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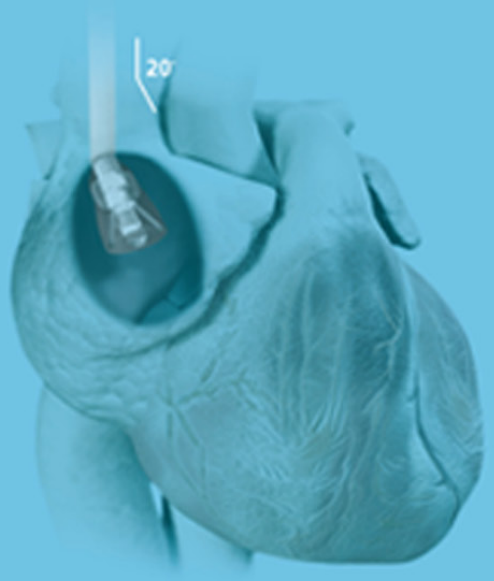
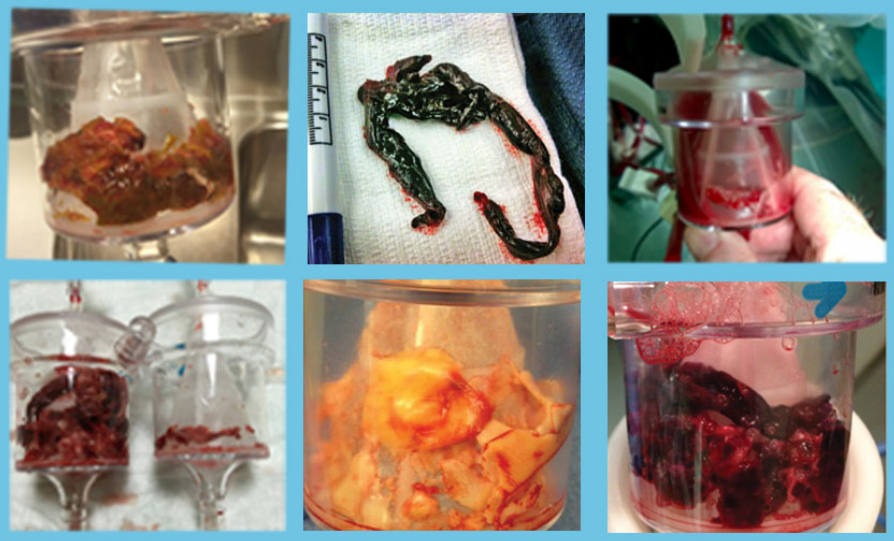
AngioVac

Cannula and Circuit



Venous Drainage Concept

The cannula is intended for use as a venous drainage cannula and for the removal of fresh, soft thrombi or emboli during extracorporeal bypass for up to six hours.



CASE REPORT & PUBLICATION SUMMARY

Designed to remove thrombi and emboli in a wider variety of anatomical locations

Ausgabe Februar 2019

AngioVac

Cannula and Circuit

Available in curved & straight tips

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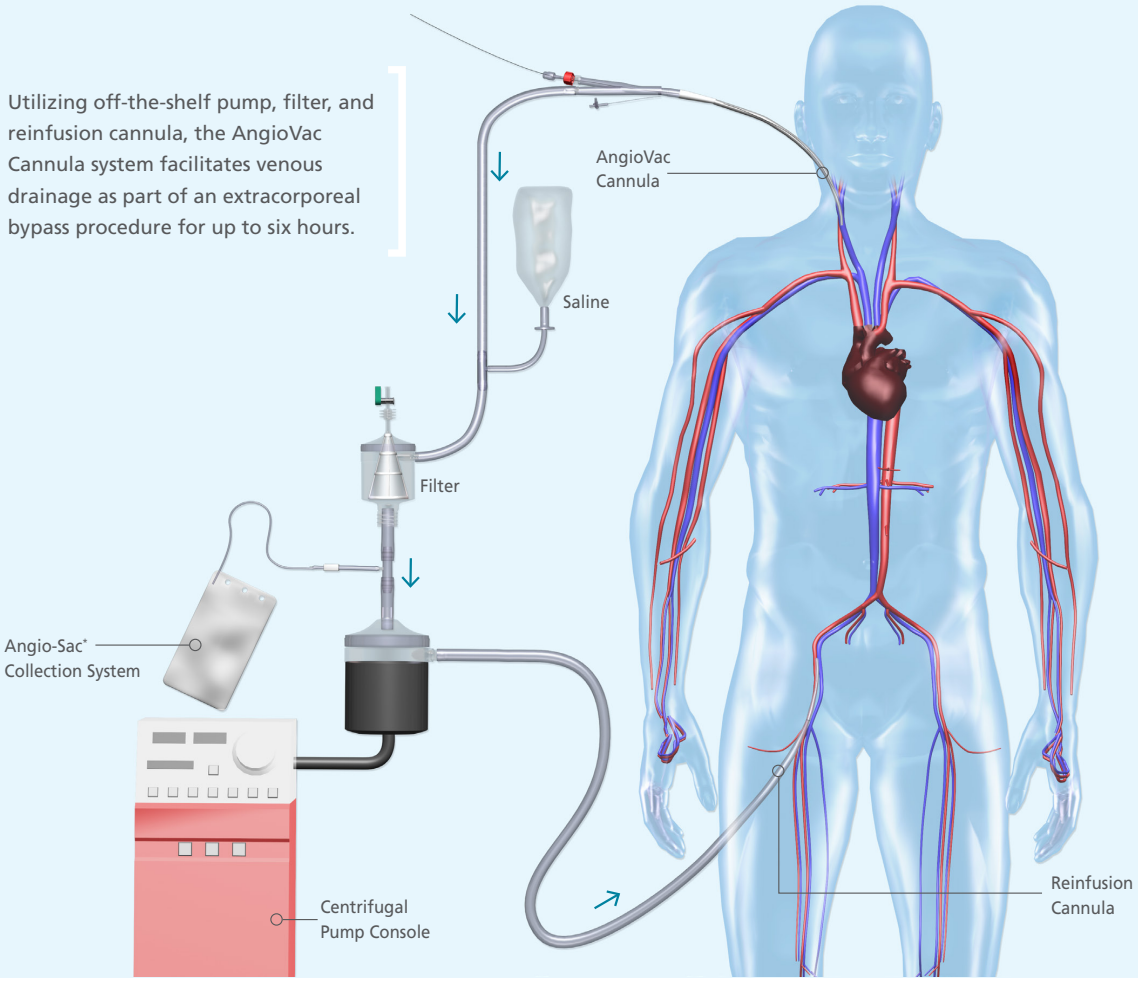
AngioVac
Cannula and Circuit

The AngioVac* Venous Drainage System includes the venous drainage cannula and the extracorporeal circuit. The cannula is intended for use as a venous drainage cannula and for the removal of fresh, soft thrombi or emboli during extracorporeal bypass for up to six hours.

Utilizing off-the-shelf pump, filter, and reinfusion cannula, the AngioVac Cannula system facilitates venous drainage as part of an extracorporeal bypass procedure for up to six hours.



Informationsmaterial im Internet:

www.angiovac.com

https://www.youtube.com/watch?time_continue=64&v=84VytDsalFk

www.aimecs.de

AngioVac CASE STUDY

Dr. Adams (IC)
CAMC Memorial Hospital
Charleston, WV

AngioVac
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DISEASE STATE:

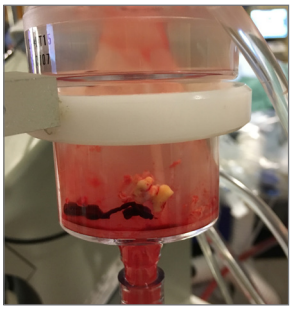
Infective Endocarditis (IE) is an infection of the inner linings of the heart or the heart valves with significant morbidity/mortality. It occurs typically in the left side of the heart while right-side IE (RSIE) is less common[1]. The majority of RSIE cases include the tricuspid valve with key risk factors being intravenous drug usage (IVDU), pacemaker/defibrillator leads and indwelling lines (such as hemodialysis and chemotherapy). Most patients are successfully treated with antibiotics; however, treatment escalates to surgical intervention in 5%–16% of the RSIE cases[1,2]

PATIENT HISTORY:

Patient is a 40-year-old female with a history of IVDU and endocarditis. In addition, she has a history of DVT, PE and stroke, as well as a Protein C deficiency. She is on Levophed and echo shows a large vegetation on her Tricuspid Valve (TV). The vegetation is highly mobile. She was referred for evaluation and was admitted with sepsis.

PRE-CASE PLANNING:

Access was done via the right internal jugular (RIJ) for aspiration and the left femoral vein (LFV) for return. The right femoral vein (RFV) will be accessed with a 14F sheath for the ICE catheter. First, the TV will be visualized with ICE to verify the vegetation is still present on the valve and define the size of the vegetation. Debulk the TV vegetation as much as possible.



Actual procedure results†

PROCEDURE NOTES:

Access Sites: 26F Gore Dryseal Sheath (2633DSF)—RIJ, 18F re-infusion cannula—LFV, 14F accessory sheath—RFV

Pump time: 11 minutes

Fluoro time: 9 minutes

Heparin Total: 8,000 IU

ACT: 260 seconds

Patient was prepped and draped in a sterile manner. ICE was advanced from the RFV and the TV was imaged. The valve vegetation was still present (2.9 cm x 1.5 cm) and highly mobile. The RIJ was accessed and dilated up to a 26F introducer sheath, and the LFV was accessed and dilated up to an 18F re-infusion cannula. The AngioVac Cannula was advanced over a Super Stiff wire to the SVC / RA junction, and funnel was deployed. An ACT of 260 seconds was determined and additional Heparin was administered, circuit was primed, and then optimal flow was achieved (2.0L).

The physician advanced the AngioVac Cannula to the TV and attempted to engage the vegetation with ICE guidance. The cannula engaged the undesirable intravascular material with a sharp drop in flows to .5L, and rebounded back to optimal flow when the cannula was pulled back and repositioned. Multiple passes were made, each time with similar results. There was significant undesireable intravascular material seen in the filter. ICE confirmed that the TV vegetation was no longer present.

The physician concluded the procedure. The patient's vitals were stable through the entire procedure. Blood was returned to the patient by a gravity feed. When an acceptable ACT was obtained, 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 for evaluation.

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

1. Hussain ST, Witten J, Shrestha NK, Blackstone EH, Pettersson GB. Ann, Tricuspid valve endocarditis, Cardiothorac Surg. 2017 May;6(3):255-261

2. Dawood MY, Cheema FH, Ghoreishi M, Foster NW, Villanueva RM, Salenger R, Griffith BP, Gammie JS. Contemporary outcomes of operations for tricuspid valve infective endocarditis. Ann Thorac Surg. 2015 Feb;99(2):539-46

Important Risk Information:

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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.

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>> TECHNICAL NOTE

Right Sided Infective Endocarditis (RSIE) Disease State Fact Sheet

Hard Facts – A new call to action: [1,2,3,5]

- Annual incidence of Infective Endocarditis (IE) ranging from 3 to 7 per 100,000 person-years[5]
- Annually, National Hospital Discharge Survey Database (NHDS) captures ~270,000 inpatient stays in 500 hospitals across the country (2007 data)[3]
- Globally, in 2010, IE was associated with 1.58 million disability-adjusted life-years or years of healthy life lost as a result of death and nonfatal illness or impairment[5]
- Patients with IE have a risk for recurrence and increased mortality rate[2,5]
- Right-sided IE (RSIE) encompasses 5-10% of IE occurrences[4]
- Majority of RSIE cases involve the Tricuspid Valve (TV), pulmonic valve involvement accounting for less than 10% of all right-sided cases[4]
- Intravenous drug users constitutes ~30-40% of RSIE (TV)[4]
- Overall mortality for RSIE is between 5 – 15%[4]
- Dominant infective organism is Staphylococcus Aureus, in most series accounting for around 70% of RSIE[1]

Risk Factors: [4]

- Intravenous drug use[4]
- Cardiac implantable electronic device (CIED) infection[4]
- Indwelling lines (hemodialysis, parenteral nutrition, and chemotherapy)[4]
- Uncorrected congenital heart disease[4]

Symptoms: [4]

- Persistent fever[4]
- Bacteremia[4]
- Multiple septic pulmonary emboli causing chest pain and cough[4]

Diagnosis: [1,2,4]

- Blood culture (Microbiological diagnosis)[2]

Note:[1,4]
Duke criteria *(positive blood culture and oscillating intracardiac mass on Echocardiogram[1])* is the gold standard for diagnosing IE[4].

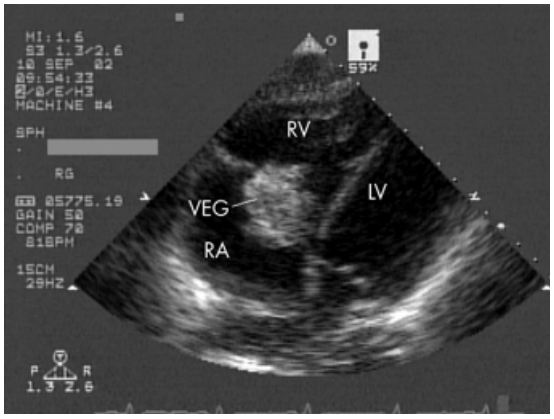

Figure 1: Echocardiographic image of a large vegetation, approximately 4cm in diameter, attached to the Tricuspid valve[1] (reproduced from Moss et al.)

- Transthoracic echocardiography, transesophageal echocardiography, and Chest x-ray[1]

Treatment: [1,4]

- **Antibiotics**[4]

a) Therapy should depend on the causative microorganism and its sensitivity[4]

b) Choice and duration of antibiotic therapy should be guided by an infectious disease expert[4]

- Surgery: 5-16% of RSIE cases eventually require surgical intervention[4]. Surgery is considered under the following circumstances:

a) TV vegetations greater than 20 mm with recurrent septic pulmonary emboli with or without concomitant right heart failure[4]

b) IE caused by microorganisms that are difficult to eradicate (e.g., fungi) despite adequate antimicrobial therapy[4]

c) Paravalvular abscess[1]

d) Right heart failure secondary to severe TR with poor response to diuretic therapy[4]

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1. Moss, R., & Munt, B. (2003). Injection drug use and right sided endocarditis. Heart, 89, 577-581.
2. Habib, G. (2015). 2015 ESC Guidelines for the management of infective endocarditis. European Heart Journal, 36(10), 3075-3123
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4. Hussain ST, Witten J (2017). Tricuspid Valve Endocarditis. Ann Cardiothoracic Surg, 6 (3), 255-261.
5. Baddour, ML. (2015). Infective Endocarditis in Adults: Diagnosis, Antimicrobial Therapy, and Management of Complications A Scientific Statement for Healthcare Professionals from the American Heart Association. Circulation, 132(15), 1435- 1486.

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AngioVac CASE STUDY

Dr. Feldtman (VS)
Methodist Dallas Medical Center
Dallas, TX

AngioVac
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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.

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Right Atrial Thrombus Removal

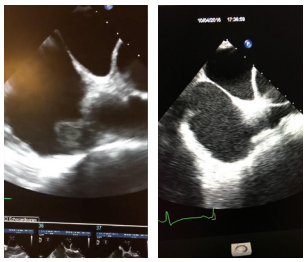
ST. ANTHONY'S HOSPITAL, DENVER, COLORADO

Dr. Nima Aghili (Interventional Cardiology)

BACKGROUND

Right heart thrombus in the absence of structural heart disease, atrial fibrillation or central venous catheters is rare. It often presents as a thrombus migrating to the lung, referred to as pulmonary embolism (PE) in-transit, which can be life-threatening.[1]

Retrospective studies indicate that PE patients with free-floating right atrial thrombus are at very high risk for mortality and would potentially benefit from direct thrombectomy when compared to treatment with medications alone.[2,3] Furthermore, in some cases, the use of thrombolytic therapy may be somewhat limited due to the known risk of significant hemorrhage (overall 22%, with up to 3% intracranial hemorrhage) and suggested risk of distal embolization.[2]



Pre AngioVac echocardiogram shows right atrial thrombus;

Post AngioVac image shows that the thrombus has been removed.

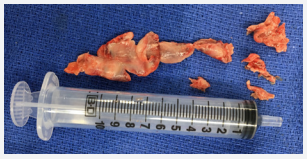
PATIENT HISTORY

Seventy-year-old female with history of long standing obstructive sleep apnea, obesity and DVT was emergently transferred to a tertiary care facility following a diagnosis of bilateral PE and tumbling right atrial (RA) thrombus originating from an upper extremity DVT. The patient's condition was critical secondary to severe hypoxia requiring intubation, right ventricular (RV) strain and a newly diagnosed gastrointestinal bleed (GIB).

Upon transfer, transesophageal echocardiography (TEE) confirmed the presence of a large mobile thrombus measuring 2x2 centimeters. The mass appeared hypo-echogenic at its core, making it more susceptible to removal with the AngioVac Cannula and Circuit. Heart team meeting was held and given that any additional PE could result in immediate fatal outcome, the decision was made to remove the RA thrombus. Treatment with the AngioVac Cannula and Circuit was chosen as an alternative to open surgery due to patient's bleeding status, morbid obesity and the morphology of the material tumbling in the RA.

PROCEDURE

Patient was prepped and draped in the usual sterile fashion. A 26F sheath was placed in the right femoral vein (RFV) for advancement of the AngioVac Cannula and an 18F arterial reinfusion cannula was placed in the left femoral vein (LFV) for blood return. An additional 6F sheath was placed in the right femoral artery (RFA) to allow for emergent extracorporeal membranous oxygenation in the event that the patient deteriorated further.



Procedure results[†]

Transesophageal echo (TEE) was performed for guidance. AngioVac Cannula was introduced through the 26F sheath and advanced to the inferior vena cava, RA junction. Heparin was given and an average clotting time (ACT) of 300 was confirmed. Flow was initiated through the AngioVac Cannula and Circuit and optimized at 3.25 liters per minute (L/min). The cannula was advanced into the RA to engage the thrombus. To aid in orienting the cannula toward the material, it was rotated allowing the angled tip to deflect off of the intra-atrial septum. Once the material was engaged the flow through the circuit stopped, as expected, due to complete obstruction of the cannula. After a short period of time, the material worked its way through the circuit and into the filter and flow was restored at its optimal rate. Subsequent passes to engage the material were successful in removing all of the material from the RA. TEE imaging confirmed material was no longer present, goals for the procedure met and the case was ended.

[†]An individual experience may not be indicative of all procedure results.

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References
1. Ahmed Al Badri, MD; Chad Kliger, MS, MD et al. Atrial Vacuum-Assisted Thrombectomy: Single-Center Experience. Journal of Invasive Cardiology. 016 May; 28(5): 196-201.
2. Rose PS, Punjabi NM, Pearse DB. Treatment of right heart thromboemboli. Chest. 2002;121:806-814.
3. Kronik G. The European Cooperative Study Group on the clinical significance of right heart thrombi. Eur Heart J. 1989;10:1046-1059.

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AngioVac
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IVC Thrombus Removal

ARROWHEAD HOSPITAL, PHOENIX, ARIZONA

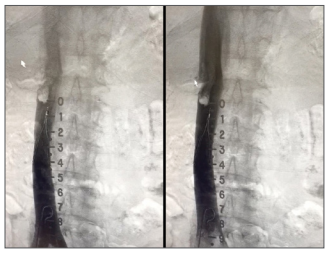
Rahul Malholtra, MD, FACC, FSCAI (Interventional Cardiology)

BACKGROUND

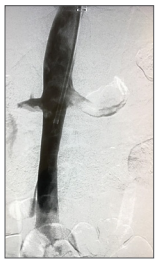
Inferior vena cava (IVC) thrombosis/occlusion is a potentially life-threatening thromboembolic complication related to filter placement. A recent CT–based follow-up study in patients who had IVC filters placed over an 8-year period at a high-volume center demonstrated an 18.6% incidence of vena cava thrombosis.[1] Of those cases, it was reported that almost 2% of those patients had total occlusions.[1]

PATIENT HISTORY

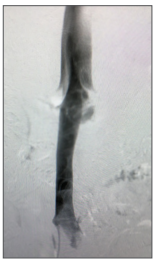
An 80-year-old male had an IVC filter placed in December 2016 due to history of VTE, May-Thurner Syndrome, and inability to tolerate chronic anticoagulation. The VTE manifested as bilateral deep venous thrombosis and pulmonary embolism. Additionally, in February 2017, patient had stents placed in the left common and external iliac veins. During stent placement, intravascular ultrasound showed a 2.39 cm x .88 cm thrombus on top of the IVC filter with a tail extending superiorly. The thrombus measured 50% of the IVC's diameter. Patient was a poor candidate for lytic therapy.



Pre AngioVac intravascular ultrasound image shows IVC filter thrombus.*



Post AngioVac image shows that the thrombus has been removed and filter retrieved.



30-day post AngioVac cavagram confirms no visible thrombus.

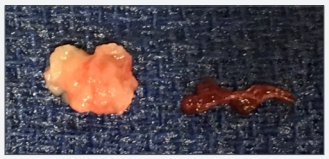
PROCEDURE

26F sheath placed in right internal jugular (RIJ) vein.

18F reinfusion cannula placed in right femoral vein (RFV).

An activated clotting time (ACT) of 315s was confirmed. AngioVac Cannula was introduced to the IVC/RA junction, funnel was deployed, and optimal flow was achieved (3L - 3.5L). The AngioVac Cannula was then advanced above the IVC filter and the tail of thrombus was engaged, with an immediate drop in flows to 0L - 0.5L. The physician withdrew the AngioVac slightly while perfusion adjusted RPMs to encourage movement of the thrombus through the cannula and circuit, successfully re-establishing optimal flow. Multiple passes were made through the IVC with the AngioVac Cannula capturing the thrombus in the filter. Subsequent imaging of the IVC showed no material remaining on top of the IVC filter, and no material in or directly below it, the filter was then retrieved. Post imaging revealed a 4mm x 2mm thrombus broadly attached to the IVC wall further below the filter. Physician determined it was not a significant enough size to pursue, AngioVac was withdrawn and the case was ended. On the 30 day post follow up cavagram the thrombus was resolved. Patient's vitals were stable throughout the procedure.

Total pump time - 12 min.



Captured thrombus post procedure.†

†An individual experience may not be indicative of all procedure results.

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IMPORTANT RISK INFORMATION

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 6 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 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. The benefits of this deice must be weighed against the risks including risks of systemic anticoagulation and must be assessed by the prescribing physician. 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.

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AngioVac
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IVC Thrombus Removal

MACON MEDICAL CENTER OF CENTRAL GEORGIA, MACON, GEORGIA

Dr. Michael Klyachkin (Vascular Surgery)

BACKGROUND

Inferior vena cava (IVC) thrombosis/occlusion is a potentially life-threatening thromboembolic complication related to filter placement. A recent computed tomography (CT)–based follow-up study (Nazzal et al.) in patients who had IVC filters placed over an 8-year period at a high-volume center demonstrated an 18.6% incidence of vena cava thrombosis. Of those cases, Ahmad et al. reported that almost 1% of those patients have total occlusions.

PATIENT HISTORY

This patient is an 18-year-old obese male with previous medical history of Type 1 and 2 diabetes mellitus, hypertension, protein S deficiency, prior pulmonary embolism and subsequent IVC filter placement. He recently had chest pain and shortness of breath. He was taken to another facility and diagnosed with bilateral pulmonary embolism.

PRE-CASE PLAN

Pre-case imaging demonstrated a large thrombus burden above the IVC filter. With the intent to perform thrombectomy using AngioVac cannula and circuit, the pre-case plan was to gain access in bilateral internal jugular (IJ) and bilateral femoral veins (FV), utilizing the right IJ for aspiration, the left femoral vein (LFV) for reinfusion and right FV for imaging.

Pre-AngioVac venogram demonstrates extensive IVC thrombus extending above the IVC filter.

PROCEDURE

A 26F sheath was placed in the right IJ. A reinfusion cannula was placed in the LFV. After gaining access and going on pump, the AngioVac cannula was advanced to engage the clot. After less than one minute on pump and three passes there was a clot visualized in the bubble trap. A venogram showed that the filter was clear of any residual thrombus.

Post-AngioVac venogram demonstrates complete removal of caval thrombus.

Bubble trap with captured thrombus post-procedure.

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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 fibrous or calcified material (e.g., atherosclerotic plaque). 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 (USA) law restricts these devices to sale by or on the order of a physician. Alone, this cannula is not a medical treatment device.

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AngioVac CASE STUDY

Dr. Zlotnick (IC) & Dr. Aldridge (CT)
Buffalo General
Buffalo, NY

AngioVac
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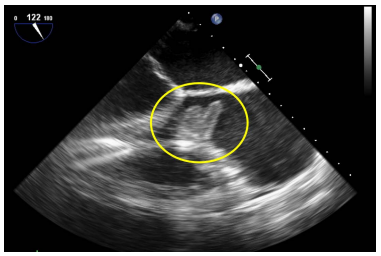
DISEASE STATE:

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.

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Important Risk Information:

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

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Right Atrial Thrombus Removal

VANDERBILT UNIVERSITY MEDICAL CENTER, NASHVILLE TN

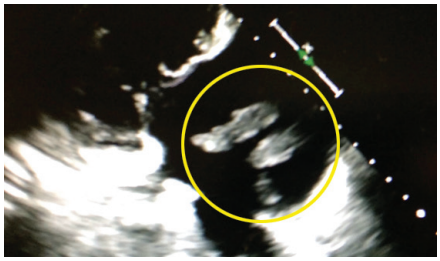
Dr. Pete Fong (Interventional Cardiology)

BACKGROUND

Floating right atrial thrombi are uncommon. Studies by Chapoutot et al. and Casazza et al. indicate that they occur in 7% to 18% of patients with proven pulmonary embolism. These thrombi are a form of venous thromboembolic disease, as they are in transit from the legs to the pulmonary arteries. They can embolize at any moment and have a documented high (>40%) mortality rate.

PATIENT HISTORY

An eighty year-old female with a history of pulmonary hypertension and atrial fibrillation presented to the hospital with new onset dyspnea. Right atrial (RA) thrombus was discovered on echo during workup, freely tumbling and occasionally protruding into the right ventricle. The AngioVac System was chosen to aspirate the thrombus to avoid an open procedure since the patient was at high-risk for complication due to advanced age and poor health.

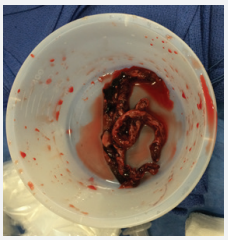


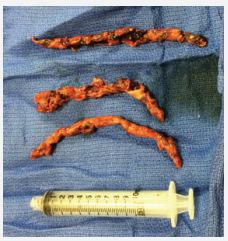
Pre-AngioVac echocardiogram shows freely tumbling right atrial thrombus, intermittently approaching the tricuspid valve.

PROCEDURE

26F sheath placed in right internal jugular (RIJ) vein.
16F reinfusion cannula placed in left femoral vein (LFV).

AngioVac cannula was introduced through the RIJ and initial flows of 2.7 liters per minute (L/min) were momentarily obtained at the SVC/RA junction. Flows abruptly dropped to 0.2 L/min before advancing to the RA. Flows were unable to be restored with the AngioVac cannula in the body. The AngioVac cannula was removed on pump (in case material was present in cannula). Upon removal, no material was noted in the cannula and physician was unable to aspirate blood from sheath. The sheath was then removed with the wire left in place then re-inserted after flushing. No thrombus was noted in the sheath. AngioVac cannula was reinserted through the Dry-seal and restarted on pump. Physician was unable to achieve any appreciable flow rates, there was no swirling noted in the filter and no blood returning from the cannula. After one minute of trying to establish flows it was noted that the material in the RA was no longer visible on TEE. The cannula balloon was deflated and the cannula withdrawn while the pump was running. The cannula was noted to be completely occluded with thrombus. The material was flushed out of the cannula and measured almost 30cm in total length. Blood in the circuit was returned to the patient by gravity feed. An IVC filter was then placed for embolic protection. Heparin was reversed with protamine and the access sites closed with figure 8 stitch. The patient remained stable throughout the procedure.





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