What is a Case Study, and How Should It Be Formatted When Writing for Publication?

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Case study reports are valuable teaching resources for practitioners and students, and are written to discuss such topics as new technologies, procedures and imaging techniques, novel uses of technology and equipment, and unusual clinical case scenarios. They are usually written by practitioners who have had clinical interactions in the procedure, and understand the challenges and technical considerations of the case. Case studies allow staff and students to make critical contributions to the body of knowledge in cardiovascular medicine and promote new ideas to their peers.

A case study is a succinct presentation that includes clinical scenarios, treatments, and outcomes. The case report should include a patient's history and physical, diagnostic imaging studies, the procedural indication, and an introduction into the intervention or procedure performed. The case study should then describe the technical steps of the procedure, treatment, or intervention that was performed.[1] Case reports should also provide concise, clinically relevant reviews of the literature on the topic, and the patient outcome. Common reasons for publishing a case include:

1. An introduction to a new technology or procedure;
2. An unexpected event in the course observing or treating a patient;
3. Findings that shed new light on the possible pathogenesis of a disease or an adverse effect;
4. Unique or rare features of a disease;
5. Unique interventional, therapeutic, or procedural approaches;
6. Anomalous anatomy or a variation of anatomical structures;
7. An adverse response to therapies and the treatment provided.[2]

When writing up a case study, patient anonymity is also an important requirement. Remember not to disclose any information that might reveal the identity of the patient. Whenever possible, it is beneficial to obtain informed consent to avoid breaches in patient-practitioner confidentiality. Be particularly careful with images, and ensure that they do not reveal the identity of the patient. Images and illustrations that are taken from other sources must also be checked for copyright protection, and waivers should be signed if obtaining images that are copyright protected. Sources such as Creative Commons (creativecommons.org) may provide visual support without the need for copyright waivers.

Format

When formatting a case report, the structure should include an appropriate title, an abstract or introduction to the case, clear explanations of key terms in the text, and a concise clinical description of the patient. It should also provide a detailed overview of the procedure that was performed, a brief literature review of the key features of the case study, and a discussion of clinical and technical success or challenges of the procedure.

Title. The title should accurately reflect the overview of the article. Readers and researchers often use the article title or abstract to determine if an article is relevant to their research interests or practice.[3] An inaccurate or vague title may mislead a reader, and hinder researchers from reviewing appropriate texts.

Abstract and Introduction. An abstract may be created as part of a case study. It should be a condensed summary of the article and include the key facts in the order that they are presented in the article. Case study abstracts should not exceed 150 words. After the abstract, keywords should be introduced. These are the words which allow researchers to find relevant topics using search engines such as ScienceDirect, PubMed, or Medline.[4]

An abstract is not necessary for *Cath Lab Digest*, but other journals may have this requirement (review the author guidelines).

Introduction. A brief introduction that overviews the article can be written instead of the abstract. An introduction consists of several concise sentences to describe the context of the case and summarize the entire article. It provides similar insight into the text as an abstract, and allows the limited word count of the article to be focused on the case study itself.

Case Presentation. This section should include an overview of the patient, case type, and historical context. If similar cases have been reported, describe them briefly, and also mention the reason why this case offers distinctive insights for practitioners.[2] This may include an unusual clinical presentation or a novel procedural indication. Once the background has been established, the clinical workup should be described.

The clinical workup should include the reasons for the patient interaction. This includes relevant history and physical assessment findings. This includes patient signs, symptoms, and physical complaints. It may also include noninvasive and invasive study results, vital signs, and critical laboratory values. The procedure, treatment or intervention that is going to be performed should be introduced at the end of this section. Relevant images, electrocardiogram findings, or illustrations may help support the presentation. This creates a smooth transition into the case description.

Case Description. The case description should discuss the patient treatment and initial post procedural outcome. This includes the access routes, technical steps of the procedure, technical challenges, and the end result of the procedure. Visual support is recommended to display new technologies and critical procedural steps. If this is a novel use of technology or approach, its role and purpose should be clearly explained. The measures and outcomes should include clinical and technical success or failure, and challenges that were navigated through during the procedure.

Post Procedure Discussion. After explaining the procedure or treatment, the post procedure discussion should be presented. This is the section that will demonstrate why the article is publishable. It should expand upon the introduction, focus on key issues, and explain why the case is noteworthy.[1,2] There should also be a concise literature review of the relevant factors of the case, such as efficacy of the treatment, measures and outcomes, and any relevant clinical trials. If this is a novel use of a product or technology, this section allows for a robust discussion of the use of the product or technology. The discussion also describes the existing theories and research findings on disease and its management.[2-4]

Conclusion. A case report should end with a conclusion or overview of the case highlights. In this section, the author can give suggestions and recommendations for practice. The conclusion may be a brief, separate section of the article or it may be woven into the end of the discussion section.

When deciding to publish a case study, ask the following questions:

Relevance

- Is the case study appropriate for the journal?
- Does it validate or add to the body of knowledge in cardiovascular medicine?

Style

- Is the case organized, does it logically flow, and does it use appropriate headings?
- Does the technical writing avoid redundancy, have smooth transitions, and correct grammar?
- Dose the case report use appropriate and current medical terminology, and does it define acronyms that were used in the text?

- Does it include accurate and relevant figures and tables, images, and illustrations that support the text?
- Does the case study follow American Medical Association writing guidelines (the journal's author guidelines will generally specify if this is the case)?[5]

References

- Are the references current, relevant, and scholarly?
- Do the references support the material presented?
- Are topics that are not common knowledge properly referenced and explained?[5]

Conclusion

The *Cath Lab Digest* editorial (review) board looks forward to supporting prospective writers. Case studies are an ideal way to make a contribution to the field because they are aligned to clinical practice and allow practitioners to share important clinical insights with professional peers. The editorial board and editorial staff will provide feedback, resources, and insights to turn prospective case studies into publishable manuscripts.

The following case study, "*Management of Submassive Pulmonary Embolism With Aspiration Thrombectomy*," has been designed to contribute to the field and offer an example of an effectively written case study. ■

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Management of Submassive Pulmonary Embolism With Aspiration Thrombectomy

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This article describes a case in which a large-bore aspiration thrombectomy system was used to successfully treat a submassive saddle pulmonary embolism (PE) in a symptomatic patient with recent SARS-CoV-2 pneumonia. Details of the clinical presentation, work-up, and management are presented herein, including a description of the technical procedural steps. A discussion covers review of submassive PE management and current safety and effectiveness data with aspiration thrombectomy.

Case Description

A 34-year-old female with class 3 obesity was admitted to the hospital with new onset of exertional dyspnea. Her past medical history included prior PE and lower extremity deep vein thrombosis. Additionally, the patient was diagnosed with SARS CoV-2 pneumonia about 1 month prior to admission. Although she did not require hospitalization at the time of pneumonia diagnosis, she reported feeling unwell and being "basically bedbound" for approximately 2 weeks. The patient recently noticed burning and pain in her right calf and lateral aspect of right thigh, without edema. One week prior to admission, she experienced dyspnea following minimal exertion that began to subside over a few days. An abrupt worsening of symptoms, including lightheadedness, chest pain, and shortness of breath, prompted her to come to the hospital.

An electrocardiogram (ECG) revealed sinus tachycardia with normal blood pressure (121/77 mmHg). There were no other remarkable findings on physical assessment. The patient underwent a chest computed tomography angiogram (CTA) to rule out PE. CTA revealed extensive, acute, nonocclusive saddle PE involving the bilateral main, lobar, segmental, and subsegmental pulmonary artery (PA) divisions (Figure 1). The right ventricle (RV) was dilated with

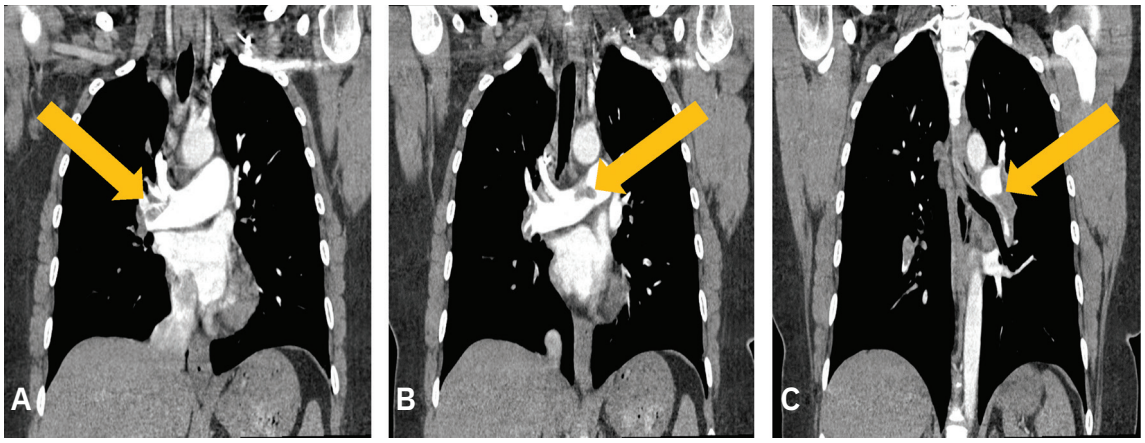

Figure 1. Submassive pulmonary embolism (PE) with lobar involvement shown across 3 computed tomography angiography (CTA) images.

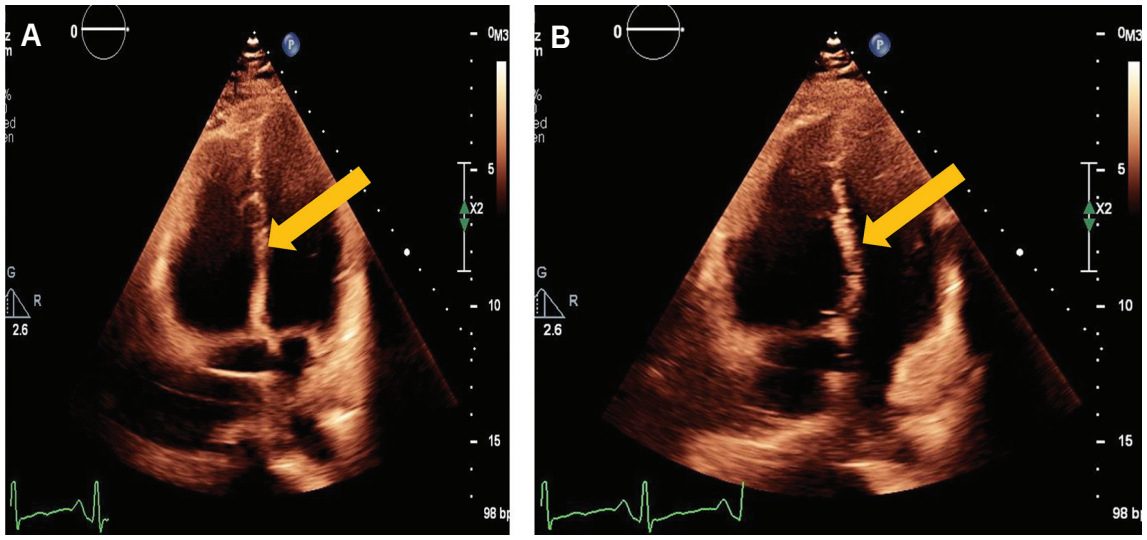

Figure 2. Right heart strain demonstrated by 2 transthoracic echocardiography (TTE) images.

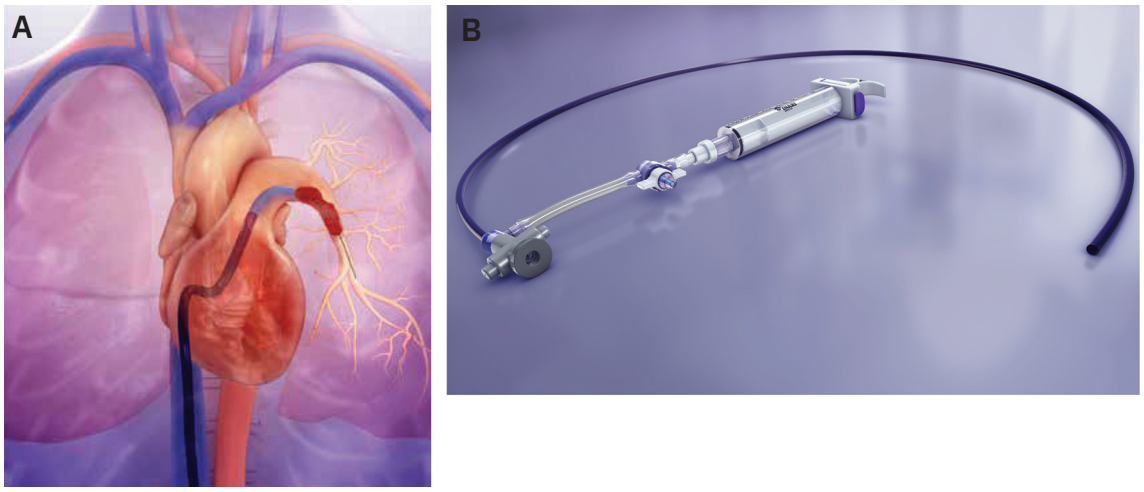

Figure 3. (A) Illustration of Triever24 and Triever20 Curve catheter (both Inari Medical) placement for removal of PE from the left pulmonary artery (PA) and (B) FlowTriever System (Inari Medical) with Triever24 catheter and large-bore syringe.

Illustration and device image provided courtesy of Inari Medical.

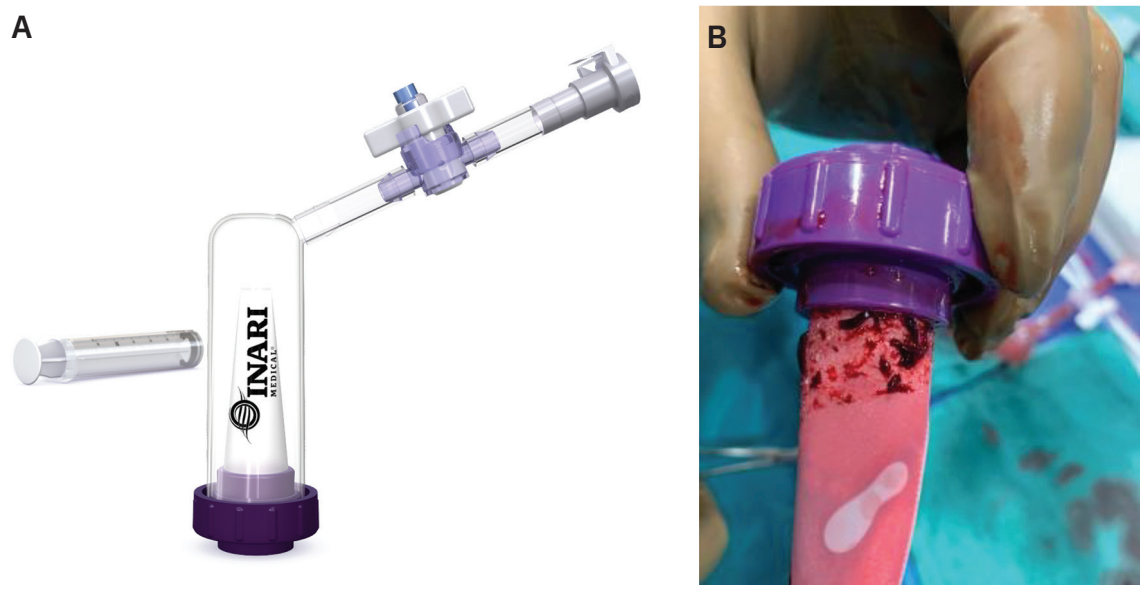

Figure 4. (A) Image of FlowSaver blood return system (Inari Medical) and (B) thrombus recovered in system after aspirated blood was filtered prior to autotransfusion.

Device image provided courtesy of Inari Medical.

straightening of the interventricular septum and the RV/left ventricular (LV) ratio was 1.57. The main PA was also slightly dilated at 3.1 cm, suggesting right heart strain. Small, patchy, subpleural ground-glass opacities were observed in the lungs and associated with SARS-CoV-2 pneumonia.

The patient's subsequent transthoracic echocardiogram (TTE) demonstrated McConnell's sign, a distinct feature of acute submassive PE. It is a pattern of RV dysfunction, with akinesia of the mid-free wall and hypercontractility of the apical wall.[1] The TTE also revealed systolic flattening of the interventricular septum consistent with RV pressure overload, moderate dilation of the RV, and moderate-to-severe reduction in systolic RV function (Figure 2).

Following symptomatic PE diagnosis, treatment options were discussed, and the patient elected to undergo aspiration thrombectomy. Clinical considerations included the patient's age, class 3 obesity, concerns for chronic thromboembolic pulmonary hypertension (CTEPH), and recent SARS-CoV-2 pneumonia.

Procedure

After obtaining informed consent, the patient was brought to the lab and right common femoral vein access was obtained. A 7 French pulmonary balloon wedge pressure catheter was advanced into the PA to measure right heart pressure and consistent with the CTA and TTE findings, elevated PA pressures were confirmed. The access site was progressively dilated with 12, 16, and 20 mm dilators. A 24 French DrySeal sheath (Gore Medical) was then introduced into the inferior vena cava.

After adequate anticoagulation, a Triever24 catheter (Inari Medical) was advanced to the left PA. A Triever20 Curve catheter (Inari Medical) was then telescoped through the 24 French catheter until the tip of the 20 French curved catheter was proximal to the thrombus in the left PA. This catheter placement technique is illustrated in Figure 3. Multiple aspirations were performed, yielding a large return of thrombotic fragments. To minimize blood loss, autotransfusions were performed during the procedure using the FlowSaver blood return system (Inari Medical) (Figure 4). Selective left PA angiography confirmed full opacification of the lung fields.

The Triever20 Curve catheter was removed and the Triever24 catheter was advanced into the right PA (Figure 5). Multiple aspirations were performed, with retrieval of significant thrombus fragments. A post thrombectomy PA angiogram revealed full opacification of the right-sided lung fields.

Significant improvements in hemodynamics were observed and PA pressures decreased from 60/23/35 pre procedure to 25/15/18 post procedure. Heart rate (HR) on ECG decreased from 120 bpm pre procedure to 94 bpm post procedure. The patient reported immediate symptomatic relief. The femoral venous sheath was removed with a figure-of-eight suture and the FlowStasis suture retention device (Inari Medical) (Figure 6) was used for hemostasis without complications. A follow-up TTE two days later revealed resolution of RV strain and otherwise normal findings. The large thrombus burden extracted from bilateral PAs during the thrombectomy is shown in Figure 7.

Discussion

Overview

PE is the third most common cause of cardiovascular death, leading to 60,000 to 100,000 deaths annually.[2-4] PE is stratified into categories that range from low to high risk. Severity is determined by factors including hemodynamic stability, comorbidities, RV strain on imaging, laboratory assessments,[5] and ECG changes.[6] High risk (massive) PE is associated with poor outcomes and clinical presentation includes hemodynamic instability (cardiac arrest, obstructive shock, or persistent hypotension). Presentation of intermediate risk (submassive) PE includes RV strain in the absence of hemodynamic instability. Patients with low risk (nonmassive) PE are hemodynamically stable, and lack imaging or laboratory features of cardiac dysfunction.[3,5,6]

Our patient's PE was classified as an intermediate-high risk (submassive) saddle PE due to symptoms and associated RV strain on CTA/TTE. Saddle PE is an uncommon, acute PE that is anatomically located at the bifurcation of the main PA, with potential hemodynamic instability.[7] The criteria for diagnosing submassive PE include:

- Systolic blood pressure ≥90 mmHg, and RV dysfunction or myocardial necrosis[6]
  - RV dysfunction:
    - RV dilation or RV systolic dysfunction on ECG or RV dilation on CT
    - Elevation of BNP >90 pg/mL or N-terminal pro-BNP >500 pg/mL
    - ECG changes (complete or incomplete right bundle-branch block, anteroseptal ST elevation or depression, or anteroseptal T-wave inversion)
  - Myocardial necrosis:
    - Elevation of troponin I >0.4 ng/mL or troponin T >0.1 ng/mL

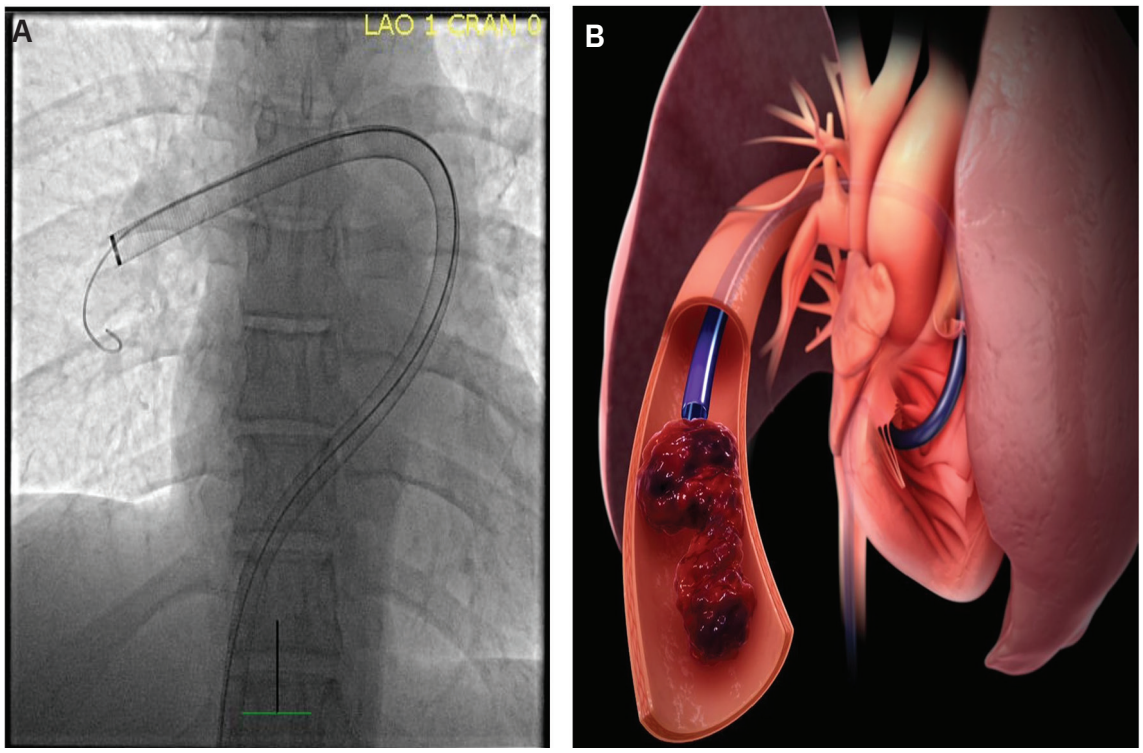

Figure 5. **(A) Procedural radiograph showing FlowTriever being advanced into right PA and (B) illustration of FlowTriever in PA to demonstrate the aspiration position of a Triever catheter.**

Illustration provided courtesy of Inari Medical.

Many patients develop long-term complications following PE, such as diminished quality of life, persistent dyspnea, impaired exercise capacity, and chronic thromboembolic pulmonary hypertension (CTEPH). This patient had a large thrombus burden and greater initial pulmonary vascular obstruction is an independent risk factor for residual pulmonary vascular obstruction (RPVO).[8] RPVO occurs in 46%-66% of patients 3 months after acute PE and persists in 25%-29% at 1 year.[9] RPVO following PE is associated with poor prognosis and increases the risk of adverse outcomes, including CTEPH.[10-12] Removing large thrombus burden may reduce the likelihood of long-term complications.

This patient had recent SARS-CoV-2 pneumonia, and emerging retrospective studies and meta-analyses highlight the correlation between COVID-19 pneumonia and PE among hospitalized patients.[13-15] Current research demonstrates a higher risk of all-cause mortality for patients who have thrombotic complications with COVID-19,[16] although further studies are needed to evaluate the impact on longer-term mortality.[14]

Treatment

A Pulmonary Embolism Response Team (PERT) is designed to improve the efficiency of PE management by establishing a cohesive approach.[17] The PERT model involves rapid consultation by a multidisciplinary team of specialists to inform treatment decisions for patients with high or intermediate risk PE. Since 2012, the number of PERTs has risen throughout the United States and across the world.[18,19] PERTs are diverse in their structure and resources. The PERT initiative serves as a multicenter research platform of PE patients.[18,19]

Treatment of submassive PE can include anticoagulation, catheter-directed thrombolysis (CDT), and mechanical/aspiration thrombectomy. While all three strategies are appropriate management for submassive saddle PE, thrombectomy offers the ability to immediately remove thrombus burden, improve hemodynamics, and alleviate right heart strain. Since our patient was obese, reduced access site bleeding risks also influenced the decision to utilize aspiration thrombectomy. There is a growing body of evidence supporting safe and effective use of thrombectomy with minimal major bleeding events. In addition to published retrospective studies,[20-22] prospective clinical studies include FLARE,[23] FLASH,[24,25] and PEERLESS.[26]

Clinical Trials

FLARE: FlowTriever Pulmonary Embolectomy Clinical Study

FLARE was a prospective, single-arm, multicenter clinical trial that evaluated percutaneous mechanical thrombectomy with the FlowTriever System for patients with intermediate-risk PE.[23] Patients with acute symptomatic PE and CTA-documented RV strain (RV/LV ratio ≥0.9) were enrolled (n=106). The primary endpoint, reduction in RV/LV ratio within 48 hours, was achieved. The average decrease in RV/LV ratio was 0.38 from baseline (P<0.0001). The major bleeding event rate was 0.9% and no device-related injuries or deaths were reported.[23]

FLASH: FlowTriever All-Comer Registry for Patient Safety and Hemodynamics

FLASH is an ongoing, prospective, multicenter registry evaluating outcomes after treatment with the FlowTriever System in patients with intermediate or high risk PE.[24] Among the first 500 patients enrolled, the primary endpoint of major adverse events within 48 hours occurred in 1.4% patients.[25] All-cause mortality was 0.2% at 48 hours, and there were no device-related major adverse events or deaths.[25] Significant on-table hemodynamic improvements included 23% reduction in mean PA pressure, 18% increase in cardiac index (CI) among patients with a baseline CI <2.0 L/min/m^2, and 11.3% decrease in HR. Improvements in cardiac function, patient symptoms, and quality of life were sustained through latest follow-up (up to 6 months).[25] Additionally, treatment with FlowTriever was resource-sparing. In FLASH, adjunctive therapy was limited (3.8%) and most patients did not require overnight intensive care unit (ICU) admission (63.1%). The all-cause readmission rate was 6.2% at 30 days. At 6 months, the rate of CTEPH was 1.6%.[25]

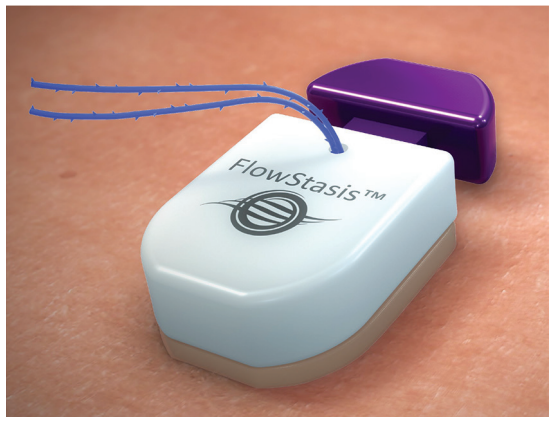

Figure 6. **FlowStasis suture retention device (Inari Medical), which is deployed with a figure-of-8 suture technique.**

Device image provided courtesy of Inari Medical.

Figure 7. **The large thrombus burden removed from bilateral PAs.**

The PEERLESS Study

PEERLESS is an ongoing, prospective, multicenter, randomized, controlled trial evaluating FlowTriever versus CDT for the treatment of acute intermediate-high risk PE.[26] This study is currently enrolling and is the first to directly compare mechanical/aspiration thrombectomy with CDT. Targeted enrollment is up to 700 patients, 550 will be randomized 1:1, and up to 150 patients with absolute contraindications to thrombolytics will

comprise a separate nonrandomized cohort.[26] The primary endpoint is a win ratio composite of all-cause mortality, intracranial hemorrhage, major bleeding, clinical deterioration and/or bailout, and ICU admission/length of stay.[26]

Summary

Numerous clinical studies have been performed to understand the efficacy and safety of PE treatment strategies. Results from studies of mechanical/aspiration thrombectomy are encouraging, and in addition to knowledge from PERT initiatives, data from ongoing trials will be essential in refining standards of PE care.

Takeaways

- Mechanical/aspiration thrombectomy devices are FDA-cleared for the treatment of PE and procedural technique is well established.
- The aforementioned studies indicate potential advantages of thrombectomy versus CDT, including:
  - o No requirement for long thrombolytic infusion (12-24 hours), which reduces bleeding risks and the need for ICU beds
    - FLARE and FLASH reported significantly lower bleeding rates compared to CDT studies, including major hemorrhages and access site bleeding.
  - o Removal of thrombus burden may reduce the incidence of CTEPH.
    - FLARE and FLASH demonstrated immediate post procedural hemodynamic and symptomatic improvements.
    - Low rates of CTEPH were reported in FLASH at 6-month follow-up.
- Thrombolysis is still an option for patients in which thrombectomy is not performed due to technical challenges with catheter placement.

Conclusion

Aspiration thrombectomy offers the opportunity to effectively manage massive and submassive PE, as demonstrated in this case, while minimizing the risks and costs associated with CDT. As more clinical data is reported, thrombectomy is becoming an increasingly important treatment strategy in massive and submassive PE. ■

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