

Novel use of a thrombus aspiration system to facilitate transvenous lead extraction for large vegetations



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Introduction

Cardiac implantable electronic device (CIED) infections remain the strongest indication for complete system extraction. The percutaneous approach is inherently less invasive and generally preferred. However, there are limited data to guide the decision of transvenous lead extraction (TLE) vs open surgical approach in situations involving larger vegetations (>2.5 cm in size).¹ Other groups have described techniques for vegetation debulking prior to TLE using AngioVac (AngioDynamics Inc, Latham, NY) and Indigo Thrombectomy systems (Penumbra, Inc, Alameda, CA) to try to minimize the risk of embolic events.²⁻⁵ The FlowTrievers system (Inari Medical, Irvine, CA) (Figure 1) is designed to remove thrombus from large vessels, such as acute pulmonary embolus, using both aspiration and mechanical mechanisms. Following success with 2 cases of right atrial and tricuspid valve thrombus aspiration using the FlowTrievers system, we highlight 2 cases using our novel multidisciplinary approach of FlowTrievers aspiration of large vegetation immediately before TLE.

Case report

Our combined approach with mass aspiration and TLE was built upon initial success with 2 cases of FlowTrievers aspiration of large masses, described briefly. The patient in case 1 was a 62-year-old woman with metastatic leiomyosarcoma found to have a large peripherally inserted central catheter-associated thrombus (7.4 cm × 1.8 cm) in the right atrium (RA) resulting in highly symptomatic superior vena cava (SVC) syndrome and hypotension (Figure 2A and 2C, Supplemental Video 1). The patient in case 2 was a 71-year-old man with end-stage renal disease (ESRD) found to

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KEY TEACHING POINTS

- Owing to the significant risk of pulmonary embolism with hemodynamic compromise, large lead-associated vegetations may limit transvenous lead extraction without a prevention strategy.
- This is the first description of using the FlowTrievers aspiration system (Inari Medical, Irvine, CA) in the removal of large vegetations at the time of transvenous lead extraction. Advantages to this system include avoiding veno-veno bypass, minimal blood loss, and catheter sizing options for accommodating large vegetations.
- Transcutaneous removal of large vegetations is feasible and may be preferred for patients with significant comorbidities. A team approach with members from multiple disciplines leads to best outcomes.

have *Enterococcus faecalis* bacteremia who suffered a massive pulmonary embolism during exchange of his tunneled dialysis catheter for a temporary one. He subsequently developed a large (3.2 cm × 3.0 cm) tricuspid valve vegetation visualized on transesophageal echocardiography (TEE). Both patients were deemed prohibitive surgical risk and offered FlowTrievers aspiration for palliation and to try to minimize risk of embolization.

All cases were performed under general anesthesia with invasive arterial monitoring in the interventional radiology suite, or in a hybrid operating room if it involved TLE of device older than 3 years. Blood products were readily available for each patient and the cardiac surgeon was available for emergent open repair if needed. After the patient was prepped and draped, a 24F sheath was placed in the right common femoral vein via ultrasound guidance and advanced to the inferior vena cava. Patients were heparinized to maintain activated clotting time between 250 and 300 seconds. The

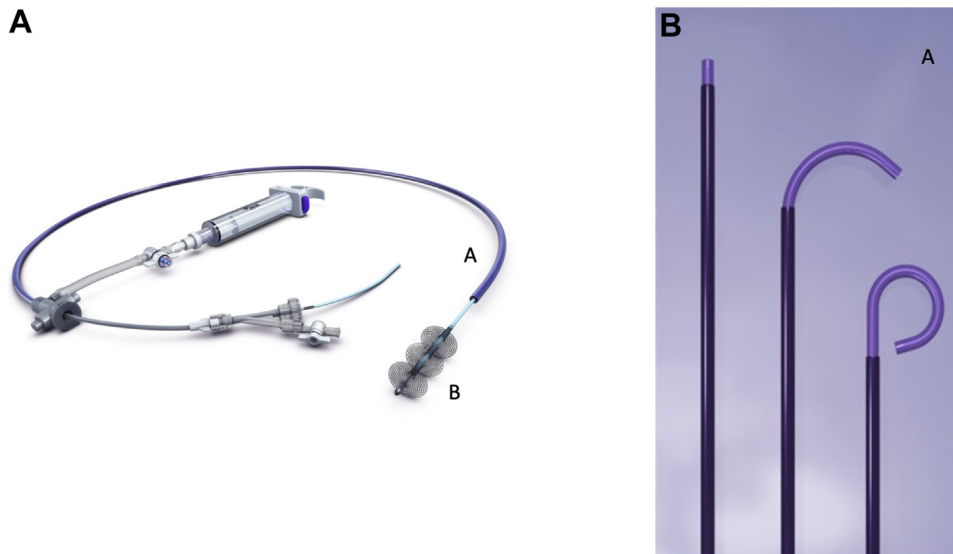


Figure 1 The FlowTrievers system (Inari Medical, Irvine, CA). **A:** The Trierer 20 Curve large lumen steerable catheter with mechanical aspiration syringe. **B:** The FlowTrievers catheter with 3 self-expanding nitinol mesh discs available in various sizes to retrieve the clot back into the Trierer catheter. Images from Inari Medical (personal communication 7/1/2022).

coaxial 24F and curved 20F sheaths were advanced into the right atrium. A cardiologist was present for TEE guidance as the interventional radiologist positioned the Trierer catheter (Figure 2). Multiple aspirations were performed to successfully remove the target mass. The nitinol discs were deployed if needed to remove residual material in the SVC or inferior vena cava if seen on TEE. Estimated blood loss of the cases ranged from 100 mL to 400 mL and aspirated blood was filtered through the Flowsaver device to be returned through the side arm of the 24F sheath. After successful aspiration, innominate venogram was performed to confirm rapid flow through the RA into the pulmonary arteries. There was no evidence of patent foramen ovale by echo color Doppler in all cases. TEE confirmed no further mass present (Figure 2B and 2D).

Building upon these experiences, we implemented our multidisciplinary approach to perform vegetation aspiration prior to concomitant TLE in the following 2 cases. A 59-year-old man with history of coronary artery bypass graft, ischemic cardiomyopathy, complete heart block with biventricular defibrillator, and ESRD on hemodialysis using a temporary dialysis catheter developed persistent *Staphylococcus epidermidis* bacteremia and infection of the 5-year-old CIED. TEE demonstrated torrential tricuspid regurgitation from a prolapsing 4.7 cm × 2.0 cm vegetation (Figure 3A–3C, Supplemental Video 2) with normal leaflet morphology. The patient was too high risk for surgery and the vegetation proximity to device leads posed risk of catastrophic embolization with TLE alone. The patient agreed to our hybrid approach with FlowTrievers aspiration immediately followed by TLE. The tricuspid valve vegetation was successfully aspirated in similar methodology to that described above and specimen culture ultimately grew *S. epidermidis* (Figure 3D). Cavogram demonstrated no residual thrombus; TEE now showed only trace tricuspid regurgitation and

attention was shifted to the TLE. A temporary externalized pacemaker was placed. Following generator removal, the RA, right ventricle (RV), and coronary sinus leads required a 14F laser sheath (Spectranetics) for extraction. Two weeks after TLE, the patient underwent successful reimplant of a right-sided biventricular device and completed a total of 6 weeks of antibiotics.

The success and feasibility of this first attempt was replicated in a second challenging case of a 49-year-old woman with uncontrolled diabetes, severe coronary artery disease, peripheral arterial disease, ESRD, and complete heart block who presented in septic shock with methicillin-resistant *Staphylococcus aureus* bacteremia and infection of a 2-year-old pacemaker. A 2.35 cm × 0.7 cm vegetation attached to the SVC portion of the device lead that was successfully aspirated with the FlowTrievers, followed by TLE without complication. Both patients that underwent the hybrid approach are doing well now with over a year of follow-up.

Discussion

This is the first case series describing a multidisciplinary approach using the FlowTrievers system to remove large vegetations prior to TLE. The potential benefits of this technique over the established Indigo Penumbra and AngioVac techniques include the following: (1) avoiding the need for extracorporeal veno-veno bypass (AngioVac), (2) lower likelihood of catheter clogging (Indigo), (3) minimizing rapid blood loss, and (4) offering different-sized thrombectomy catheters to tailor to the target.

The AngioVac system has been used to remove vegetations before TLE.⁴ Since acutely infected patients with many comorbidities often are high surgical risk, this offers some data on a promising approach to minimize major pulmonary embolus during TLE for CIED infection. The

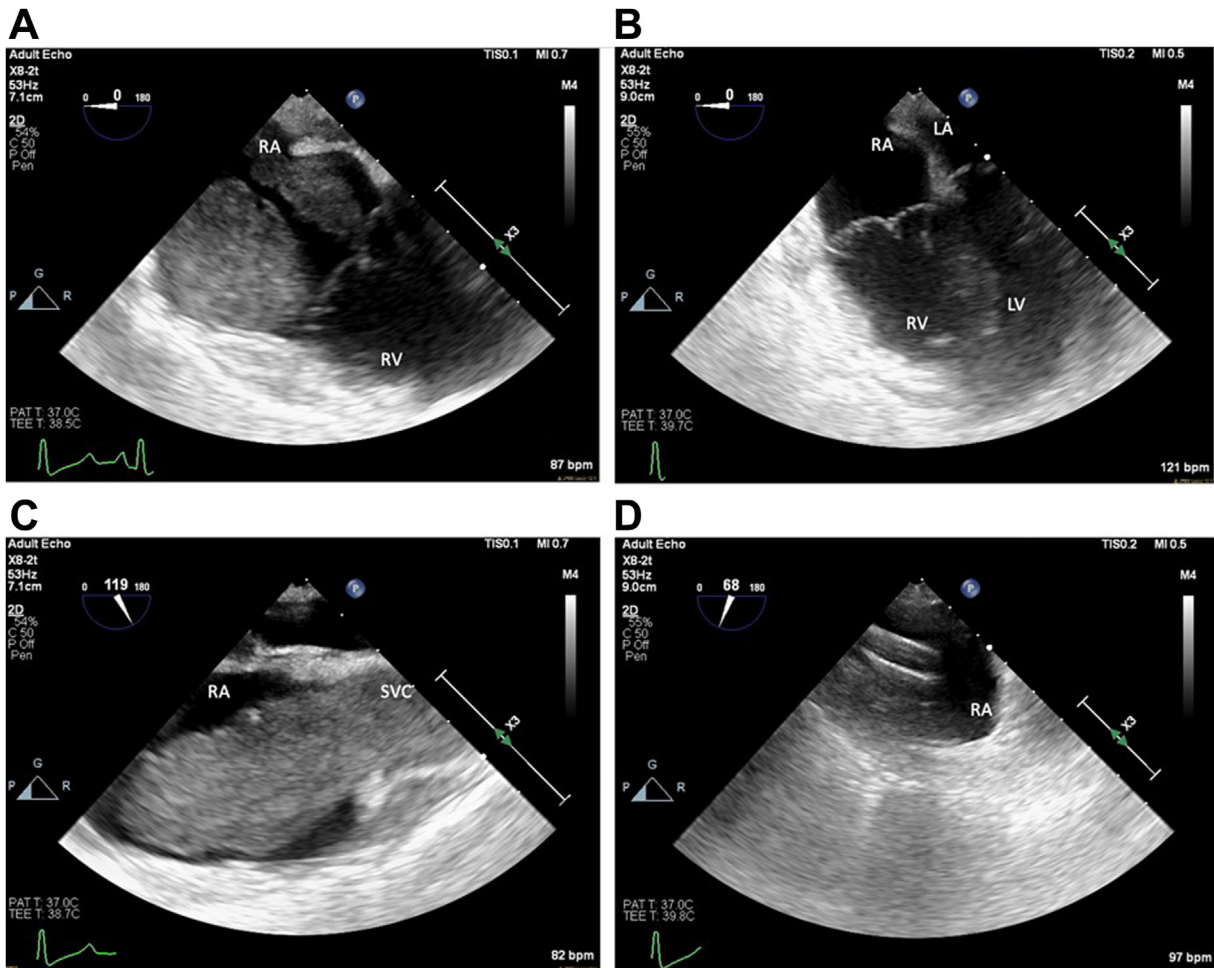


Figure 2 Case 1. **A, C:** A 7.4 cm \times 1.8 cm mass visualized from superior vena cava extending to tricuspid valve in 4-chamber and bicaval transesophageal echocardiography (TEE) views, respectively. **B:** Postaspiration images in 4-chamber TEE view. **D:** Triever catheter visualized in right atrium post aspiration. LA = left atrium; LV = left ventricle; RA = right atrium; RV = right ventricle; SVC = superior vena cava.

large-bore AngioVac system can evacuate large clot burden at the cost of requiring veno-veno bypass. Suction rates of 3–5 L/min while therapeutically anticoagulated poses concern in patients with anemia and borderline hemodynamics. Alternatively, the Indigo Penumbra has been used for aspiration of a 0.26 \times 3.6 cm vegetation through a smaller venous access (16F) without the need for systemic anticoagulation prior to TLE.⁵ The steerability can be a helpful advantage for mobile vegetations over the AngioVac. However, a smaller-bore catheter might increase likelihood of catheter clogging, which may require repeated removal and flushing of the entire catheter.

The FlowTriever system offers a combined vacuum aspiration with mechanical retraction (Figure 1) to capture residual thrombus after the initial clot is disrupted. A 22F aspiration sheath is required for the combined effect; however, there is an option of using the inner nitinol wire for clot fragmentation and disruption only through a 12F sheath. We elected to use the combined system given the very large target vegetation sizes. In all cases, patients had acute on chronic anemia and tenuous hemodynamics, so we opted to avoid the veno-veno bypass requirements of AngioVac.

Using the Flowsaver we were able to return about 90% of aspiration blood back into the sheath. The FlowTriever and Indigo systems offer greater catheter steerability over the AngioVac, but the Indigo system lacks ability to return aspirated blood (Table 1).

Fortunately, there were no procedural complications in the reported cases. The multidisciplinary team was crucial to our early experiences in this approach to be prepared for severe complications, including iatrogenic embolization of the target mass resulting in obstructive pulmonary embolism. Our interventional radiologist was already experienced in FlowTriever aspiration of pulmonary emboli, but if that failed the cardiac surgeon was present and prepared for open surgical thrombectomy if needed. When coupled with TLE, vascular injury and cardiac perforation resulting in cardiac tamponade are possible. Our electrophysiologist was comfortable with SVC balloon tamponade and pericardiocentesis if needed to temporize to surgical repair. Although the multidisciplinary approach was very much a strength in our experience, it can also be a limitation when considering the generalizability of this approach. Depending on the practice setting, it may not be logistically or fiscally feasible to

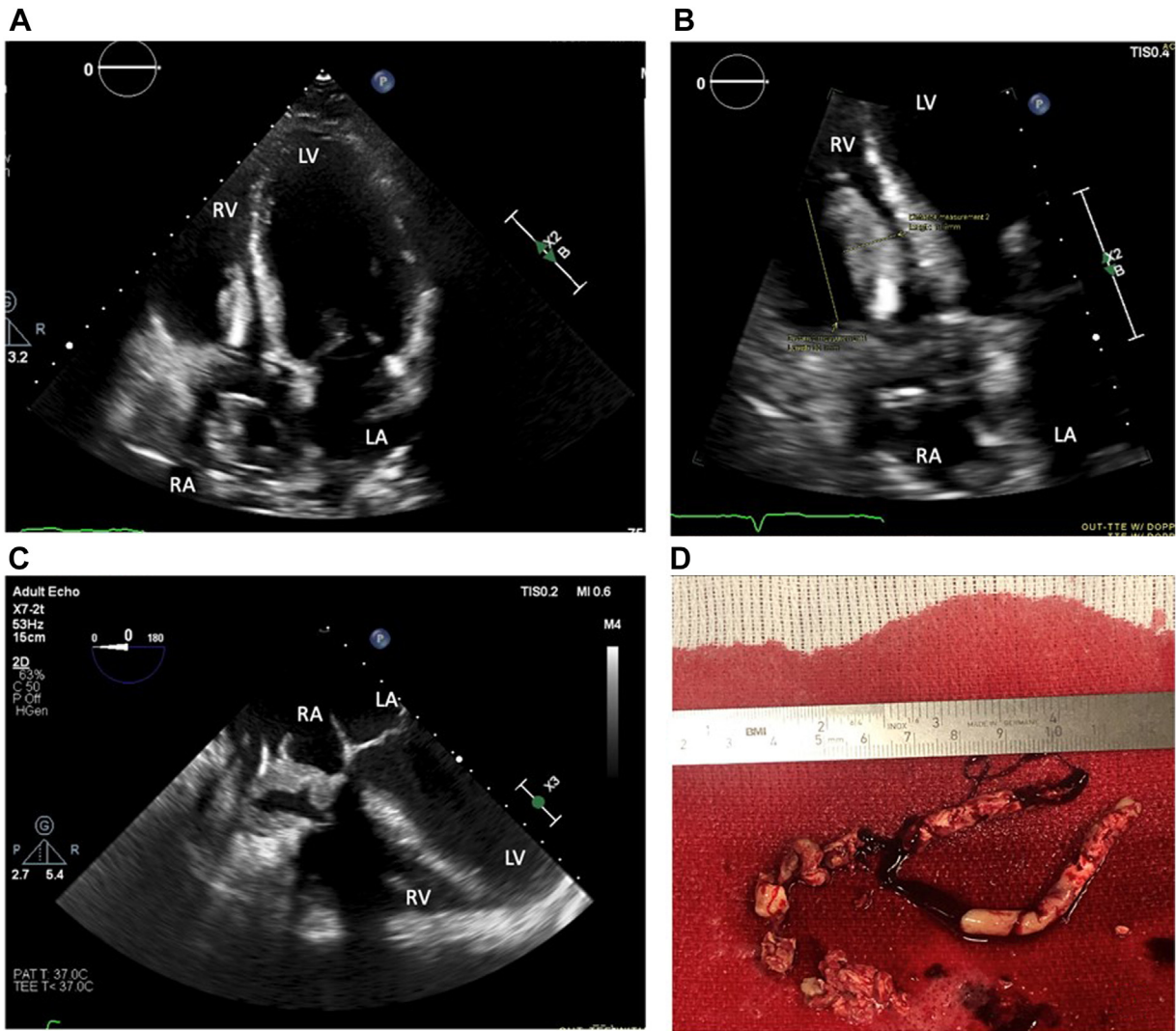


Figure 3 Case 3. **A:** Apical 4-chamber (A4C) view of lead-associated vegetation on transthoracic echocardiogram (TTE). **B:** Zoomed-in A4C view of 4.7 cm × 2.0 cm vegetation on TTE. **C:** Vegetation visualized on transesophageal echocardiography. **D:** Gross images of dense rubber-consistency vegetation after FlowTriever aspiration. Abbreviations as in Figure 2.

allocate multiple specialized operators to 1 case. Perhaps a larger registry of combined aspiration with TLE would be helpful to understand outcomes and ways to streamline the needed team members.

Conclusion

This case series demonstrates a novel multidisciplinary approach to percutaneous vegetation removal during TLE to minimize risk of embolization and may offer improved

Table 1 Aspiration system comparison

| Product | Catheter sizes | Reported for lead extraction | Largest vegetation reported | Advantages | Disadvantages |
|-----------------------|-----------------------------|------------------------------|-----------------------------|--|---|
| AlphaVac | 22F | No | N/A | Self-expanding funnel tip | Limited catheter sizing, large access sheath |
| AngioVac [†] | 16F–20F inflow, 26F outflow | Yes | 4.0 × 1.5 cm ^{2†} | Filter and return blood | Perfusion team, systemic anticoagulation, large access sheath |
| FlowTriever | 6F–22F | Present report | 4.7 × 2.0 cm [‡] | Multiple catheter sizes, filter and return blood, add-on disks | Large access sheath |
| Penumbra Indigo | 3F–12F | Yes | 3 × 4 cm ⁶ | More flexible | Small diameter limits size of aspirate, no blood return |

[†]Note there may be a larger vegetation reported for AngioVac given the large number of cases reported in the literature.

[‡]Current report.

success with retrieval of larger vegetations, lower likelihood of residual debris, and flexibility in catheter steering and size without the need for extracorporeal veno-veno bypass. Larger studies using a similar approach would help elucidate the generalizability of this approach and provide additional data on patient outcomes.

Appendix Supplementary Data

Supplementary data associated with this article can be found in the online version at [10.1016/j.hrcr.2023.04.020](https://doi.org/10.1016/j.hrcr.2023.04.020).

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