for CDI compared to ST, at an expense of higher odds of hematoma in the CDI group (Figure 2). Length of stay remained higher in the CDI group (CDI: median 8d, IQR [5–14]; ST: 7d [5–12]; P=.004) as did total charges (CDI: median \$103,934, IQR [\$64,593–\$180,636]; ST: \$82,025 [\$50,501–\$151,698]; P<.001).

DISCUSSION

Systemic thrombolysis has been established as the standard of care for patients with highrisk PE, but the role of CDI for high risk patients and ST for intermediate-risk patients is poorly defined^{1–3}. Regardless, the usage of ST even in patients with hemodynamic shock is inconsistent and is though to be underutilized nationwide⁶, potentially due to the risk of severe hemorrhagic complications including intracranial hemorrhage. Catheter-directed interventions provide a viable alternative based on the presumption that these interventions provide a similar benefit as ST while decreasing the risk of major hemorrhagic complication by decreasing thrombolytic dose, increasing the thrombolytic infusion time, or utilizing mechanical thrombectomy in place of or adjunctive to thrombolysis^{11,12}. However, these

differences have yet to be consistently demonstrated as few head-to-head studies have been performed.

Our study compared mortality and major hemorrhagic complications of CDI to ST using a propensity-matched cohort to create comparable cohorts balanced in clinical and comorbid characteristics. Our results showed a decreased mortality for CDI compared to ST in the unmatched cohort due to the overall higher acuity of patients receiving ST. However, after matching, mortality did not differ between CDI and ST in the overall cohort or in either of the subgroups (high-risk, intermediate-risk).

Our finding of comparable mortality after adjustment by propensity-matching is not surprising based on mechanistic similarities between CDI and ST¹³; however, this has not been well demonstrated in the literature as comparative effectiveness studies of CDI are limited¹⁴. A recent study by Patel and colleagues¹⁵ using NIS data found that CDI provided a significant benefit for in-hospital mortality compared to ST, with nearly a 40% relative risk reduction and significant decrease in odds (CDI: 13.36%; ST: 21.81%; OR 0.55, 95% CI [0.36–0.85]; P=.007). Our methodology differed from theirs in terms of patient selection, resulting in a larger amount of patients in our study and reflecting a higher sensitivity of identification of acute PE.

The finding of improved mortality in the Patel study is difficult to interpret considering the difficulty of demonstrating improved efficacy of systemic thrombolysis just in comparison to anticoagulation alone in previous trials. These studies have definitively shown improvement after ST in clinical surrogates such as RV function and RV/LV ratio¹⁶. However, they have not consistently individually demonstrated improvement in mortality attributable to ST when compared to anticoagulation alone, requiring meta-analysis of pooled data from randomized trials to demonstrate a mortality benefit for ST^{17,18}. An analysis of NIS data prior to 2009 by Stein and colleagues⁶ found lower case-fatality rates for those with high-risk PE receiving ST, but the study design did not include adjustment for confounding covariates, limiting the ability to draw causal inference.

Likewise, benefits for CDI in improving right heart function have been quantified in several studies^{11,12,14,19,20} but improvement in mortality compared to anticoagulation has not been demonstrated. This casts into doubt the accuracy of results claiming significant improvement in in-hospital mortality for CDI compared to ST in matched cohorts, especially when the efficacy difference between the two treatments is yet unknown but is unlikely to be large, if presuming efficacy of CDI based on mechanistic similarities¹³. Our results showing no difference between the two treatments for improvement of in-hospital mortality suggest that benefit, if it exists, may be found in outcome measures other than mortality.

Conversely, our results showed a higher rate of intracranial hemorrhage for those receiving ST. This is supported by rough historical comparison of single-arm and comparative anticoagulation studies suggesting that CDI carries a decreased risk of bleeding relative to ST, although head-to-head prospective studies comparing ST and CDI have not been performed. Previous studies pooling randomized trials of thrombolytic therapy for acute PE have showed an intracranial bleeding risk^{17,18,21} between 1.5–2.2%, compared to almost no

Our findings suggest that pursuit of a CDI-first strategy in patients stable enough to tolerate the time required to initiate a catheter-directed intervention may be beneficial, due to similar mortality results with systemic thrombolysis with a decreased risk of intracranial hemorrhage. Although this is offset somewhat by the higher incidence of other bleeding complications, previous evidence has shown that these hemorrhagic events tend to be mild and of minimal clinical consequences^{19,20}.

This study is limited by the dataset used for analysis. Although the NIS contains a wealth of clinical data, the granularity and temporal specifics are limited by the use of ICD-9 coding. The limitations of NIS for diagnosis of PE has been previously reported, and the usage of secondary coding positions for identification of acute diagnoses carries a known tradeoff of specificity for sensitivity. In addition, certain selection biases may be present, as bias due to unmeasured disease-specific covariates may confound any analysis despite adjustment. Selection bias may also arise from the types of procedures and patient populations performed, as many patients with severe cardiogenic shock and hypotension may not have had time to receive catheter-directed intervention and so received systemic thrombolysis as primary therapy. The accuracy of classification of high-risk and intermediate-risk groups is predisposed to some unknown level of misclassification despite being performed to the best extent possible given data coding. The extent of risk identification for ICH in the clinical setting is also unable to be determined, leaving potentially relevant factors such as magnitude of hypertension and medication or anticoagulant usage unable to be assessed. The two cohorts demonstrated several important differences at baseline, notably the increased rate of deep venous thrombosis and placement of vena cava filters. The increased rate of DVT in the CDI group is difficult to interpret in the absence of further data granularity but may potentially be due to selection bias from DVT screening, or even due to the effect of systemic thrombolytics on deep venous thrombus. The increased rate of vena cava filter placement likewise is difficult to explain or interpret but may be due in part to filter placement for protection during CDI cases. Despite these limitations, we believe that the study design, large sample size, the continued proliferation of catheter-directed interventions, and use of hard endpoints and propensity-based adjustment mechanisms allows for a reasonable interpretation of these results to be used in clinical practice.

CONCLUSIONS

This study does not demonstrate any differences for in-hospital mortality between systemic thrombolysis and catheter-directed intervention in the treatment of acute massive or submassive pulmonary embolism in a propensity matched cohort of patients. However, systemic thrombolysis carries significantly increased odds of intracranial hemorrhagic complications compared to catheter-directed intervention. Based on the results of this study,

a first-line strategy of catheter-directed intervention should be considered an acceptable option whenever feasible and safe. Further prospective studies should attempt to corroborate these findings in patients suitable for either intervention.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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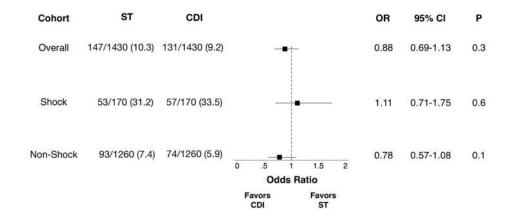


Figure 1. Matched In-Hospital Mortality

OR: odds ratio. CI: confidence interval. ST: systemic thrombolysis. CDI: catheter-directed intervention. ST and CDI columns are mortalities/total cohort (N%).

Secondary Outcome	ST	CDI		OR	95% CI	Р
Overall Hemorrhagic	126/1430 (8.8)	121/1430 (8.5)	-	0.96	0.74-1.24	0.7
Intracranial Hemorrhage	40/1430 (2.8)	19/1430 (1.3)		0.47	0.27-0.82	0.01
GI Bleeding	57/1430 (4.0)	69/1430 (4.8)		1.22	0.86-1.73	0.3
Procedural Hematoma	35/1430 (2.4)	54/1430 (3.8)	0 .5 1 1.5 2 Odds Ratio	1.56	1.01-2.41	0.04
			Favors Favors CDI ST			

Figure 2. Matched Secondary Outcomes

OR: odds ratio. CI: confidence interval. ST: systemic thrombolysis. CDI: catheter-directed intervention. ST and CDI columns are events/total cohort (N%)

Table 1

Unmatched Cohort Characteristics

	Total	ST	CDI	Р
	N=5727	N=4272	N=1455	
Age	57.13±16.7	57.41±16.7	56.32±16.7	.032
Female	2849 (49.8)	2195 (51.4)	654 (44.9)	<.001
Hypertension	2890 (50.5)	2198 (51.5)	692 (47.6)	.010
Congestive Heart Failure	776 (13.5)	621 (14.5)	155 (10.7)	<.001
Diabetes Mellitus	1185 (20.7)	932 (21.8)	253 (17.4)	<.001
Chronic Renal Failure	516 (9.0)	421 (9.9)	95 (6.5)	<.001
Emphysema	1029 (18.0)	777 (18.2)	252 (17.3)	.46
Cancer	618 (10.8)	446 (10.4)	172 (11.8)	.14
Respiratory Failure	1500 (26.2)	1192 (27.9)	308 (21.2)	<.001
Hypotension	953 (16.6)	779 (18.2)	174 (12.0)	<.001
Deep Venous Thrombosis	2198 (38.4)	1530 (35.8)	668 (45.9)	<.001
Vena Cava Filter Placement	2158 (37.7)	1328 (31.1)	830 (57.0)	<.001

all values are mean \pm sd or N(%).

Table 2

Unmatched Cohort Outcomes

	ST	CDI	Р
	N=4272	N=1455	
In-Hospital Mortality	714 (16.7)	136 (9.4)	<.001
Any Major Bleed	335 (7.8)	123 (8.5)	.46
Intracranial Hemorrhage	96 (2.2)	20 (1.4)	.041
GI Bleed	151 (3.5)	70 (4.8)	.029
Procedural Hematoma	111 (2.6)	55 (3.8)	.020
Discharge Location			<.001
Home	2674 (62.6)	1025 (70.4)	
Skilled or Rehab Facility	882 (20.7)	293 (20.2)	

all values are N(%).

Table 3

Matched Cohort Characteristics

	ST	CDI	Р	Std Diff
	N=1430	N=1430		
Age	55.80 ± 16.5	56.39 ± 16.7	.34	0.02
Female	647 (45.2)	641 (44.8)	.82	0.01
HTN	671 (46.9)	683 (47.8)	.65	0.04
CHF	121 (8.5)	153 (10.7)	.042	0.03
DM	227 (15.9)	247 (17.3)	.31	0.04
Chronic Renal Failure	88 (6.2)	94 (6.6)	.65	0.01
COPD	242 (16.9)	248 (17.3)	.77	0.01
Any Cancer	170 (11.9)	170 (11.9)	1.00	0.01
Respiratory Failure	293 (20.5)	302 (21.1)	.68	0.02
Hypotension	161 (11.3)	170 (11.9)	.60	0.07
DVT	655 (45.8)	658 (46.0)	.91	0.01
IVC Filter Placement	804 (56.2)	819 (57.3)	.57	0.03

all values are mean±sd or N(%). A standardized difference of <0.1 suggests adequate variable balance after propensitymatching. Std Diff: standardized differences.