AngioVac CASE STUDY

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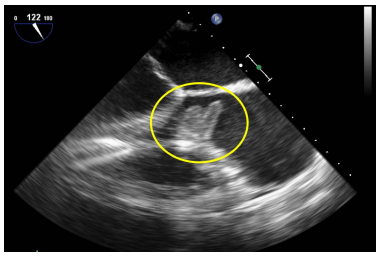
AngioVac
Cannula and Circuit

DISEASE STATE:

The global incidence of cardiac implantable electronic device (CIED) infection is now increasing out of proportion to the rate of device implantation, driven predominantly by the implantation of devices in patients with increasing complexity and medical comorbidities.[1] CIED infections typically require complete device and lead removal.[2] The prevalence of vegetations is high in patients with infective indications who are referred for lead extraction.[2] Vegetations on the leads can dislodge and block the main pulmonary artery or one of its branches, causing hemodynamic collapse.[3] Transoesophageal echocardiography (TOE) is the preferred technique for diagnostic imaging because its sensitivity for detection of lead-related vegetations is greater than transthoracic echocardiography (TTE).[4] Often, patients with vegetation size larger than 20 mm are referred for consideration of open surgical lead extraction and debridement.[2] Mortality rates for infected CIEDs vary in the published literature, with highest rates occurring among patients treated with antibiotics alone (31% to 66%) and as low as 13% to 33% with antibiotics and lead removal.[5]



Photos courtesy of Dr. Zlotnick.
Actual procedure results.†

PATIENT HISTORY:

Patient is a 34-year-old male with non-ischemic cardiomyopathy status post implantable cardioverter-defibrillator (ICD) placement 3 months prior to admission. Patient was admitted with Methicillin-sensitive staphylococcus aureus (MSSA) bacteremia, and was found to have vegetations involving his ICD lead and Tricuspid Valve (TV).

PRE-CASE PLANNING:

Goal was to debulk the vegetations with AngioVac followed by laser lead extraction.

PROCEDURE NOTES:

Access Sites: AngioVac Cannula and Snare—RIJ x2

Re-infusion cannula—LFV

Pump time: 15 minutes

Fluoro time: 30 minutes

Heparin Total: 20,000 IU

ACT: 307 seconds

The patient was prepped and draped in sterile fashion. Patient was brought to operating room (OR) and anesthetized. Patient was then intubated, and a TEE probe was placed to visualize the TV vegetations. Ultrasound was used to gain access to all sites using a micro puncture needle. Access was done via a double right internal jugular (RIJ) stick for aspiration, left groin was used for the 20F reinfusion cannula. A 6F sheath was placed in the right groin and at the end of the case was replaced by a dialysis catheter. The left femoral was dilated up to 18F over a wire, then a 20F percutaneous reinfusion cannula was placed and connected to the circuit via a wet to wet connection and flushed appropriately. RIJ access was serially dilated up to 24F.

Heparin was given to achieve an initial ACT of 233. An additional 5000u was provided reaching an ACT of 278.

The 26F sheath was then placed over a super stiff wire, into the RIJ with no complications. A 6F sheath was also placed into the RIJ to pass the 35mm goose neck snare through, to help guide the AngioVac as needed. The AngioVac cannula was attached to the circuit and flushed with normal saline, then placed through the sheath to the superior vena cava (SVC) right atrium (RA) junction, the balloon tip was inflated to 2 atmospheres (ATM), and the centrifugal pump was turned on. Flows were maximized at 2200 revolutions per minute (RPM) = 3.5 liters per minute (LPM).

The cannula was advanced via TEE guidance. The AngioVac was easily navigated through the RA to debulk the vegetation on the lead and then into the TV while on pump. The vegetations were easily accessed and engaged by the cannula. The physician could feel material coming through the cannula and the vegetations were no longer visible on the TEE. Laser lead extraction was then performed by the thoracic surgeons. The AngioVac cannula was removed and the blood was returned to the patient via gravity feed. The large bore sites were closed via mattress suture. The material was sent to pathology.

†This case study represents the experience of one institution and is not indicative of all procedure results.

1. Harper MW, Uslan DZ, Greenspon AJ, et al. Clinical presentation of CIED infection following initial implant versus reoperation for generator change or lead addition. *Open Heart.* 2018 March 6;5(1).
2. Issa ZF, Goswami NJ. Simultaneous lead extraction and vacuum-assisted vegetation removal. *HeartRhythm Case Rep.* 2015 Aug 21;2(1):17-19.
3. Wazni O, Wilkoff BL. Considerations for cardiac device lead extraction. *Nat Rev Cardiol.* 2016 Apr;13(4):221-9.
4. Podoleanu C, Deharo JC. Management of Cardiac Implantable Electronic Device Infection. *Arrhythm Electrophysiol Rev.* 2014 Nov;3(3):184-9.
5. Schaerf RHM, Najibi S, Conrad J. Percutaneous Vacuum-Assisted Thrombectomy Device Used for Removal of Large Vegetations on Infected Pacemaker and Defibrillator Leads as an Adjunct to Lead Extraction. *J Atr Fibrillation.* 2016 Oct 31;9(3):1455.

Important Risk Information:

Refer to directions for use provided with the device for Indications for Use, Contraindications, Warnings and Precautions.

CANNULA INDICATIONS FOR USE: The AngioVac Cannula is indicated for use as a venous drainage cannula during extracorporeal bypass and for removal of fresh, soft thrombi or emboli during extracorporeal bypass for up to six hours.

CIRCUIT INDICATIONS FOR USE: The AngioVac Circuit is indicated for use in procedures requiring extracorporeal circulatory support for periods of up to six hours.

CONTRAINDICATION: Do not use if the patient has severe arterial or venous vascular disease. The device is contraindicated in the removal of chronic firmly adherent intravascular material (e.g., atherosclerotic plaque, chronic pulmonary embolism). The device is contraindicated for use in the right heart or pulmonary arteries during active cardiopulmonary resuscitation.

WARNING: Selection of the patient as a candidate for use with this device and for such procedures as it is intended is the physician's sole responsibility. The outcome is dependent on many variables including, patient pathology, surgical procedure, and perfusion procedure/technique.

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilizing may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilizing may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

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