AngioVac CASE STUDY

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AngioVac
Cannula and Circuit

DISEASE STATE:

The incidence of infection associated with cardiac implantable electronic devices (CIEDs) is rising at a rate faster than that of the number of implants. CIED infections typically require complete device and lead removal.[1] The prevalence of vegetations is high in patients with infective indications who are referred for lead extraction.[1] Vegetations on the leads can dislodge and block the main pulmonary artery or one of its branches, causing hemodynamic collapse.[2] Transesophageal echocardiography (TEE) is the preferred technique for diagnostic imaging because its sensitivity for detection of lead-related vegetations is greater than transthoracic echocardiography (TTE).[3] Often, patients with vegetation size larger than 20 mm are referred for consideration of open surgical lead extraction.[1] 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.[4]

**Photo of actual procedure results, courtesy of Dr. Feldtman.*

PATIENT HISTORY:

Patient is a 72-year-old male with sepsis and endocarditis, along with congestive heart failure. The patient reports symptoms that are unchanged. Transesophageal echocardiography (TEE) visualizes a vegetation approximately 1.5cm on the atrial lead.

PRE-CASE PLANNING:

Initial imaging showed a material on the distal portion of the right atrium automated implantable cardioverter defibrillator (RA AICD) lead. Access the right femoral vein (RFV) for aspiration, and the left femoral vein (LFV) for return. TEE will be used to confirm the material is still present and guide the AV cannula. Debulk as much of the vegetation as possible and remove the AICD leads.

PROCEDURE NOTES:

Access Sites: 26F Gore Dryseal Sheath (2628DSL) – RFV

18F Medtronic re-infusion cannula – LFV

Pump time: 9 minutes

Fluoro time: 3.5 minutes

Heparin Total: >30,000 IU

Patient was prepped and draped in a sterile manner. TEE was advanced and imaging showed the material on the lead near the tricuspid valve (TV). The RFV was accessed and dilated up to a 6F sheath. The RFV was then accessed and dilated up to an 8F sheath. The physician then opened the AICD pocket and removed the device. The AICD leads were freed and prepared for extraction. The physician up-sized the RFV to a 26F introducer sheath. The LFV was then up-sized to an 18F re-infusion cannula. The AngioVac cannula was advanced over a super stiff wire to below the superior vena cava / right atrium (SVC / RA) junction, and funnel was deployed. An activated clotting time (ACT) greater than 300 seconds was confirmed and additional heparin was administered, circuit was primed, and then optimal flow was achieved (2.0L).

The physician advanced the AngioVac cannula into the RA, and several passes were made along the lead. The material was no longer present under TEE and there was no material seen in the filter. The AngioVac cannula was then repositioned facing the TV and optimal flow was raised to 3L. The physician then extracted the leads. The AngioVac cannula was pulled back to the right atrium / inferior vena cava (RA / IVC) and TEE was used to visualize the RA. The vegetation was no longer present under TEE imaging, and there was material seen in the filter.

The physician concluded the procedure. The patient's vitals were stable throughout the entire procedure. Blood was returned to the patient by gravity feed, and 315 mg of Protamine was administered. AICD pocket was closed, the sheaths were removed and the access sites were closed. The filter was drained, material was inspected and documented for the physician. The material was then sent to pathology.

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

References:

1. Issa ZF, Goswami NJ. Simultaneous lead extraction and vacuum-assisted vegetation removal. HeartRhythm Case Rep. 2015 Aug 21;2(1):17-19.

2. Wazni O, Wilkoff BL. Considerations for cardiac device lead extraction. Nat Rev Cardiol. 2016 Apr;13(4):221-9.

3. Podoleanu C, Deharo JC. Management of Cardiac Implantable Electronic Device Infection. Arrhythm Electrophysiol Rev. 2014 Nov;3(3):184-9.

4. 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 physicians' 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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