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Large-bore aspiration thrombectomy versus catheter-directed thrombolysis for the treatment of pulmonary embolism: A retrospective case review from a community hospital

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ABSTRACT

Objectives: This study aimed to assess acute outcomes following pulmonary embolism (PE) treatment with large-bore aspiration thrombectomy (LBAT) versus catheter-directed thrombolysis (CDT).

Material and Methods: This single-center retrospective analysis included patients who received interventional therapy for acute PE from 2018 to 2022. The primary outcomes were changes in pre-procedural mean pulmonary artery pressure (PAP), heart rate (HR), oxygen saturation, and supplemental requirements following the procedure. Mean PAP was measured immediately post-procedure for LBAT patients and on postoperative day 1 (POD#1) for CDT patients.

Results: A total of 48 patient cases were reviewed, 31 underwent LBAT and 17 underwent CDT. The majority of patients were female and most had intermediate-high-risk PE. No major bleeding events or device-related complications occurred. LBAT resulted in a significant decrease in average mean PAP immediately post-procedure (31.3 ± 9.0–21.4 ± 8.1 mmHg; $P < 0.001$). On POD#1, CDT resulted in a significant decrease in mean PAP (31.7 ± 11.2–25.6 ± 7.9 mmHg; $P = 0.005$). The decrease in mean PAP was greater in the LBAT versus CDT group ($P < 0.05$). Through POD#1, a similar reduction in average HR was observed between groups; however, a statistically significant reduction in HR was noted immediately post-procedure with LBAT and not with CDT. LBAT patients had a significant reduction in average supplemental oxygen requirements post-procedure.

Conclusion: LBAT was associated with a greater reduction in mean PAP than CDT at an earlier post-procedural time point. LBAT may be advantageous over CDT due to rapid thrombus extraction; however, further studies with increased sample sizes are needed.

Evidence-based medicine: Level of Evidence: Level 3, Local non-random sample.

Keywords: Catheter-directed thrombolysis, Interventional radiology, Mechanical thrombectomy, Pulmonary embolism

INTRODUCTION

Pulmonary embolism (PE) treatment has been evolving over the past decade, with a shift toward interventional treatment for intermediate- or high-risk PE patients. PE is categorized as high-risk or massive if the patient is hemodynamically unstable.[1] Intermediate-risk or submassive

PE occurs in the absence of hemodynamic instability and can be classified as intermediate-high-risk, defined by right ventricular (RV) dysfunction on echocardiogram (echo) or computed tomography along with elevated serum cardiac markers,[2-4] or intermediate-low-risk, defined by either RV dysfunction or elevated cardiac markers, or, in the absence of either sign, a Pulmonary Embolism Severity Index (PESI) score class III or higher.[1,5]

Interventional PE treatment modalities include catheter-directed thrombolysis (CDT) and large-bore aspiration thrombectomy (LBAT).[2] With CDT, a thrombolytic agent is slowly infused through a catheter in the pulmonary artery (PA) to lyse thrombus.[2] CDT can be performed with infusion catheters across thrombus in the bilateral PAs or with a pigtail catheter in the main PA, which is equally effective.[6,7] Although the risk of bleeding with targeted CDT is lower than that with systemic thrombolysis, using any thrombolytic agent still carries some risk for major bleeding.[2,8,9] As such, newer thrombectomy devices that avoid the use of thrombolytics have gained popularity in the treatment of PE.[10] LBAT utilizes mechanical aspiration to remove the thrombus from the PAs. In this retrospective case review, the acute outcomes of PE patients who underwent treatment with CDT were compared to those who underwent LBAT.

MATERIAL AND METHODS

Study design

This single-center retrospective case review conducted at Silver Cross Hospital included all patients with acute PE who received interventional treatment with CDT or LBAT from 2018 through 2022. Silver Cross Hospital is a 348-bed institution with 36 intensive care unit (ICU) beds including both a medical-surgical and cardiovascular ICU. Interventional radiology (IR) is onsite with standard Monday–Friday operations as well as 24/7 on-call service. This is a community hospital; therefore, no residents or fellows were present throughout the hospital. Silver Cross is a free-standing hospital with several university-level hospital affiliations in an effort to provide the best care and services to all patients in the community.

Procedural details

On presentation, all patients had a computed tomography angiogram (CTA) of the chest with a protocol optimized to diagnose and visualize PE. After PE confirmation, patients were started on a weight-based heparin intravenous (IV) infusion following the hospital's thromboembolism protocol. All patients also received an echo before or after the procedure depending on treatment urgency. All patients underwent PE risk stratification during presentation taking into account thrombus burden and the patient's overall clinical picture. A PE response team is not present and treatment decisions for PE intervention are made through discussion between the pulmonologist, emergency room physician (if presenting from the emergency department), and interventional radiologist.

For patients receiving CDT, a central catheter was placed before obtaining groin femoral vein access to allow blood draws without repetitive venipuncture. After obtaining access, a 7 French sheath was placed and a wire and simple straight pigtail or angled pigtail catheter (Cook Medical, Bloomington, IN) was advanced into the PAs. PA angiography was performed and pulmonary artery pressure (PAP) was measured through the pigtail catheter. After the appropriate placement of the lysis catheter, connections were made to an IV pump with a tissue plasminogen activator (tPA) drip rate of 0.5–1 mg/h. In some instances, the proceduralist injected 4–6 mg of the PA through the catheter before initiating the drip. The catheter and sheath were maintained in place, a sterile dressing was applied, and the patient was sent to the ICU while tPA was infused. Fibrinogen levels obtained every 4–6 h were used to titrate or stop the rate of infusion. The following day, usually 12–24 h after CDT catheter placement, the patient returned to the lab for repeat angiography and PAP measurement. If there was a large amount of residual thrombus, the proceduralist injected a bolus of tPA before catheter removal. Following catheter removal, hemostasis was achieved using manual compression.

For LBAT, the FlowTriever System (Inari Medical, Irvine, CA) was used. Right common femoral vein access was obtained, and a 5–7 French sheath was placed. As with CDT, a wire and pigtail catheter were advanced into the PAs for angiography and PAP measurement. Next, serial dilation of the groin access site was performed, and the sheath was exchanged for a 22–24 French sheath. Through this sheath, a Triever Catheter was advanced to the location of the PA thrombus burden, and manual aspiration was conducted using the 60 mL large-bore syringe. For several cases, the FlowSaver Blood Return System (Inari Medical, Irvine, CA) was used to filter blood removed during aspiration to allow the return of blood to the patient. After approximately 3–4 aspirations, repeat angiography was conducted to visualize residual thrombus burden. If the thrombus remained, the Triever Catheter was repositioned and additional aspirations were performed. This process continued until no significant residual thrombus was seen on repeat angiography. Heparin boluses were administered throughout the procedure to achieve an activated clotting time goal of 250–300 s. Repeat PAP measurements were taken before removing the catheter and wire. Following sheath removal, hemostasis was achieved through purse string suture and manual compression. A sterile dressing was applied to the access site and the patient was sent to the ICU for observation.

Data collection and outcomes

Data regarding patients' pertinent medical history, vital signs, procedural information, laboratory values, and imaging studies were collected through chart review and used to calculate PESI scores and determine the PE risk category using the American Heart Association stratification criteria.[1]

Procedural safety included a review of intraprocedural adverse events (AEs) or device malfunctioning, access site complications, major bleeding events, and death before discharge. The primary outcomes aimed to assess clinical improvement in patient condition immediately and/or approximately 24 h after the procedure and included change in mean PAP, heart rate (HR), oxygen saturation (SpO_2), and supplemental oxygen requirements.

Statistical analysis

A Kruskal–Wallis test was used to compare mean age and PESI scores between groups at baseline. Two-tailed paired *t*-tests were used to compare the clinical outcomes of patients receiving CDT and LBAT. Continuous variables were given as measures of mean with standard deviation, categorical variables defined as count with percentage, and discrete variables as median with interquartile range. Statistical significance was defined as $P < 0.05$.

RESULTS

Baseline characteristics

A total of 48 patients were identified during the case review, 17 received CDT and 31 received LBAT. Patient characteristics and baseline clinical data are summarized in [Table 1]. The mean age and PESI score were higher in the LBAT group versus the CDT group, although these differences were not statistically significant. A higher proportion of patients in the LBAT versus CDT group had chronic lung disease. Most patients in each group had troponin levels elevated above the critical range (>34 ng/L or >0.040 ng/mL) and signs of right ventricular (RV) strain. Likewise, most patients had intermediate-high-risk PE.

Procedural characteristics and safety

Procedural characteristics are outlined in [Table 2]. Patients who underwent CDT received a mean total of 10.5 mg of tPA; no patients treated with LBAT received tPA. All three patients who received general anesthesia were intubated in either the ICU or emergency department before interventional suite arrival. Some patients received anesthesia due to patient instability and physician requests for additional hemodynamic support requiring a higher level of care beyond the capabilities of the registered nurse present in the room.

Table 1: Baseline patient presenting characteristics.

Characteristics	CDT patients (*n*=17)	LBAT patients (*n*=31)	*P*-value
Demographics and clinical history			
Age, years	58.8±12.2	64.7±11.5	0.093
Male	7 (41.2)	11 (35.5)	
Female	10 (58.8)	20 (64.5)	
Chronic lung disease	0 (0.0)	6 (19.4)	
Cancer	5 (29.4)	7 (22.6)	
PE presentation			
Elevated troponin	14 (82.4)	28 (90.3)	
RV strain	16 (94.1)	28 (90.3)	
PESI score	86.4±25.0	93.7±42.9	0.838
High-risk	1 (5.9)	2 (6.5)	
Intermediate-high-risk	13 (76.5)	25 (80.6)	
Intermediate-low-risk	3 (17.6)	4 (12.9)	

Values are mean±standard deviation or *n* (%). CDT: Catheter-directed thrombolysis, LBAT: Large-bore aspiration thrombectomy, PE: pulmonary embolism, PESI: Pulmonary embolism severity index, RV: Right ventricular

Table 2: Procedural characteristics, safety, and length of in-patient hospital stay.

Characteristics	CDT patients (*n*=17)	LBAT patients (*n*=31)
Total tPA dose, mg	10.5±4.2	0.0±0.0
Anesthesia type		
MAC	0 (0.0)	1 (3.2)
General anesthesia	1 (5.9)	2 (6.5)
Conscious sedation	3 (17.6)	27 (87.1)
Local only	13 (76.5)	1 (3.2)
Safety		
Intraprocedural adverse events	0 (0.0)	0 (0.0)
Major bleeding events	0 (0.0)	0 (0.0)
Access site complications	0 (0.0)	1 (3.2)[a]
In-hospital all-cause mortality	1 (5.9)[a]	0 (0.0)
Length of stay		
ICU, days	2.0 [2.0–4.0]	2.0 [1.0–2.0]
Hospital, days	4.3 [3.0–5.0]	4.0 [3.0–5.0]

Values are mean±standard deviation, *n* (%), or median [Interquartile range]. [a]Non-device-related event. CDT: Catheter-directed thrombolysis, ICU: Intensive care unit, MAC: Monitored anesthesia care, LBAT: Large-bore aspiration thrombectomy, tPA: Tissue plasminogen activator.

No intraprocedural AEs or device malfunctions were recorded for either group. One non-device-related access site complication was recorded for a patient in the LBAT group. The proceduralist inadvertently initially obtained access into the femoral artery instead of the femoral vein immediately removed the 4 French micropuncture needle, and held manual pressure. Following the procedure, this

patient developed a small 2 mm hematoma that required no further treatment. No major bleeding events occurred. One in-hospital death occurred in a high-risk PE patient treated with CDT who expired in the ICU before returning to the interventional suite for catheter removal; this death was not considered device-related.

The median length of ICU stay for both groups was 2 days, none of the CDT patients stayed in the ICU for less than 24 h while three LBAT patients left the ICU within 24 h. The median overall hospital length of stay was slightly longer for CDT versus LBAT patients [Table 2].

Primary outcomes

Five patients were excluded from mean PAP calculations; three in the CDT group due to death before catheter removal (n = 1), transfer to another institution before follow-up angiogram (n = 1) and receiving only a tPA bolus without overnight infusion (n = 1), and two in the LBAT group based on hemodynamic instability preventing safe pre-procedural measurement (n = 1) and a missing post-procedural measurement due to recording error (n = 1). In addition, two patients from the CDT group (1 expired and 1 transferred) were excluded from the comparison of HR and oxygenation status 24 h post-procedure; immediately post-procedure, these data were obtained for all patients in both groups. The patient death that occurred in the CDT arm was due to a large thrombus burden not responsive to TPA therapy leading to the progression of hemodynamic instability and death.

The average reduction in mean PAP immediately following LBAT was 12.4% greater than the average decrease after 12–24 h of tPA infusion through CDT ($P < 0.05$). Before the procedure, the average mean PAP was 31.3 ± 9.0 mmHg in the LBAT group and 31.7 ± 11.2 mmHg in the CDT group [Figure 1]. Immediately following the procedure, patients in the LBAT group had a statistically significant 31.6% decrease in mean PAP, a 9.9 mmHg average reduction (95% confidence interval [CI]: 9.6–10.2; $P < 0.001$). On POD#1, patients in the CDT group had a 19.2% decrease in mean PAP, an average reduction of 6.1 mmHg (95% CI: 4.4–7.8; $P = 0.005$).

There was a significant decrease in average HR immediately following the LBAT procedure with an average drop of 8.8 bpm (95% CI: 8.5–9.1; P <0.001) and further reduction 24 h post-procedure (12.6 beats per minute [bmp] average reduction, 95% CI: 11.5–13.7; P <0.001). The average pre-procedure HR among CDT patients was 108.9 ± 17.1 bpm [Figure 1]. There was not a significant decrease in HR immediately following the procedure in CDT patients (4.0 bmp, 95% CI: 3.9–4.1; P = 0.143). However, 24 h after the CDT procedure, there was a significant reduction in average HR (17.4 bmp reduction, 95% CI: 15.5–19.3; P = 0.002). Although HR was reduced more quickly in the LBAT group, there was not a significant difference in overall reduction when comparing the change from pre- to immediate post-procedure with LBAT versus pre- to 24-h post-procedure with CDT.

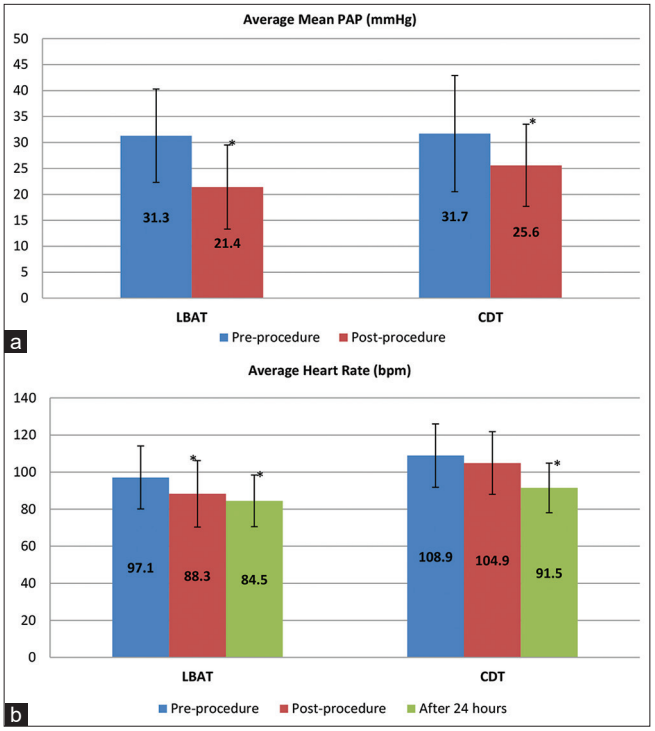

Figure 1: Hemodynamic outcomes following treatment with LBAT or CDT. (a) Change in average mean PAP from pre- to post-procedure in LBAT and CDT groups. Note: Post-procedure PAP for LBAT was measured immediately after the thrombus burden was removed while the patient was still on the procedural table and CDT was measured during follow-up angiography on POD#1, meaning after tPA had been infusing for 12–24 h. (b) Change in average HR from pre- to post-procedure and after 24 h in LBAT and CDT groups. *Statistically significant change from pre-procedure value ($P < 0.05$); error bars represent SD. Bmp: Beats per minute, CDT: catheter-directed thrombolysis, LBAT: Large-bore aspiration thrombectomy, PAP: Pulmonary artery pressure, POD#1, Post-operative day 1, SD, Standard deviation, tPA: Tissue plasminogen activator.

In both groups, there was no significant change in SpO_2 immediately or 24 h after the procedure [Figure 2]. In the LBAT group, SpO_2 was 94.9 ± 6.1% pre-procedure, 96.4 ± 3.0% immediately post-procedure (P = 0.229), and 96.5 ± 2.0% 24 h after the procedure (P = 0.155). In the CDT group, SpO_2 was 95.9 ± 2.2% pre-procedure, 94.1 ± 5.4% immediately post-procedure (P = 0.155), and 95.8 ± 2.4% 24 h after the procedure (P = 0.771). Before the procedure, the average oxygen requirement was 6.3 ± 5.3 L/min in the LBAT group and 2.9 ± 3.3 L/min in the CDT group. There was a reduction in average supplemental requirements both immediately following LBAT and 24 h later [Figure 2]. In the LBAT group,

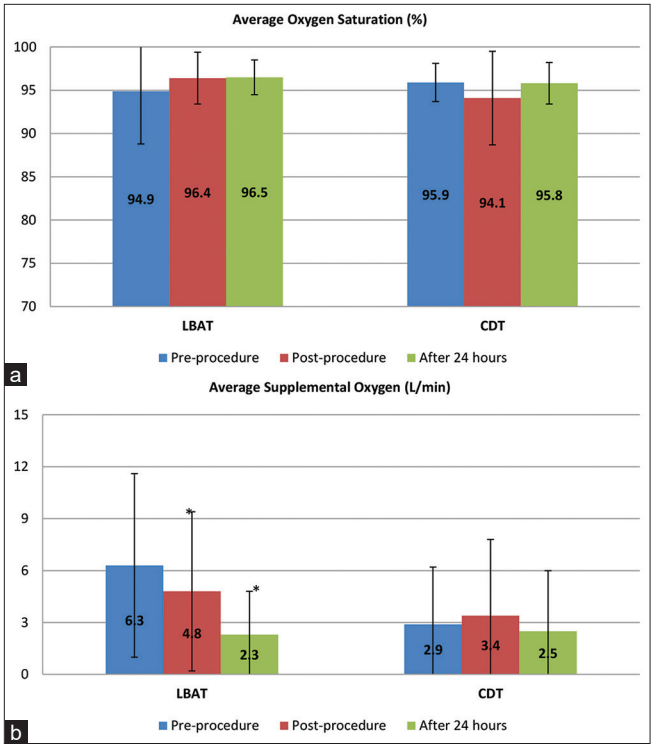

Figure 2: Oxygen status and supplementation following treatment with LBAT or CDT. (a) Change in average oxygen saturation from pre- to post-procedure and after 24 h in LBAT and CDT groups. (b) Change in average supplemental oxygen requirement from pre- to post-procedure and after 24 h in LBAT and CDT groups. *Statistically significant change from pre-procedure value ($P < 0.05$); error bars represent standard deviation. CDT: Catheter-directed thrombolysis, LBAT: Large-bore aspiration thrombectomy, SD: Standard deviation.

the average reduction in supplemental oxygen was 23.8% (1.5 L/min) immediately post-procedure (95% CI: 1.3–1.7; P =0.026) and 63.5% (4.0 L/min) 1 day after procedure (95% CI: 3.0–5.0; $P < 0.001$). There was not a significant decrease in supplemental requirements immediately following CDT ($P = 0.179$) or 24 h post-procedure ($P = 0.630$).

DISCUSSION

This single-center retrospective case review suggests that LBAT may allow faster, and potentially greater, improvements in acute clinical status compared with CDT. There was a greater overall reduction in average mean PAP in patients receiving LBAT therapy compared to the CDT group who had mean PAP measured on POD#1. If LBAT post-procedure PAP measurements were obtained during the same time frame as CDT, perhaps the improvement would be even more substantial as cardiac function further recovered.

Results with the FlowTriever System from the FLASH registry showed immediate improvements in hemodynamic outcomes, including a 7.6 mmHg mean reduction (23.0%) in mean PAP, which is lower than the 9.9 mmHg reduction (31.6%) observed in this study. Furthermore, FLASH reported a 12.0 bpm mean reduction (11.2%) in HR; in this study, an 8.8 bpm reduction (9.1%) was observed.[11] Proceduralists may be initially apprehensive about using the FlowTriever System because it is a large caliber device. However, in the FLASH registry, there were no major venous access complications or pulmonary vascular injuries among 788 patients.[11]

It is known that CDT can help reverse RV strain in PE patients.[12] Although no major bleeding events were captured in this case review, CDT has been associated with a 4–10% major bleeding rate in other studies.[9,13] LBAT is safe in patients who are not candidates for thrombolytic therapy but who can receive therapeutic anticoagulation.[10,11] Patients who were not candidates for CDT due to contraindications such as stroke, intracranial hemorrhage, head trauma, or recent surgery were included in FLASH, which reported a 1.4% major bleeding rate.[11]

Of the patients in this case review that received LBAT, three patients spent <24 h in the ICU before transferring to lower acuity care. All but one CDT patient stayed in the ICU for a minimum of 2 days. A visit to the ICU can drive costs of care up significantly; thus, lowering the length of ICU stay is a priority.[14] In addition, patient comfort and safety should be considered. CDT patients are sent to the ICU with a sheath and catheter in place at their groin and are on strict bed rest until the catheter is removed which affects the patient's ability to perform activities of daily living. LBAT patients are typically on bed rest for 2–4 h after which the patient may sit up and move around more freely. Due to the novelty of LBAT interventional therapy, increased patient monitoring in the ICU post-procedure may have occurred. As providers become more familiar with LBAT treatment and patients' response postprocedurally, ICU length of stay times may shorten.

As with all retrospective studies, the effect of potential confounders should be considered when interpreting results. This study has a relatively small sample size and lacks matched patient groups. Although statistically significant differences in assessed baseline characteristics were not detected, the LBAT group had a numerically higher mean PESI score than the CDT group and a sicker population could explain greater improvements. This could also highlight selection bias given the potential greater applicability of LBAT in sicker patients due to fewer exclusion criteria. Another important consideration is the methods of CDT and LBAT performed at the study hospital which may vary at other institutions. Although the pigtail CDT method shown is clinically effective, it is not the standard method. Similarly, thrombectomy at the study hospital is performed with

large-bore syringe-based aspiration versus other modes with smaller-bore continuous aspiration. Finally, the outcomes assessed in this study may not be correlated to the overall longer-term patient outcomes.

CONCLUSION

Although CDT is a valid option for interventional PE treatment, the greater reduction in mean PAP and earlier reduction in HR and supplemental oxygen requirements following LBAT observed in this study, and the potential for shortened ICU stay, make LBAT an attractive treatment option at our institution. However, post-discharge data were not available and further studies of patients treated with CDT versus LBAT should be conducted in larger populations to provide conclusive data regarding long-term patient outcomes.

Ethical approval

Institutional Review Board (IRB) approval was obtained from Silver Cross Hospital, reference 1885989-1 on March 23, 2022.

Declaration of patient consent

Patient's consent is not required as the patient's identity is not disclosed or compromised.

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Associated publication fees were covered by Inari Medical.

Conflicts of interest

KT declares no conflicts of interest; FR has received consultancy fees from Inari Medical.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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