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ORIGINAL ARTICLE

Comparing Management Strategies in Patients With Clot-in-Transit

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BACKGROUND: Clot-in-transit is associated with high mortality, but optimal management strategies remain uncertain. The aim of this study was to compare the outcomes of different treatment strategies in patients with clot-in-transit.

METHODS: This is a retrospective study of patients with documented clot-in-transit in the right heart on echocardiography across 2 institutions between January 2020 and October 2023. The primary outcome was a composite of in-hospital mortality, resuscitated cardiac arrest, or hemodynamic decompensation.

RESULTS: Among 35 patients included in the study, 10 patients (28.6%) received anticoagulation alone and 2 patients (5.7%) received systemic thrombolysis, while 23 patients (65.7%) underwent catheter-based therapy (CBT; 22 mechanical thrombectomy and 1 catheter-directed thrombolysis). Over a median follow-up of 30 days, 9 patients (25.7%) experienced the primary composite outcome. Compared with anticoagulation alone, patients who received CBT or systemic thrombolysis had significantly lower rates of the primary composite outcome (12% versus 60%; log-rank $P<0.001$; hazard ratio, 0.13 [95% CI, 0.03–0.54]; $P=0.005$) including a lower rate of death (8% versus 50%; hazard ratio, 0.10 [95% CI, 0.02–0.55]; $P=0.008$), resuscitated cardiac arrest (4% versus 30%; hazard ratio, 0.12 [95% CI, 0.01–1.15]; $P=0.067$), or hemodynamic deterioration (4% versus 30%; hazard ratio, 0.12 [95% CI, 0.01–1.15]; $P=0.067$).

CONCLUSIONS: In this study of CBT in patients with clot-in-transit, CBT or systemic thrombolysis was associated with a significantly lower rate of adverse clinical outcomes, including a lower rate of death compared with anticoagulation alone driven by the CBT group. CBT has the potential to improve outcomes. Further large-scale studies are needed to test these associations.

GRAPHIC ABSTRACT: A graphic abstract is available for this article.

Key Words: catheters ■ pulmonary embolism ■ thrombectomy ■ thrombosis

Pulmonary embolism (PE) stands as the third leading cause of cardiovascular mortality among hospitalized patients.[1,2] Occasionally associated with acute PE, clot-in-transit (CIT) involves mobilized deep venous thromboses temporarily lodged in the right atrium or ventricle. Right heart thrombi is detectable echocardiographically in ≈4% of patients with PE and can be adherent or free-floating.[3] CIT has been shown to be associated with high mortality, with prior studies demonstrating a mortality rate of up to 20.4%.[4]

The current treatment modalities for CIT include anticoagulation alone, systemic thrombolysis (ST), catheter-based therapy (CBT), or surgical embolectomy. Despite the high mortality, the optimal therapy for CIT remains uncertain, sparking ongoing debates in treatment selection. European Society of Cardiology 2019 guidelines for acute PE also do not provide specific recommendations for the treatment of CIT.[5] The increasing utilization of CBT in acute PE treatment has sparked interest in its application for CIT as well but

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WHAT IS KNOWN

- Clot-in-transit is associated with high mortality, but the optimal treatment strategy remains unclear.

WHAT THE STUDY ADDS

- Catheter-based thrombectomy is a promising treatment option for patients with clot-in-transit and may improve outcomes in this patient population.

Nonstandard Abbreviations and Acronyms

BNP	B-type natriuretic peptide
CBT	catheter-based therapy
CIT	clot-in-transit
HR	hazard ratio
PE	pulmonary embolism
ST	systemic thrombolysis

has not been rigorously evaluated in this patient population.[6,7] Additionally, no studies have directly compared the outcomes of CBT and other treatment options in this patient population. As a result, we conducted a 2-center study to assess and compare treatment modalities in patients with CIT.

METHODS

The study was approved by the New York University institutional review board with a waiver of informed consent. The data that support the findings of this study are available on reasonable request from the corresponding author. This study involved the collaboration of 2 large academic tertiary care centers. The study cohort comprised patients aged at least 18 years, with documented CIT on echocardiography between January 2020 and October 2023. At institution A, a comprehensive search was conducted in the echocardiography reporting system syngo Dynamics workplace using the keywords "thrombus," "clot," "mass," and "transit" to identify all patients diagnosed with CIT. The report findings were subsequently adjudicated by a board-certified echocardiographer. Conversely, at institution B, where patients with CIT routinely underwent mechanical thrombectomy, participants were identified from an existing database comprising those with CIT who had undergone mechanical thrombectomy.

Management decisions on any CIT patient involved a multidisciplinary discussion, which included a PE response team. If the decision to proceed with catheter intervention was taken, the CBT was determined by the interventional team, which included catheter-directed lysis or mechanical thrombectomy. Institution B primarily used a strategy of mechanical thrombectomy.

Baseline demographics, echocardiographic data, invasive hemodynamics, procedural and in-hospital clinical outcomes were collected and analyzed. Patients were classified as high, intermediate, or low risk according to the criteria specified by the European Society of Cardiology PE guidelines.[5] Cardiac index was calculated using the Fick equation with an estimated oxygen consumption.[8] The simplified pulmonary embolism severity index, Bova scores, and composite PE shock scores were calculated based on the original derivation and validation studies.[9–12]

Study Outcomes

The primary outcome was a composite of in-hospital mortality, resuscitated cardiac arrest, or hemodynamic decompensation. Hemodynamic decompensation was defined as a systolic blood pressure <90 mm Hg for at least 15 minutes or a drop of systolic blood pressure by at least 40 mm Hg for at least 15 minutes with signs of end-organ hypoperfusion (cold extremities, low urinary output < 30 mL/hour, or mental status change) or need for catecholamine administration to maintain adequate organ perfusion and SBP ≥90 mm Hg. Secondary outcomes were individual components of the primary outcome and intensive care unit length of stay. Outcomes were adjudicated by 2 physicians.

Statistical Analyses

Continuous variables were presented as mean±SD or median with interquartile range for skewed data, while categorical data are expressed as frequency and proportions. The paired Student *t* test was utilized to compare paired continuous variables when assumptions were met for normal distribution, and the Wilcoxon signed-rank test was used when distribution was not normal. Categorical variables were compared using the χ^2 test or the Fisher exact test. To assess the relationship between treatment modalities and clinical outcomes, we categorized patients into 2 groups: anticoagulation alone versus those who received ST or CBT in addition to anticoagulation. A Kaplan-Meier curve was generated for the 2 groups, and the log-rank test was used to compare differences between the 2 groups. Cox proportional hazards models were constructed to assess the association between the primary and secondary outcomes between the treatment groups. Schoenfeld residuals were used to test the proportional hazard assumption of the Cox model. Sensitivity analysis was performed comparing mechanical thrombectomy (the predominant CBT strategy) versus anticoagulation alone. We then performed an additional analysis comparing outcomes between the 2 institutions based on practice patterns. Institution A generally adopts a conservative approach of anticoagulation alone with ST or CBT reserved for select cases as decided by the PE response team, while institution B adopts a routine invasive approach, employing urgent upfront mechanical thrombectomy in patients who present with CIT as decided by the PE response team. This was performed to potentially minimize selection bias in observational studies (eg, relatively healthier patients selected for CBT). All tests were considered significant at a 2-sided α level <0.05. All analyses were performed using Stata software (StataCorp 18 LP, College Station, TX).

RESULTS

A total of 35 patients with CIT were included, and the majority (97%) of patients also had documented

concomitant PE. Among them, 10 patients (28.6%) received anticoagulation alone, while 23 patients (65.7%) underwent upfront therapy involving CBT (22 mechanical thrombectomy [FlowTriever System and Inari Medical] and 1 catheter-directed thrombolysis) in addition to anticoagulation. Additionally, 2 patients (5.7%) received upfront therapy with ST in conjunction with anticoagulation. Baseline demographics and clinical variables are summarized in Table 1.

Compared with the group that received anticoagulation alone, patients who received ST or CBT had lower rates of active cancer (12% versus 60%; *P*=0.003), higher rates of high-risk PE (40% versus 22%; *P*=0.046), and lower systolic blood pressures at presentation (116±22 versus 139±26; *P*=0.024) but no difference in other demographics, comorbidities, and presentation characteristics including those with cardiac arrest (12% versus 20%; *P*=0.54), shock (44% versus 30%; *P*=0.45), documented concomitant PE (100% versus 90%; *P*=0.10), saddle PE (23% versus 20%; *P*=0.86), and need for preprocedure veno-arterial extracorporeal membrane oxygenation (8% versus 0%; *P*=0.38). Patients who received ST or CBT also had higher rates of elevated troponins (84% versus 50%; *P*=0.04) and right ventricle dysfunction (100% versus 60%; *P*<0.001) but no difference in BNP (B-type natriuretic peptide), lactate levels, and creatinine. The Bova (2.5±0.9 versus 1.8±1.0; *P*=0.04) was higher in the CBT or ST group, but there was no difference in the simplified pulmonary embolism severity index and composite PE shock score. In patients who underwent CBT, the median time from diagnosis of CIT to intervention was 6.8 (interquartile range, 5–21) hours with a mean preprocedure cardiac index of 1.7±0.5 that improved 2.1±0.4 (*P*<0.001) after CBT.

Overall, a total of 9 (25.7%) patients experienced the primary composite outcome over a median follow-up time of 30 (interquartile range, 10–30) days. The primary composite outcome was significantly lower in the group that received ST or CBT compared with those on anticoagulation alone (12% versus 60%; log-rank *P*<0.001; hazard ratio [HR], 0.13 [95% CI, 0.03–0.54]; *P*=0.005; Figure 1; Table 2). Patients who received ST or CBT also had lower rates of 30-day all-cause mortality (8% versus 50%; log-rank *P*<0.001; HR, 0.10 [95% CI, 0.02–0.55]; *P*=0.008; Figure 2), resuscitated cardiac arrest (4% versus 30%; log-rank *P*=0.02; HR, 0.12 [95% CI, 0.01–1.15]; *P*=0.067; Figure 3), and new or worsening hemodynamic instability (4% versus 30%; log-rank *P*=0.02; HR, 0.12 [95% CI, 0.01–1.15]; *P*=0.067; Figure 4). Patients on anticoagulation alone also required a higher rate of rescue therapy (30% versus 0%; *P*=0.017) with 2 patients requiring CBT and 1 patient requiring ST. Both patients who received upfront ST did not experience the primary composite outcome.

In a sensitivity analysis comparing mechanical thrombectomy versus anticoagulation alone, patients who underwent upfront mechanical thrombectomy had lower rates of the primary composite outcome (14% versus 60%; log-rank *P*=0.003; HR, 0.14 [95% CI, 0.04–0.62]; *P*=0.009; Figure 5).

In an additional comparative analysis of outcomes between the 2 different institutions, there were 13 patients from institution A and 22 patients from institution B. There was no difference in age and female gender, but institution A (predominantly conservative strategy) had higher rates of a history of malignancy (46% versus 14%; *P*=0.033; Table S1). Institution A had lower rates of high-risk PE (17% versus 45%; *P*=0.049), higher systolic blood pressure on presentation (136±21 versus 114±27 mm Hg; *P*=0.019), lower rates of troponin elevation (54% versus 86%; *P*=0.033), lower BNP (587±1064 versus 6635±8689 pg/mL; *P*=0.030), and lower rates of right ventricle dysfunction (69% versus 100%; *P*=0.006) compared with institution B (predominantly invasive strategy). Institution A had a higher rate of the primary composite outcome (40% versus 13.6%; log-rank *P*=0.02) and 30-day all-cause mortality (33.3% versus 9%; log-rank *P*=0.02) despite an overall lower risk clinical group (Figure 6; Table S2).

DISCUSSION

The primary finding of our study is that patients with CIT have a high risk of the primary composite outcome, including a high risk of 30-day mortality. Those treated with upfront advanced therapies (92% CBT and 8% ST) had a lower rate (12% versus 60%) of the primary composite outcome (composite of in-hospital mortality, resuscitated cardiac arrest, or hemodynamic decompensation) than those treated with anticoagulation alone. Additionally, patients treated with CBT or ST had a lower rate of the individual components of the primary composite outcome, including a lower rate of all-cause death, resuscitated cardiac arrest, or hemodynamic decompensation.

The well-established high mortality rate linked to CIT has not prompted the adoption of upfront aggressive management strategies, primarily due to the elevated risk of intracranial hemorrhage associated with systemic thrombolytics and the nonnegligible morbidity and mortality associated with surgical embolectomy. Our findings make a valuable contribution to the ongoing discourse in the literature about the optimal management of CIT, an area currently marked by controversy with existing guidelines that do not provide explicit recommendations on optimal management strategies. Prior analyses of registries and meta-analyses have suggested conflicting data about the efficacy of ST in the treatment of CIT.[4,13,14] It is likely that similar to acute PE, any potential benefit seen with ST is largely offset by major bleeding and a known nonnegligible risk of intracranial hemorrhage. Additionally, many patients may have relative or absolute contraindications to ST, making them ineligible for this

Table 1. Baseline Characteristics and Clinical Data

	Anticoagulation alone (n=10)	CBT or ST (n=25)	*P* value
Demographics			
Age, y	58.6±15.4	60.1±18.0	0.82
Male	7 (70%)	16 (64%)	0.74
Obesity	2 (20%)	10 (42%)	0.23
Hypertension	5 (50%)	10 (40%)	0.59
Active cancer	6 (60%)	3 (12%)	0.003
Diabetes	3 (30%)	7 (28%)	0.91
History of chronic lung disease	2 (20%)	3 (12%)	0.54
CKD (III–V)	1 (%)	3 (%)	0.87
Recent surgery	3 (30%)	4 (16%)	0.35
Immobilization	3 (30%)	16 (64%)	0.07
History of PE	2 (20%)	1 (4%)	0.14
History of DVT	3 (30%)	1 (4%)	0.03
Clinical variables			
PE with CIT	9 (90%)	25 (100%)	0.11
PE classification			
Low risk	2 (22%)	0 (0%)	0.046
Intermediate risk	5 (56%)	15 (60%)	
High risk	2 (22%)	10 (40%)	
Preprocedure			
Cardiac arrest preprocedure	2 (20%)	3 (12%)	0.54
Shock preprocedure	2 (20%)	10 (40%)	0.45
Vasopressors preprocedure	2 (20%)	8 (32%)	0.48
Inotropes preprocedure	1 (10%)	4 (16%)	0.65
VA ECMO	0 (0%)	2 (8%)	0.38
Initial SBP, mm Hg	138.8±22.4	116.4±26.2	0.024
Initial DBP, mm Hg	92.4±12.4	77.0±18.6	0.023
Initial heart rate, beats/min	114.3±21.0	110.8±20.1	0.65
Saddle PE	2 (20%)	5 (23%)	0.86
Proximal DVT			
Yes	3 (30%)	15 (60%)	0.10
No	2 (20%)	6 (24%)	
Troponin elevation	5 (50%)	21 (84%)	0.038
BNP, pg/mL	718.6±1240.1	5867.8±8401.1	0.097
Lactate, mmol/L	3.4±3.4	3.5±2.4	0.90
Hemoglobin, g/dL	11.4±2.3	12.5±2.5	0.24
WBC count, 10^9/L	11.5±4.9	13.5±4.5	0.26
Creatinine, mg/dL	2.3±4.1	1.7±1.4	0.52
RV dysfunction	6 (60%)	25 (100%)	<0.001
sPESI	2.6±1.0	1.8±1.1	0.056
Bova	1.8±1.0	2.5±0.9	0.044
CPES	4.8±1.2	5.2±0.9	0.36
Cardiac index preprocedure		1.7±0.5	
PASP preprocedure, mm Hg		53.6±15.1	
mPAP preprocedure, mm Hg		33.1±10.2	
Cardiac index postprocedure		2.1±0.4	

Values are mean±SD or n/N (%). BNP indicates B-type natriuretic peptide; CBT, catheter-based therapy; CIT, clot-in-transit; CKD, chronic kidney disease; CPES, composite pulmonary embolism shock; DBP, diastolic blood pressure; DVT, deep vein thrombosis; mPAP, mean pulmonary artery pressure; PASP, pulmonary artery systolic pressure; PE, pulmonary embolism; RV, right ventricle; SBP, systolic blood pressure; sPESI, simplified pulmonary embolism severity index; ST, systemic thrombolysis; VA ECMO, veno-arterial extracorporeal membrane; and WBC, white blood count.

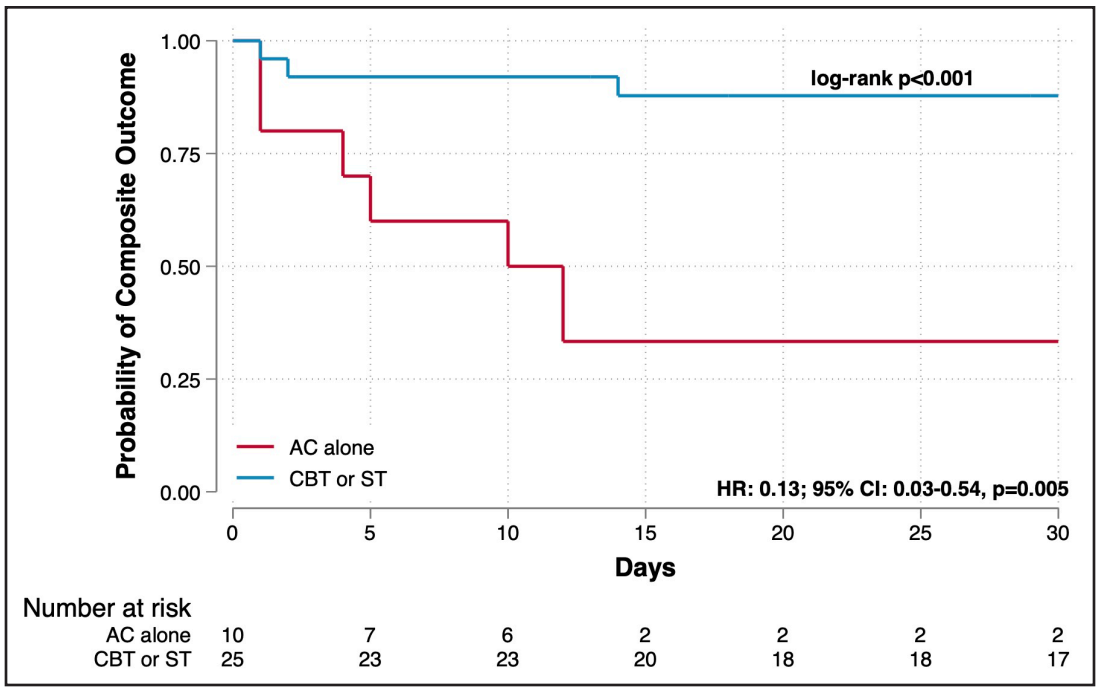

Figure 1. Kaplan-Meier curve stratified by patients who received anticoagulation (AC) alone vs catheter-based therapies (CBTs) or systemic thrombolysis (ST) for the primary composite outcome.
HR indicates hazard ratio.

therapy. However, relying solely on anticoagulation in this population has proven inadequate, with prior meta-analyses reporting mortality rates of up to 20.4% and many patients spending a substantial duration outside the therapeutic anticoagulation range.[4,15]

Given the recent and rapid advancements in CBT, there has been a growing interest in percutaneous therapies in patients with CIT. This approach offers thrombus extraction without an increased risk of intracranial hemorrhage. However, this treatment approach has not been thoroughly examined in this patient population, and existing data are predominantly confined to small case series, individual case reports, or registries with a heterogeneous patient population.[16] In the Registry of AngioVac Procedures in Detail, the study reported outcomes of the removal of caval thromboembolism, right heart masses, and catheter-related thrombi using the AngioVac system (AngioDynamics, Latham, NY). While the overall mortality rate was low (1.3% within 24 hours after the procedure), drawing direct comparisons with our study proves challenging due to the heterogeneity of the populations studied; notably, the right heart mass population included tumors, vegetations, and intracardiac thrombi (n=47). While the Registry of AngioVac Procedures in Detail documented 47 patients with intracardiac thrombi alone, it did not specify whether these thrombi were adherent to cardiac structures or CIT, whereas all 35 patients in our cohort presented with CIT. Furthermore, outcomes for these subgroups were not independently reported in the study. The AngioVac system also requires a perfusionist and a venovenous extracorporeal membrane oxygenation circuit and, as such, potentially rendering it less convenient to use than the FlowTriever.[17,18]

Table 2. Clinical Outcomes

	Anticoagulation alone (n=10)	CBT or ST (n=25)	*P* value	Hazard ratio (95% CI)	*P* value
Primary composite outcome	6 (60%)	3 (12%)	<0.001*	0.13 (0.03–0.54)	0.005
Death at 30 d	5 (50%)	2 (8%)	<0.001*	0.10 (0.02–0.55)	0.008
Cardiac arrest	3 (30%)	1 (4%)	0.02*	0.12 (0.01–1.15)	0.067
New or worsening shock	3 (30%)	1 (4%)	0.02*	0.12 (0.01–1.15)	0.067
Rescue therapy					
CBT	2 (20%)	0 (0%)	0.017		
Systemic thrombolysis	1 (10%)	0 (0%)			
ICU length of stay	7.1 (8.7)	9.7 (17.0)	0.77		

CBT indicates catheter-based therapy; ICU, intensive care unit; and ST, systemic thrombolysis.
**P* value derived from log-rank test.

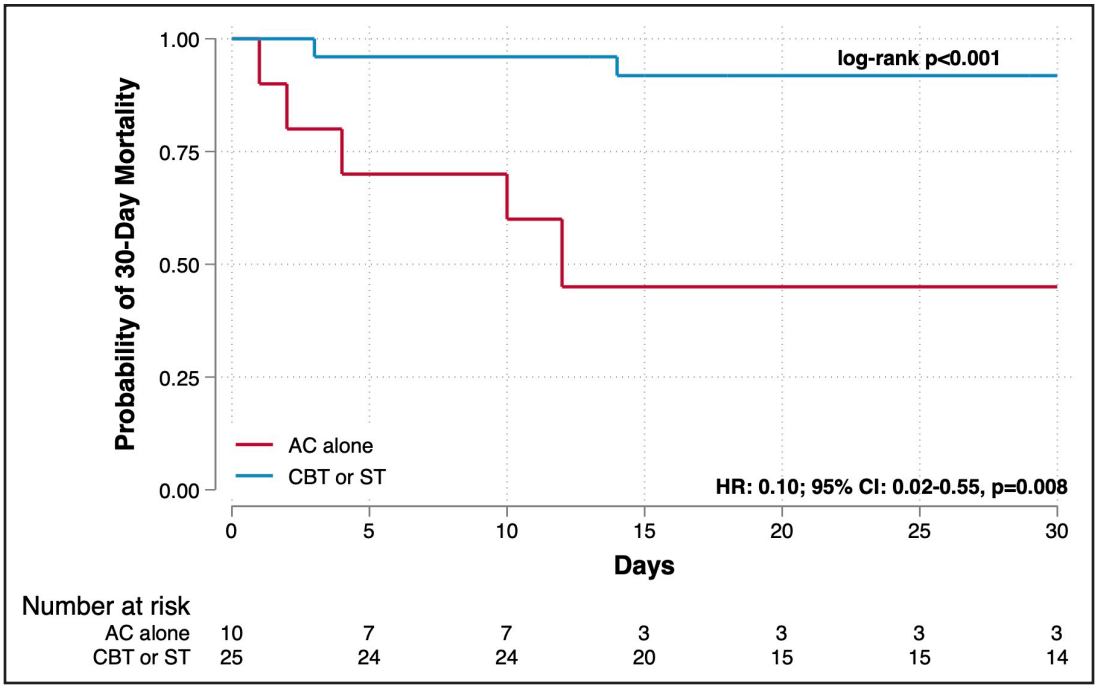

Figure 2. Kaplan-Meier curve stratified by patients who received anticoagulation (AC) alone vs catheter-based therapies (CBTs) or systemic thrombolysis (ST) for 30-day all-cause mortality.
HR indicates hazard ratio.

In our cohort, we found that a primary strategy with either CBT (96% mechanical thrombectomy) or ST in patients with CIT was associated with absolute 30-day mortality of 8%, which is much lower than what has been reported in the literature and is in stark contrast to the high rates of mortality in the anticoagulation alone group (50%). Importantly, this observation is noteworthy despite the higher proportion of patients in the advanced therapy

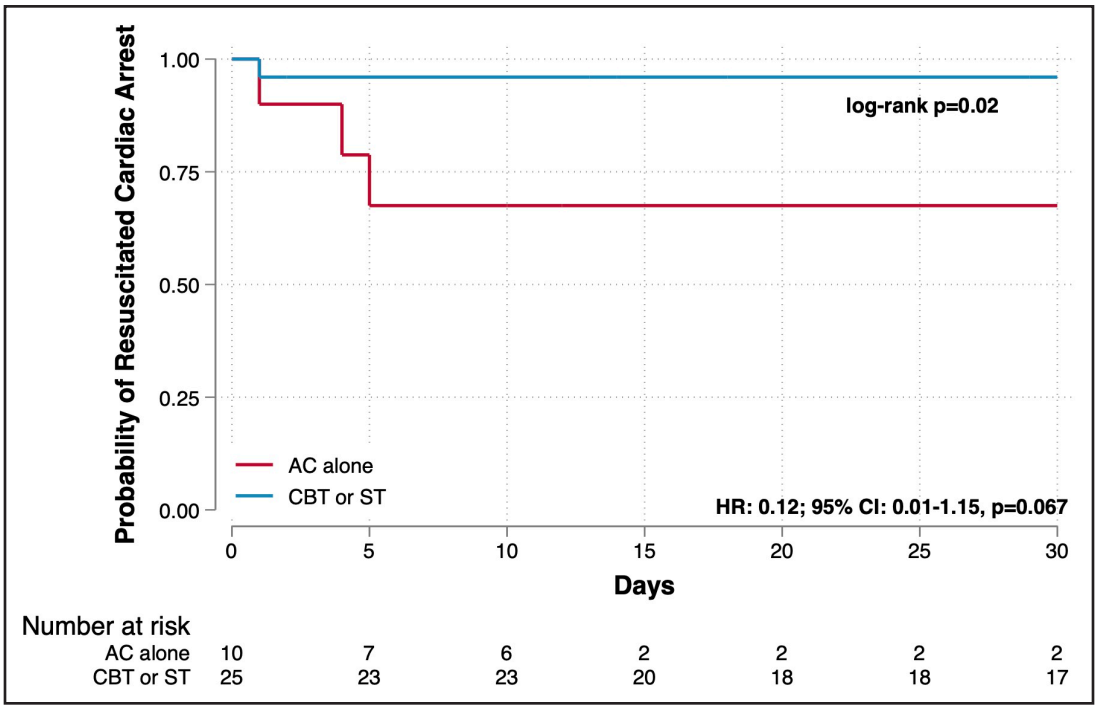

Figure 3. Kaplan-Meier curve stratified by patients who received anticoagulation (AC) alone vs catheter-based therapies (CBTs) or systemic thrombolysis (ST) for resuscitated cardiac arrest.
HR indicates hazard ratio.

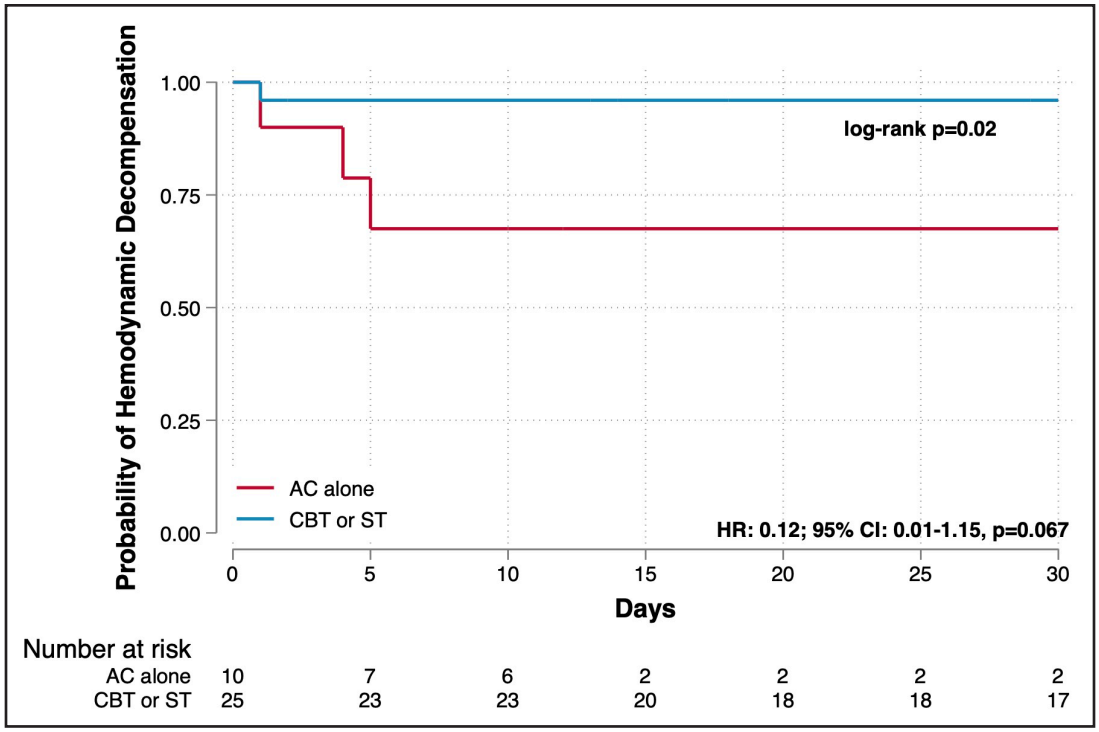

Figure 4. Kaplan-Meier curve stratified by patients who received anticoagulation (AC) alone vs catheter-based therapies (CBTs) or systemic thrombolysis (ST) for hemodynamic decompensation.
HR indicates hazard ratio.

group presenting with high-risk PE and other clinical markers of elevated risk such as lower systolic BP, higher rates of right ventricle dysfunction, and elevated biomarkers. This underscores the concept that despite presenting with stable hemodynamics, patients with CIT face a potentially imminent, unpredictable, and sudden risk of hemodynamic decompensation. This risk is likely in part dependent on the existing underlying burden of

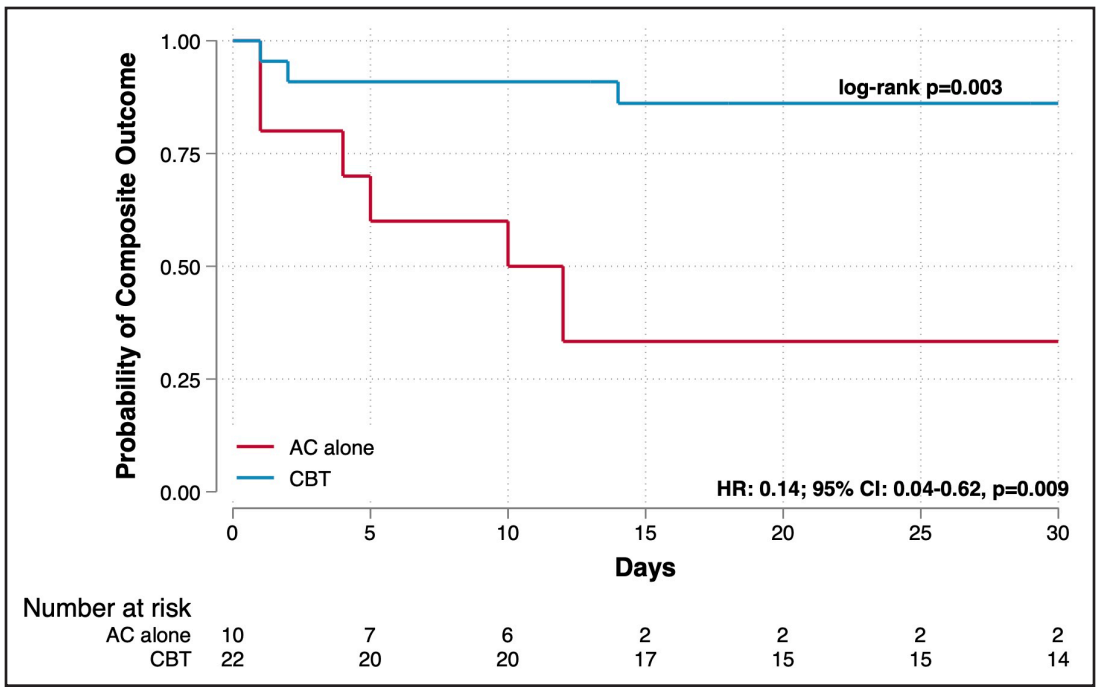

Figure 5. Kaplan-Meier curve stratified by patients who received anticoagulation (AC) alone vs mechanical thrombectomy for the primary composite outcome.
HR indicates hazard ratio.

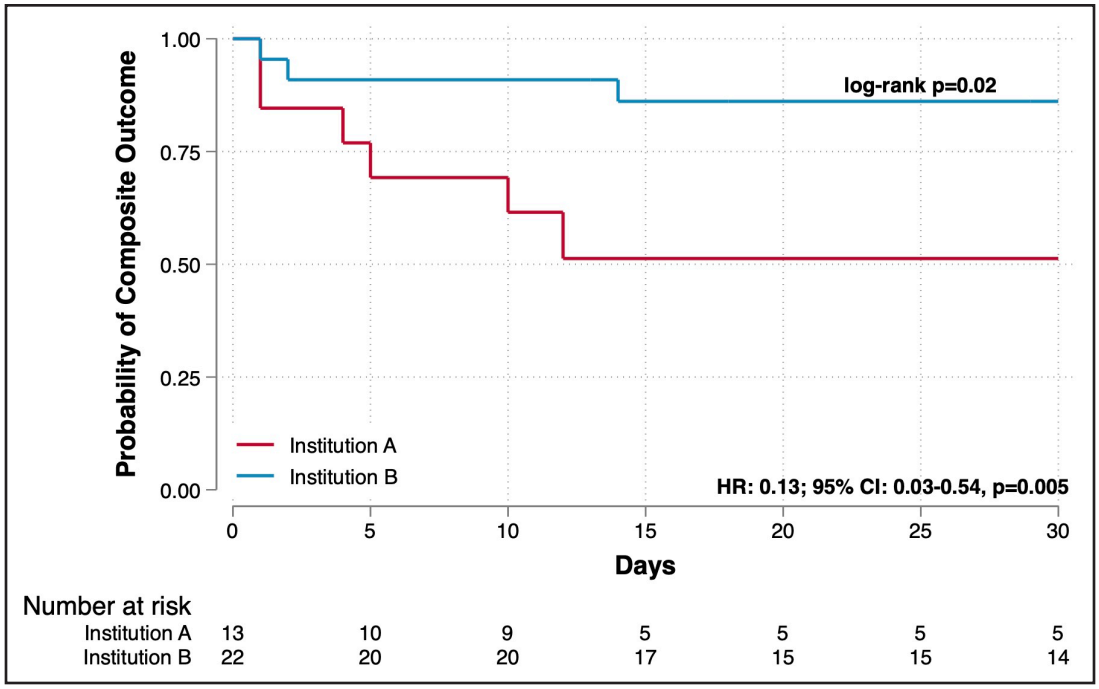

Figure 6. Kaplan-Meier curve stratified by patients from institution A vs institution B for the primary composite outcome.
HR indicates hazard ratio.

PE. Importantly, traditional risk stratification tools, such as the European Society of Cardiology PE classification, may not comprehensively capture the unique risk profile of this specific cohort. In our cohort, 30% of patients on anticoagulation alone had new or worsening hemodynamic decompensation, and 30% needed rescue therapy highlighting the unstable nature of this patient population. Our findings suggest that upfront mechanical thrombectomy (the predominant nonanticoagulation-alone strategy), which offers a thrombus removal strategy without additional risks of intracranial hemorrhage, is a promising treatment option for patients with CIT.

Finally, our comparative analysis of 2 institutions with distinct approaches to CIT provides a unique opportunity to compare an upfront invasive strategy with mechanical thrombectomy against a more conservative strategy. Overall, the primary composite outcome (40% versus 13.6%; log-rank *P*=0.002) and 30-day all-cause mortality (33.3% versus 9%; log-rank *P*=0.003) were significantly lower at institution B, where upfront mechanical thrombectomy is consistently provided for patients without contraindications and when in line with their goals of care. Despite the retrospective and nonrandomized nature of our analysis, the unique ability to compare these 2 general management strategies potentially reduces selection bias and is likely to provide valuable guidance for physicians operating in an area where prospective evidence is currently lacking. Moreover, conducting large prospective trials in this patient population remains challenging due to the low prevalence of CIT. Nonetheless, there is still likely significant residual confounding in this analysis, making it difficult to draw definitive conclusions from this data.

Several limitations must be acknowledged when interpreting the findings of this study. First, the retrospective nature of the analysis introduces inherent selection biases and limitations associated with data collection and potential confounding variables. Additionally, the study's sample size increases the risk of a type I error. Additionally, the small sample size does not allow the analysis to adjust for confounders (measured or unmeasured). The lack of randomization and the absence of a prospective design pose challenges in establishing causal relationships between treatment strategies and outcomes, and increases the risk of selection bias. While the comparative analysis between institutions may mitigate some selection bias, it is crucial to acknowledge that variations in clinical practices between the 2 institutions, such as differences in patient selection criteria, procedural techniques, and threshold to escalate therapy, may influence the observed outcomes. Given the retrospective nature of this study, there is a possibility that not all cases during the specified time period were captured. This limitation could impact the accuracy of the study's findings and conclusions, potentially resulting in an incomplete or skewed understanding of the population of interest. The absence of data on PE-related mortality represents a limitation inherent in our current study; however, many completed and ongoing randomized controlled trials have used all-cause mortality as the mortality end point.[19–21]

CONCLUSIONS

In our study examining CBT in patients with CIT, despite a higher-risk cohort, both CBT and ST were found to be associated with lower rates of adverse clinical outcomes, including a reduced incidence of death compared with patients treated with anticoagulation alone. Among those who received anticoagulation alone, the risk of the primary composite outcome was 60%, with all-cause death of 50%, resuscitated cardiac arrest, and hemodynamic decompensation of 30%, underscoring the high-risk nature of the current management practices for this cohort. The implementation of CBT or ST demonstrates the potential for improving overall outcomes. However, additional large-scale studies are necessary to validate and further explore these associations.

ARTICLE INFORMATION

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Disclosures

Dr Bangalore is on the Advisory Board of Abbott Vascular, Boston Scientific, Biotronik, Amgen, Pfizer, Merck, Reata, Inari, and Truvic. The other authors report no conflicts.

Supplemental Material

Tables S1–S2

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