Use of vacuum-assisted aspiration for removal of vegetations during transvenous lead extraction

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Introduction

Transvenous lead extraction (TLE) is recommended for cardiac implantable electronic device infections. While existing literature reports experience using routine TLE for vegetations <2 cm in size without a major incidence of clinically significant pulmonary embolism, there are limited data on outcomes for patients with larger vegetation.1–4 Surgical lead extractions are considered for patients who have other reasons for cardiac surgery, who have failed TLE, or who have vegetation or thrombus >2.5 cm.5 Ho and colleagues6 recently reported an 18.5% incidence of lead thrombi, all of which were <2 cm, and there were no immediate complications associated with TLE in these patients. The standard of care for patients with large vegetations on the leads has been to refer patients directly to surgical extraction. There is significant morbidity for the surgical lead extraction compared to patients undergoing TLE.7 It has been noted that there is a significant increase in risk of stroke with the presence of cardiac implantable electronic device leads8; therefore the risk of stroke is likely higher with TLE in patients who have patent foramen ovale or an atrial septal defect.

In patients without cardiac implantable electronic devices, isolated right-sided endocarditis constitutes 5%–10% of all cases of endocarditis.9 Among these, approximately 20% require surgical intervention. Similarly, there are limited data for the management of active infections.10 Percutaneous options for treatment of large right-sided vegetations may now be available. Numerous reports have demonstrated the use of the AngioVac™ system (AngioDynamics Inc, Latham, NY) to debulk and remove vegetations and thrombi prior to and/or during TLE.11 However, multiple concerns remain about the use of this system in a critically ill patient with high operative morbidities, including portability, vascular complications, size of cannulas for the system, need for system anticoagulation, difficulty steering the catheter, and cost of acquiring/maintaining the system. The Indigo™ Thrombectomy System (Penumbra, Inc, Alameda, CA) is an aspiration catheter designed to engage the clot and extract it with a continuous vacuum pump.

Case report

A 66-year-old man with a history of dual-chamber pacemaker implanted owing to sick sinus syndrome and a history of paroxysmal atrial fibrillation, presented with complaints of severe lumbar back pain. The patient deteriorated rapidly with mental status changes, hypotension, acute renal failure, and hypoxemic respiratory failure with emergent intubation in the emergency room. He was diagnosed with severe sepsis requiring aggressive critical care management, including hemodynamic support with 2 vasoactive agents (vasopressin and norepinephrine). Blood cultures on admission yielded methicillin-sensitive Staphylococcus aureus, and he was empirically started on vancomycin until organisms were shown to be pan-sensitive, after which antibiotic coverage

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was narrowed to nafcillin. Transthoracic echocardiogram demonstrated left ventricular ejection fraction of 55% with a positive bubble study, demonstrating the presence of a patent foramen ovale. Doppler of the intra-atrial septum demonstrated that a medium-sized patent foramen ovale measuring approximately 2.99 cm was present on color Doppler without Valsalva maneuver. Computed tomography scan of the chest, abdomen, and pelvis revealed osteomyelitis of the lower spine in the region of L2–L3. Magnetic resonance imaging of the brain demonstrated multiple small, 2- to 3-mm, acute infarctions in multiple vascular distributions. The examination was notable for septic emboli to the distal extremities. Repeat blood cultures revealed the same organism for 3 consecutive days.

A transesophageal echocardiogram (TEE) was recommended and showed a long (0.26 × 3.6 cm), independently mobile structure within the right atrium (RA), consistent with a vegetation (Figure 1, Supplemental Video 1). We were also able to demonstrate this via 3-dimensional TEE (Supplemental Video 2). The structure appeared to be attached to the pacemaker lead just above the tricuspid valve. There was also a second mobile structure attached to the pacemaker lead within the right ventricle (Supplemental Figure 1, Supplemental Video 3). There was no evidence of aortic and/or mitral valve endocarditis, or of aortic arch infected atheromata.

Owing to the size of the vegetation and persistent bacteremia despite appropriate medical therapy, cardiothoracic surgery was consulted for the possibility of surgical intervention, but the patient was deemed a poor surgical candidate owing to hemodynamic instability. After discussion with the family regarding the patient’s critically ill state and poor prognosis, a decision was made to perform a laser lead extraction procedure. Owing to concerns about the consequences of septic pulmonary embolism and potential fragmentation of the vegetation leading to further cerebral and systemic emboli, given the presence of a patent foramen ovale, we decided to devise a system to debulk/remove the vegetations without subjecting the patient to anticoagulation and venovenous bypass using the AngioVac system. The patient’s device was approximately 3.6 years old with RA lead and right ventricular (RV) lead, both being Medtronic 5076 leads.

The patient arrived in the hybrid operating room intubated and sedated. Bilateral femoral veins were accessed using the modified Seldinger technique. A 16F GORE® DrySeal Flex introducer sheath with hydrophilic coating was placed in the right common femoral vein, and an 8F sheath was inserted into the left common femoral vein. A 9F sheath was placed in the right femoral vein, through which an 8F catheter (CARTO SoundStar; Biosense Webster, Irvine, CA) was advanced from the right femoral vein into the RA. Using the 16F DrySeal sheath as a guiding sheath (for the Indigo CAT8 system), we advanced a 91.4-cm 12F 45-degree curved sheath (Cook Medical, Bloomington, IN) for enhanced steering of the CAT8 system into the RA with a long 0.035 wire. A 115-cm Indigo CAT8 XTORQ with a 45-degree curve catheter was then advanced through the 12F guiding sheath into the RA. We chose to use intracardiac echocardiography (ICE) given the versatility of steering to obtain precise slices of the RV lead vegetations in view (Figure 2 and Supplemental Video 4). The vegetation was attached to the RV lead with the stalk at the level of the tricuspid valve. The goal was to align the mouth (inner diameter 8F) of the CAT8 catheter to the body of vegetation closest to the stalk/attachment point so that we could suction the vegetation as a whole without fragmentation. This required coordination between 2 physician operators, 1 experienced in ICE and another with the Penumbra system. The aspiration was accomplished by connecting the perfusion catheter to the aspiration pump, which generated a vacuum of -20 inHg. We performed 2 aspiration passes with 100

Figure 1 Primary vegetation displayed, measuring greater than 3.8 cm (pointed to by the yellow bracket), as observed by transesophageal echocardiogram. Associated video, Supplemental Video 1.
mL drawn with each pass until the intraprocedural ICE revealed no lingering vegetation on the RV lead (Supplemental Figure 2 and Video 5). During the first pass, blood in the vacuum container was strained and revealed the presence of the smaller vegetation in the container (Figure 2). But we noted the continued presence of the larger vegetation on ICE. A second pass was performed closer to the body of the vegetation, with the strained blood revealing the large vegetation and resolution of vegetation on the ICE imaging (Figure 3). The Indigo Penumbra system was withdrawn into the inferior vena cava to allow us to proceed with the lead extraction. Using well-described procedural steps for laser lead extraction, we successfully extracted the RA and RV leads. The pocket was carefully inspected and closed with suture, since it was free of pus. The Penumbra and ICE systems were removed from the body and hemostasis was achieved in both the right and the left common femoral venous accesses via figure-of-8 closures. The patient tolerated the procedure well. The total procedure time was 72 minutes and the blood loss was 200 mL.

Both vegetations were sent to pathology for analysis and aerobic cultures. Pathology of the vegetation specimens showed via gram staining that there were gram-positive cocci in chains and culture-positive for methicillin-sensitive *Staphylococcus aureus*. The patient’s condition improved for the first 48 hours after the procedure.

Unfortunately, after 72 hours of stability, the patient’s condition took a turn for the worse owing to tissue necrosis of the distal upper and lower extremities, lactic acidosis, and worsening renal failure. Given a grim prognosis, the family decided to withdraw care. The patient was extubated to comfort care and died.

**Discussion**

We believe this is the first case reporting the use of the Indigo Penumbra CAT8 catheter for removing lead-associated vegetations prior to TLE. The proposed benefits of the newly described technique are the lack of systemic anticoagulation requirement, single and smaller venous access requirement, and greater flexibility in positioning the aspiration catheter, including a greater variety of directable sheaths available.

In 2014, the US Food and Drug Administration approved the AngioVac system for the removal of unwanted intravascular materials (thrombi and emboli). A recent study of the AngioVac system by Starck and colleagues reported 101 cases of cardiac device–related infective endocarditis patients who underwent aspiration of large vegetations (mean size 30.7 ± 13.5 mm) followed by transvenous lead removal that showed complete procedural success of 94%. It also showed a very high success rate in using AngioVac prior to infected lead extraction, which further supports the use of percutaneous aspiration as highly effective and safe, with a low complication rate. The aspiration of vegetations immediately before and during the lead extraction procedure may...
prevent septic embolization into the pulmonary circulation, and this may lead to better short- and long-term survival. In this unstable patient, we were concerned about the ability to tolerate venovenous bypass with suction flow rates of 3–5 L/min required by the AngioVac system. We were concerned about anticoagulation in this patient owing to ongoing thrombocytopenia. Steerability was an important factor in directing the aspiration at the vegetation. The Indigo system addressed these concerns and could be introduced into the preshaped long delivery sheath for delivery as in our case, or into a deflectable sheath such as a 12F FlexCath Advance Steerable Sheath (Medtronic, Minneapolis, MN). In comparison, the AngioVac catheter system is not deflectable and is challenging to use in patients with pulmonary embolism, partly because of the difficulty in steering a large cannula into pulmonary arteries.

The use of percutaneous aspiration during a TLE has potential implications for use during procedures in noninfected cases in which a large debris burden is anticipated. We hypothesize here that this may result in a reduction of debris embolization infection and reduce the risk of adverse pulmonary vascular disease. Abubakar and colleagues reported that the risk of septic pulmonary embolism remains significant at 34%–55% in this subset of patients with vegetations >1 cm, as it predisposes them to further infectious complications, including pulmonary abscesses and refractory sepsis.

A major limitation of the system is that there is no existing capability for blood return to the patient postaspiration. The patient lost 200 mL of blood with 2 passes of suction. Further passes would have led to even more blood loss. Future consideration should be given to using a cell salvage system to recover blood lost and reinfusing it into the patient. This technique is most applicable to a small-size vegetation with malleability in order to successfully be pulled into the catheter. However, other case reports in the interventional radiology literature regarding thrombectomy have reported using the “corking method,” whereby material that may not fully deform into the primary thrombectomy catheter may be withdrawn out of the body with progressive larger outer guiding catheters, and it is likely that this technique could be used with this device too. However, the use of this device may not be generalized to all vegetations, particularly those that are calcified and/or large.

The need for ICE in the technique described adds an additional layer of complexity to the case, with additional vascular access and a second physician to direct the catheter, as well as expense. Our institution routinely uses ICE to track for development of pericardial effusion during TLE. It is likely that programs that use TEE during TLE could achieve similar success.

**Conclusion**

This case introduces a new management option for large vegetations on the leads with proposed benefits of lack of systemic anticoagulation requirement, single and smaller venous access requirement, and greater flexibility in steering the aspiration catheter.

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**Appendix**

**Supplementary data**

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.hrcr.2020.01.005.

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