AngioVac
Cannula and Circuit

IVC Thrombus Removal

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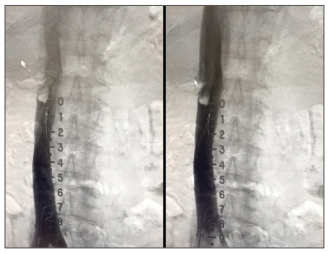
BACKGROUND

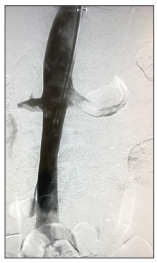
Inferior vena cava (IVC) thrombosis/occlusion is a potentially life-threatening thromboembolic complication related to filter placement. A recent CT–based follow-up study in patients who had IVC filters placed over an 8-year period at a high-volume center demonstrated an 18.6% incidence of vena cava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

PATIENT HISTORY

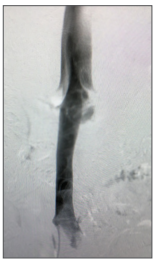
An 80-year-old male had an IVC filter placed in December 2016 due to history of VTE, May-Thurner Syndrome, and inability to tolerate chronic anticoagulation. The VTE manifested as bilateral deep venous thrombosis and pulmonary embolism. Additionally, in February 2017, patient had stents placed in the 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.

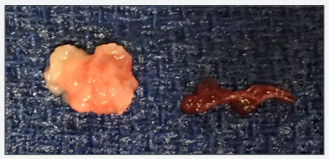
PROCEDURE

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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1. Ahmad I, Yeddula K, Wicky S, Kalva SP. Clinical sequelae of thrombus in an inferior vena cava filter. Cardiovasc Intervent Radiol. 2010;33:285–289.

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.

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

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