Title: Percutaneous debulking of tricuspid valve endocarditis in severe COVID-19 pneumonia after prolonged VV-ECMO with right ventricular support: a case series

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Abstract:

Background: Over the past two years, the utilization of venovenous extracorporeal membrane oxygenation (VV-ECMO) for the treatment of coronavirus disease 2019 (COVID-19) acute respiratory distress syndrome (ARDS) has increased. While supporting respiratory function, VV-ECMO requires large-bore indwelling venous cannulas, which risk bleeding and infections, including endocarditis.

Case Summary: We describe two adults hospitalized for COVID-19 pneumonia who developed ARDS and right ventricular failure, requiring VV-ECMO and ProtekDuo cannulation. After over 100 days with these devices, both patients developed tricuspid valve vegetations. Our first patient was decannulated from ECMO and discharged, but re-presented with a segmental pulmonary embolism and tricuspid mass. The Inari FlowTriver system was chosen to percutaneously remove both the tricuspid mass and pulmonary thromboembolism. Pathological examination of the mass demonstrated *Candida albicans* endocarditis in the setting of *Candida* fungemia. Our second patient developed a tricuspid valve vegetation which was also removed with the FlowTriever system. Pathologic examination demonstrated endocarditis consistent with *Pseudomonas aeruginosa* in the setting of *Pseudomonas bacteremia*. Both patients experienced resolution of fungemia and bacteremia after percutaneous vegetation removal. After ECMO decannulation and percutaneous debulking, both patients experienced prolonged hospital stays for ventilator weaning and were eventually discharged with supplemental oxygen.

Discussion: VV-ECMO and right ventricular support devices are invasive and create various risks, including bloodstream infection and infective endocarditis. Percutaneous debulking of valvular vegetations associated with these right-sided indwelling devices may be an effective means of infection source control. It is unclear whether prolonged use of VV-ECMO provides a mortality benefit in COVID-19 ARDS.

Learning Points

- Prolonged VV-ECMO and ProtekDuo right ventricular cannulation increase the risk of device-associated bloodstream infection and may also increase the risk of developing tricuspid valve endocarditis.
- The Inari FlowTriever system, approved for the percutaneous removal of pulmonary thromboembolism, may show promise for debulking large valvular vegetations as a method of infection source control, and to reduce the need for surgical intervention.
- It is unclear whether the utilization of VV-ECMO in cases of COVID-19-associated ARDS provides a significant mortality benefit.

Patient 1	*Time*	*Event*
	Presentation	Admitted to an outside hospital
		Tested positive for COVID-19
	Day 3	Transferred to our institution
		Intubated and mechanically ventilated
		Cannulated for VV-ECMO
	Day 8	Tracheostomy Placed
	Day 20	Blood cultures positive for *Enterococcus faecalis;* treated with vancomycin
	Day 39	Protek Duo cannula connected to VV-ECMO circuit
	Day 52	Occlusive deep vein thrombosis in the right common femoral vein and saphenous junction to right posterior tibial vein
	Day 100	Blood cultures positive for *Candida albicans;* treated with micafungin
	Day 123	Decannulated from VV-ECMO
		Decannulated from tracheostomy
	Day 149	Discharged home with oral apixaban and supplemental oxygen
	Day 174	Re-presented to our institution with dyspnea and increased oxygen requirement
		CT Angiogram with right pulmonary artery thromboembolism
		Taken for thrombectomy of PTE with Inari FlowTriever
		Tricuspid valve mass debulked with Inari FlowTriever, consistent with *Candida* endocarditis
	Day 175	Intubated; pressors initiated for hemodynamic collapse
		Blood cultures, drawn on admission, returned positive for *Candida albicans*; treated with amphotericin B
	Day 185	Surveillance blood cultures negative
	Day 186	Tracheostomy placed
		Transferred to Pulmonary Special Care Unit
	Day 248	Decannulated from tracheostomy
	Day 255	Discharged to inpatient rehabilitation facility on supplemental oxygen

Patient 2	*Time*	*Event*
	Presentation	Tested positive for COVID-19
		Admitted to acute care hospital room
	Day 3	Oxygen requirement escalates to high-flow nasal cannula at 100% FiO2 and transferred to intensive care unit
		Normal transthoracic echocardiogram
	Day 9	Intubated and mechanically ventilated
	Day 15	Chronic renal replacement therapy initiated for acute kidney failure
	Day 16	Cannulated for VV-ECMO
	Day 29	Atrial fibrillation with a rapid ventricular response
		Direct current cardioversion, reverted to sinus rhythm
		Repeat transthoracic echocardiogram with reduced left ventricular ejection fraction to 40-45% and severe right ventricular dilation
	Day 51	Protek Duo cannula placed due to hypotension and persistent right ventricular failure
	Day 70	Blood cultures positive for *Enterococcus faecalis;* treated with ampicillin and ceftriaxone
	Day 157	Blood cultures positive for *Candida parapsilosis;* treated with micafungin
	Day 160	Blood cultures positive for *Candida glabrata;* micafungin escalated to amphotericin B
	Day 167	Transthoracic echocardiogram demonstrates new tricuspid valve vegetations and Protek Duo-associated vegetations
		Protek Duo cannula removed, VV-ECMO reconfigured
	Day 171	Transthoracic echocardiogram demonstrates persistent tricuspid valve vegetation
	Day 173	Inari FlowTriever used to debulk tricuspid valve vegetation
	Day 174	Blood cultures positive for *Pseudomonas aeruginosa;* treated with amikacin
	Day 181	Negative blood cultures
	Day 193	Decannulated from VV-ECMO
	Day 213	Discharged home
	Day 217	Re-presented to our institution with dyspnea and hypercapnic respiratory failure
	Day 221	Intubated and mechanically ventilated
	Day 223	Tracheostomy placed, continued ventilator weaning
	Day 233	Patient discharged home with tracheostomy in place

VV-ECMO: Venovenous ECMO; CT: computed tomography; PTE: pulmonary thromboembolism; FiO2: fraction of inspired oxygen;

Introduction:

The coronavirus disease 2019 (COVID-19) pandemic has profoundly affected the United States healthcare system. Based on a 2021 analysis of data from the U.S. National COVID Cohort Collaborative, 20.2% of adults hospitalized for COVID-19 experienced a severe clinical course involving either invasive ventilatory support, extracorporeal membrane oxygenation (ECMO), or death.[1] Of those 6,565 severe cases, 2,790 (42.5%) required invasive ventilatory support or ECMO. We present two patients with similar hospital courses: both patients were not fully vaccinated and developed COVID-19 acute respiratory distress syndrome (ARDS) requiring mechanical ventilation and venovenous ECMO (VV-ECMO) initiation. Each patient then had right ventricular failure requiring reconfiguration to a ProtekDuo right ventricular support system (LivaNova, London). Both patients developed tricuspid valve vegetations and underwent percutaneous debulking with the FlowTriever system (Inari Medical, Irvine, CA).

CASE 1

A 48-year-old female with obesity and anxiety presented to the emergency department with worsening shortness of breath. She was discharged one month earlier, after a hospitalization for COVID-19 ARDS and right ventricular failure requiring four months of VV-ECMO via ProtekDuo configuration. Her hospitalization was complicated by a pneumothorax, candidemia, a right femoral deep vein thrombosis, and chronic hypoxic respiratory failure requiring three liters of home oxygen at discharge. She had received one dose of the mRNA COVID-19 vaccine series. The patient reported worsening exertional dyspnea for three days prior to presentation, which prompted her return. On presentation, she was tachycardic, tachypneic, and her oxygen saturation levels were below 80% despite five liters of supplemental oxygen via nasal cannula. Initial laboratory values returned with a lactic acid of 1.1 mMol/L, creatinine of 1.2 mg/dL, white cell count of 53.0 x 10^9 cells/L, venous blood pH of 7.1, and venous blood CO_2 of 76.6

mmHg. A computed tomographic pulmonary angiogram demonstrated a new occlusive pulmonary thromboembolism (PTE) in the right main pulmonary artery (Figure 1). A bedside transthoracic echocardiogram demonstrated mild dilation of her right ventricle and masses in the right atrium and on the tricuspid valve, believed to be a thrombus-in-transit. She was started on a heparin infusion and admitted to the cardiac critical care unit. She was administered vancomycin, cefepime, and micafungin.

Given the large amount of thrombus, and the patient's respiratory failure, mechanical thrombectomy of her PTE with the FlowTriever system was performed under fluoroscopic and transesophageal echocardiographic guidance. The same system was used to first debulk the right atrial and tricuspid valve masses (Figure 2, Video 1), followed by the removal of a large quantity of embolic material from the right pulmonary artery. Multiple tan-brown fragments were retrieved from the tricuspid valve, in aggregate measuring 6.4 x 5.5 x 0.5 cm. Pathology of the fragments demonstrated filamentous organisms suggestive of fungal endocarditis (Figures 3-4). Her blood cultures, drawn on admission, returned positive for *Candida albicans*. The following night, the patient became unresponsive and hypotensive requiring intubation and the addition of three vasopressors. Repeat transthoracic echocardiogram demonstrated normal right and left ventricular systolic function without vegetation or thrombus. She was continued on the heparin infusion to clear the remaining clot burden, and her hemodynamics gradually improved without additional interventions. She required tracheostomy placement for chronic respiratory failure 12 days following re-presentation to the hospital and was transferred to the ventilator weaning unit. She was decannulated from her tracheostomy 248 days following her original presentation and was discharged to a rehabilitation facility one week later, requiring one liter of supplemental oxygen. She required two months of inpatient rehabilitation and subsequently underwent a tricuspid valve replacement. She continues to follow with our cardiothoracic surgery clinic.

CASE 2

A 39-year-old male with obesity and no other past medical history presented with symptoms of COVID-19 after a recent exposure. He was unvaccinated. He was tachycardic, tachypneic, and required four liters via nasal cannula to maintain an oxygen saturation of 95%. Subsequent COVID-19 polymerase chain reaction test was positive, and he was admitted to an acute care bed for acute hypoxemic respiratory failure and was treated with dexamethasone and remdesivir. His respiratory status continued to worsen, and he was eventually transferred to the intensive care unit and intubated. Despite continued supportive care, he progressed to severe ARDS and was subsequently cannulated for VV-ECMO via a right femoral vein to right internal jugular configuration. His ECMO course was further complicated by ventilator-associated *Pseudomonas aeruginosa* pneumonia, pneumothorax, acute kidney failure requiring dialysis, and atrial fibrillation with a rapid ventricular response requiring mechanical cardioversion. On ECMO day 35, he developed progressive shock and was diagnosed with right ventricular failure, for which he was reconfigured to a ProtekDuo cannula for additional support. On ECMO day 124, a transthoracic echocardiogram was performed due to *Candida glabrata* and *Candida parapsilosis* fungemia, demonstrating new vegetations on the tricuspid valve and the ProtekDuo cannula. The largest vegetation measured 1.4 x 1.1 cm (Figure 5, Video 2). An area of non-mobile thickening was also noted on the right atrial wall, adjacent to the tricuspid valve, measuring 2.1 x 1.3 cm. Also present was moderate to severe tricuspid regurgitation and a flattened interventricular septum consistent with right ventricular pressure overload. The right ventricle was severely dilated with preserved systolic function, and the left ventricular ejection fraction was 55-60%.

His endocarditis was presumed to be catheter-associated, therefore the ProtekDuo cannula was removed and his ECMO cannulation strategy was reconfigured to a right femoral

vein to left internal jugular approach. On ECMO day 141, the tricuspid valve and right atrial vegetations were aspirated with the Inari FlowTriever system under transesophageal echocardiographic and fluoroscopic guidance. A large vegetation was present above the posterior leaflet of the tricuspid valve, comprised of two mobile components with a central portion adherent to the posterior right atrial wall. Multiple tan-gray specimens were retrieved, aggregating to 3.0 x 2.8 x 0.5 cm. Pathologic examination demonstrated infective endocarditis with bacterial colonies consistent with *Pseudomonas aeruginosa* bacilli (Figure 6). Blood cultures drawn the following day were positive for multi-drug resistant *Pseudomonas aeruginosa*.

On transesophageal echocardiogram, the post-procedure tricuspid regurgitation remained severe but had improved compared to pre-procedure. Repeat blood cultures four days post-debulking demonstrated no growth and remained clear thereafter. The patient was gradually weaned from mechanical ventilation and was decannulated from VV-ECMO on hospitalization day 193. He was discharged home on hospitalization day 213, however he returned four days later with worsening hypoxemia and hypercapnia due to volume overload from an inadequate oral diuretic regimen. He required re-intubation followed by tracheostomy placement for chronic respiratory failure. He was eventually weaned to a tracheal collar and discharged home with a continued need for respiratory support via tracheal collar and portable ventilator. He continues to follow with our outpatient pulmonary clinic and is no longer tracheostomy dependent.

Discussion

We present two cases, one incompletely vaccinated patient and one unvaccinated patient, hospitalized with severe COVID-19 pneumonia requiring VV-ECMO and ProtekDuo cannulation who subsequently developed tricuspid valve vegetations, removed with the Inari FlowTriever system. We would like to highlight three main points that arise from these cases.

First, we observed an increased risk of right-sided endocarditis secondary to nosocomial bloodstream infections as a likely consequence of VV-ECMO and ProtekDuo support, although there is insufficient data to support this association currently. Our cases also propose a potential utility in percutaneous debulking of right-sided vegetations, specifically using the Inari FlowTriever, as a means of source control for endocarditis and bacteremia in poor surgical candidates. Lastly, we question whether there a significant benefit of long-term ECMO with right ventricular support in cases of acute respiratory distress syndrome (ARDS) caused by COVID-19.

The ProtekDuo is a dual lumen catheter inserted into the internal jugular vein that drains from the right atrium into the pulmonary artery, bypassing the right ventricle. This form of support is particularly useful in cases of right ventricular dysfunction. The addition of a membrane oxygenator also allows the device to function in a VV-ECMO capacity. Potential disadvantages of the ProtekDuo include greater technical expertise for its utilization, as well as indwelling device-associated infection. The most common microbes among ECMO-associated bloodstream infections are coagulase negative *Staphylococcal* species followed by the *Candida* species, *Enterococcus*, and *Pseudomonas*.[2] The incidence of *Candida* fungemia has been associated with prolonged intensive care unit stays, procedures, and broad-spectrum antibiotic use among others.[3,4] Right-sided native valve endocarditis, seen in both cases, makes up only 5-10% of endocarditis cases.[5] Of these, approximately 9% are related to intracardiac devices while over 10% are associated with intravenous drug use.[6] We were unable to find data describing the incidence of VV-ECMO or ProtekDuo-associated bloodstream infection or endocarditis. Nonetheless, these cannulas were likely the cause of the bloodstream infections and tricuspid endocarditis in our patients, especially given that the ProtekDuo has direct contact with the tricuspid valve.

In cases of right-sided native valve infective endocarditis where medical management alone is insufficient or the valve is considerably damaged, guidelines recommend an operative approach via median sternotomy followed by either valvular repair or prosthetic replacement.[7] However, case reports have described successful percutaneous debulking of large valvular vegetations with the AngioVac system (AngioDynamics, Latham, NY), which was designed for the removal of intravascular thrombi and emboli.[8] Such an approach may decrease right heart strain and reduce the risk of pulmonary embolism, persistent bacteremia, and mortality.[9] The AngioVac system, however, utilizes extracorporeal circulation, requiring two venous access sites: one for the AngioVac cannula and a second for the reinfusion cannula. The FlowTriever system is a catheter-based device designed for the removal of PTE.[10] It requires one venous access site, introduced over a single guidewire, and does not require extracorporeal support (Figure 7). Both of our patients experienced resolution of persistent candidemia and bacteremia after tricuspid valvular debulking with the FlowTriever system. This device may show promise as a potentially safe and effective method of removing right-sided infective valvular vegetations, but data demonstrating its efficacy for this purpose are not available.

Despite the risks of VV-ECMO noted above, its implementation in severe COVID-19 disease is increasing. Thousands of adults hospitalized for COVID-19 have developed severe disease leading to invasive ventilatory support, ECMO, or death.[1] Though approximate numbers have not been reported, over 90% of COVID-19 ARDS cases requiring pulmonary support have employed VV-ECMO as opposed to venoarterial ECMO.[11] The 90-day mortality associated with VV-ECMO utilization in COVID-19 ARDS is between 39% and 55%, which is similar to pre-pandemic mortality rates of ECMO for ARDS.[11-13] We could not find randomized controlled trials demonstrating a mortality benefit with VV-ECMO in cases of COVID-19 ARDS, though the EOLIA trial demonstrated no short-term mortality benefit in viral ARDS treated with early VV-

ECMO compared to invasive mechanical ventilation with VV-ECMO as a rescue therapy.[14] An observational study reported improved mortality at six months among patients with COVID-19 ARDS compared to patients with viral ARDS treated with VV-ECMO.[15] However, the patients included in this study were on VV-ECMO for 8 to 30 days, which is considerably shorter than the duration of ECMO in our patients. Prolonged use of VV-ECMO may be complicated by bleeding, kidney injury, nosocomial bloodstream infections, and thromboembolic events, limiting its benefits.[16] There may be hesitancy among researchers toward designing trials for ECMO support in COVID-19 ARDS given ethical concerns.

In conclusion, we reported two patients with COVID-19 ARDS requiring invasive cardiopulmonary support, an increasingly common scenario. These cases are unique, however, in that both patients developed nosocomial bloodstream infections and tricuspid valve endocarditis, likely a result of the prolonged placement of the intravascular VV-ECMO cannulas and intracardiac ProtekDuo devices. The utilization of the minimally invasive FlowTriever system to debulk the tricuspid vegetations allowed for infectious source control in both patients while reducing their vegetation burdens. Further investigation is needed to examine the benefits of percutaneous debulking of valvular endocarditis with this device in patients who may be poor surgical candidates. At the time of the drafting of this manuscript, both patients have been discharged from the hospital requiring some degree of respiratory support and significant physical rehabilitation, therefore the question of whether prolonged ECMO support provides a mortality benefit in severe COVID-19 ARDS remains to be answered.

Patient Consent Statement

The authors confirm that written consent for submission and publication of this case series, including images and associated text, have been obtained from each patient in line with COPE guidance.

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Figure Legends

Figure 1: Computed tomographic pulmonary angiogram demonstrating an occlusive thromboembolism in the right pulmonary artery (RPA) in patient 1.

Figure 2: Mid-esophageal four-chamber view on transesophageal echocardiography demonstrating mobile tricuspid valve vegetation. RA = Right atrium; RV = Right ventricle; TV = tricuspid valve

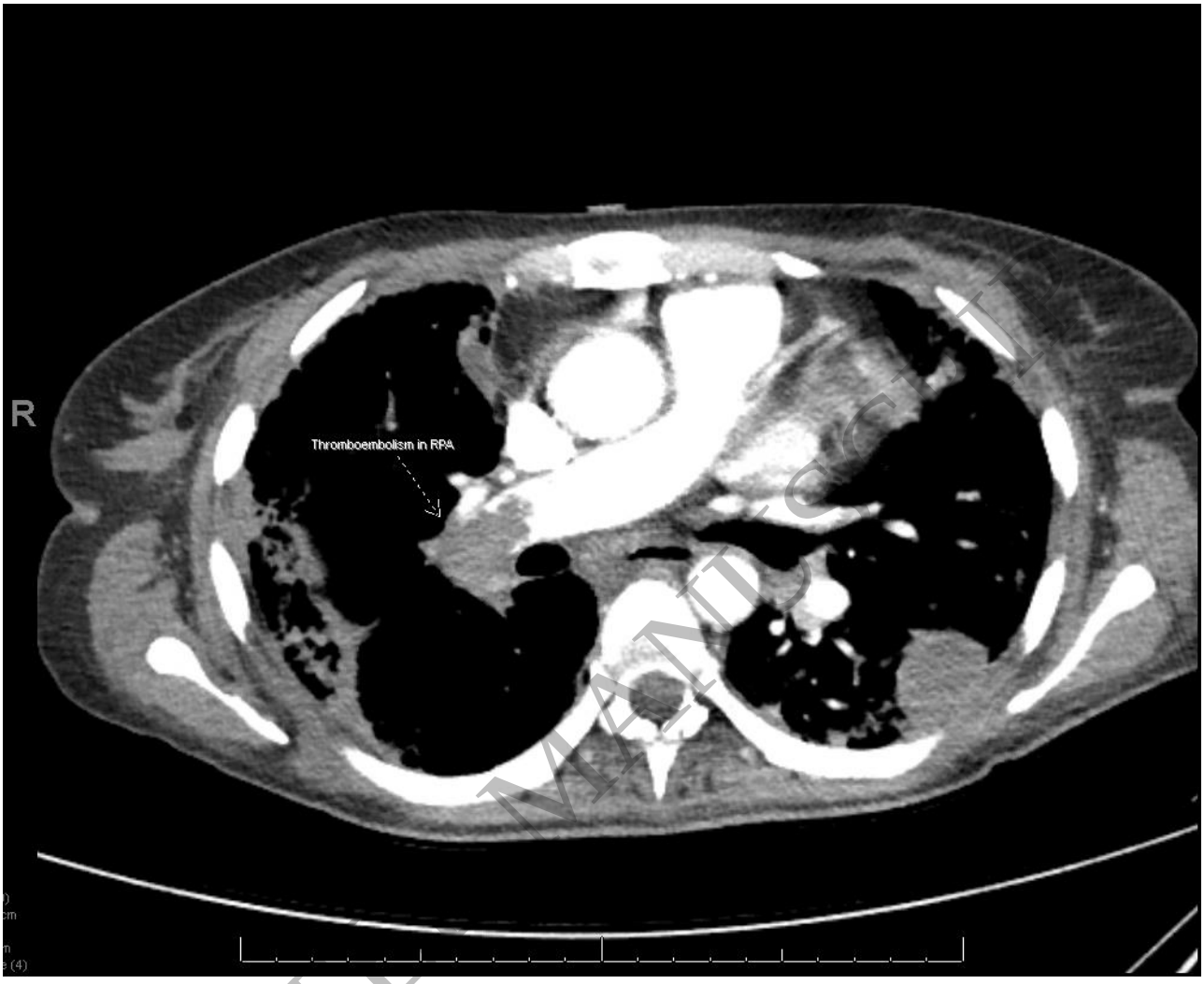
Figure 3: Hematoxylin & eosin (H&E) stain of tricuspid valve vegetation specimen from patient 1 indicative of fungal endocarditis. Arrow = fibrin; Circle = acute inflammation; Triangle = fungal colonies consistent with *Candida albicans.*

Figure 4: Grocott methenamine silver (GMS) stain of the tricuspid valve vegetation specimen from patient 1 demonstrating fungal organisms consistent with *Candida albicans* pseudohyphae. Arrow = fungal organism.

Figure 5: Subcostal four-chamber view on transthoracic echocardiogram demonstrating tricuspid valve vegetation. RA = right atrium; RV = right ventricle; TV = tricuspid valve; LA = left atrium; LV = left ventricle

Figure 6: Hematoxylin & eosin (H&E) stain of tricuspid valve vegetation specimen from patient 2. Arrow = fibrin; Circle = acute inflammation; Triangle = bacterial bacilli colonies consistent with *Pseudomonas aeruginosa.*

Figure 7: The Inari Medical FlowTriever system, comprised of a vascular introducer (A), a large-bore syringe for aspiration (B), a single trackable catheter (C), and Nitinol mesh discs at the terminal end (D) to directly engage the clot or vegetation. Permission was obtained from Inari Medical for the reproduction of the schematic image of the FlowTriever® System for publication in this manuscript. Inari Medical retains the copyright to the above image per USC Title 17.



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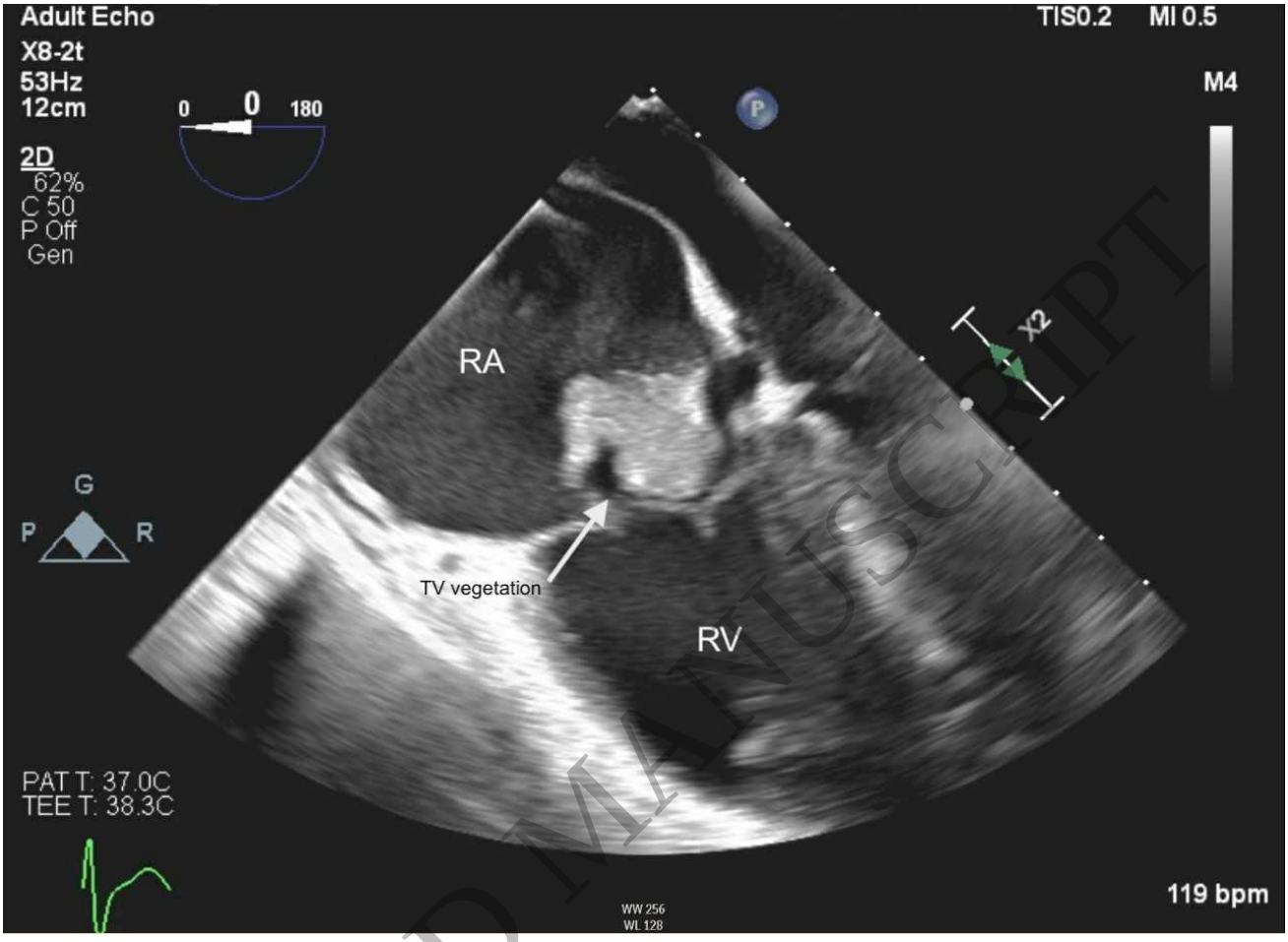

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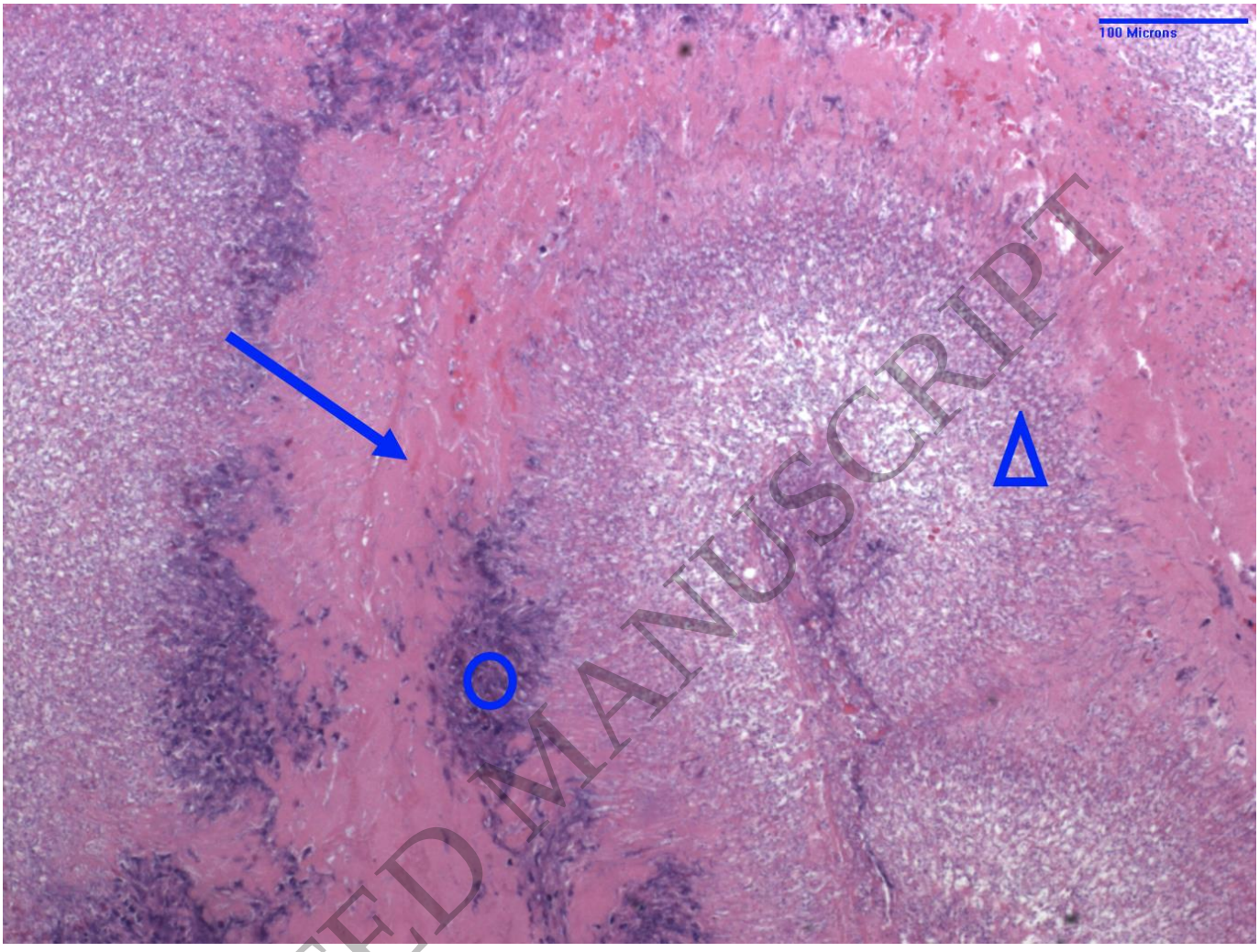

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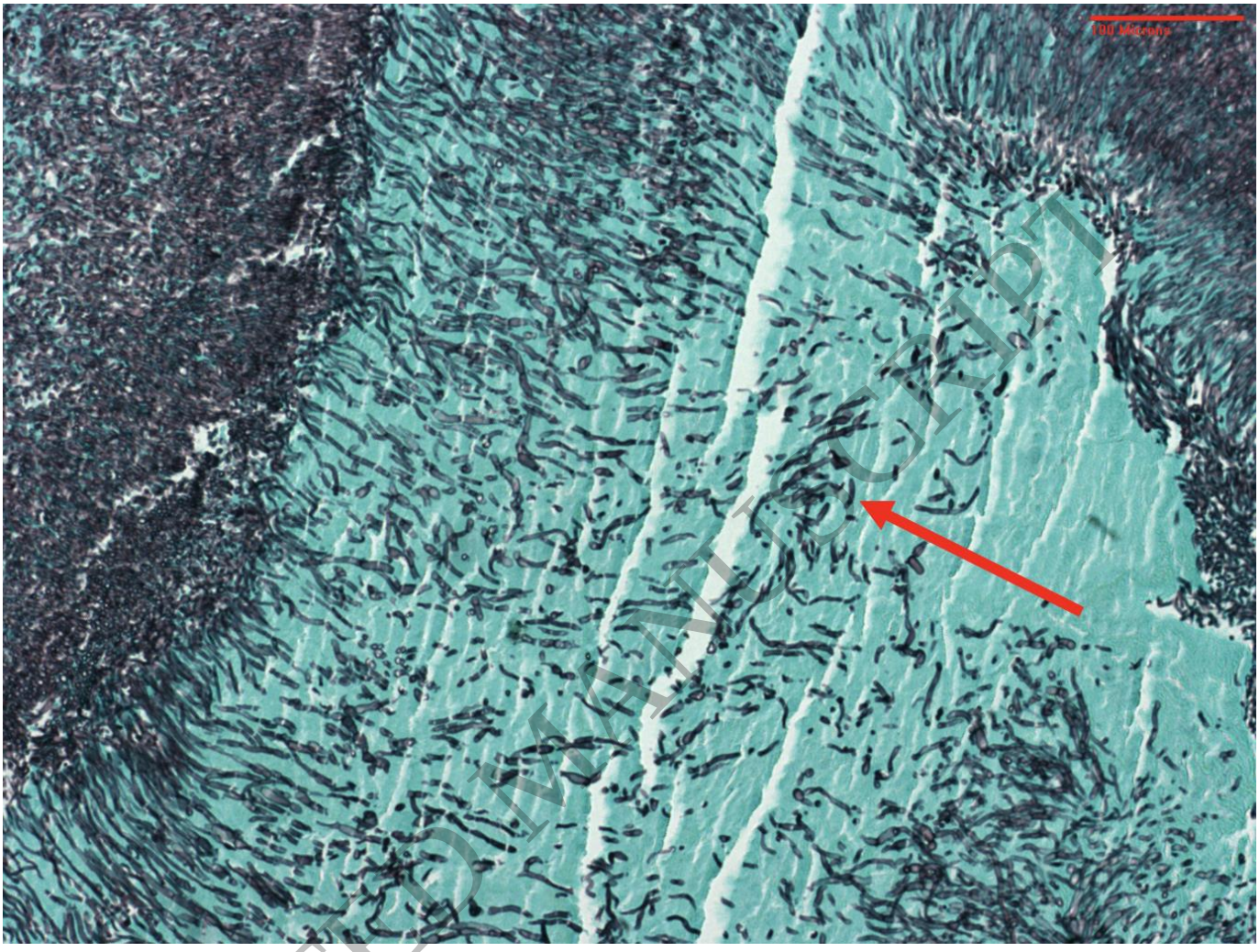

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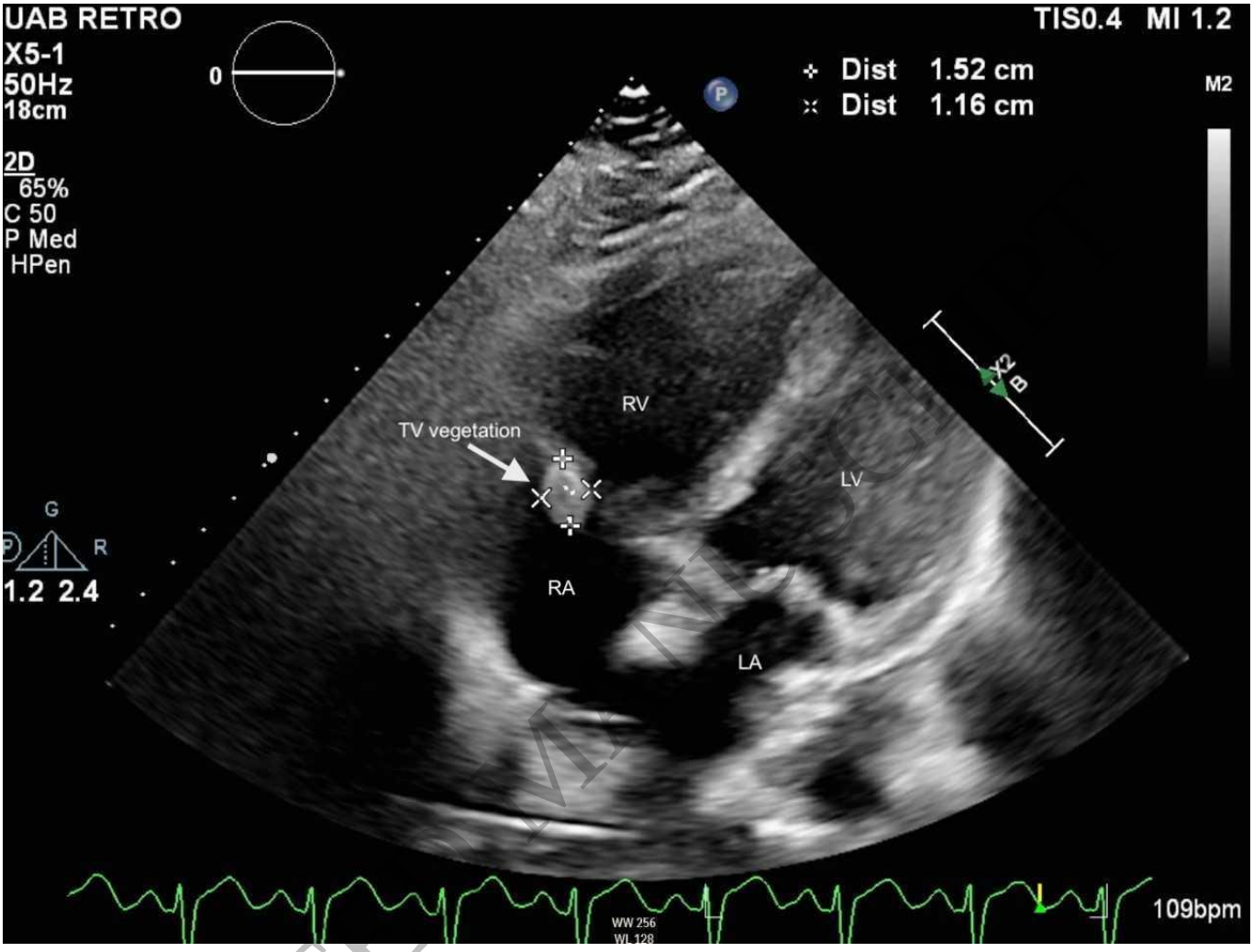

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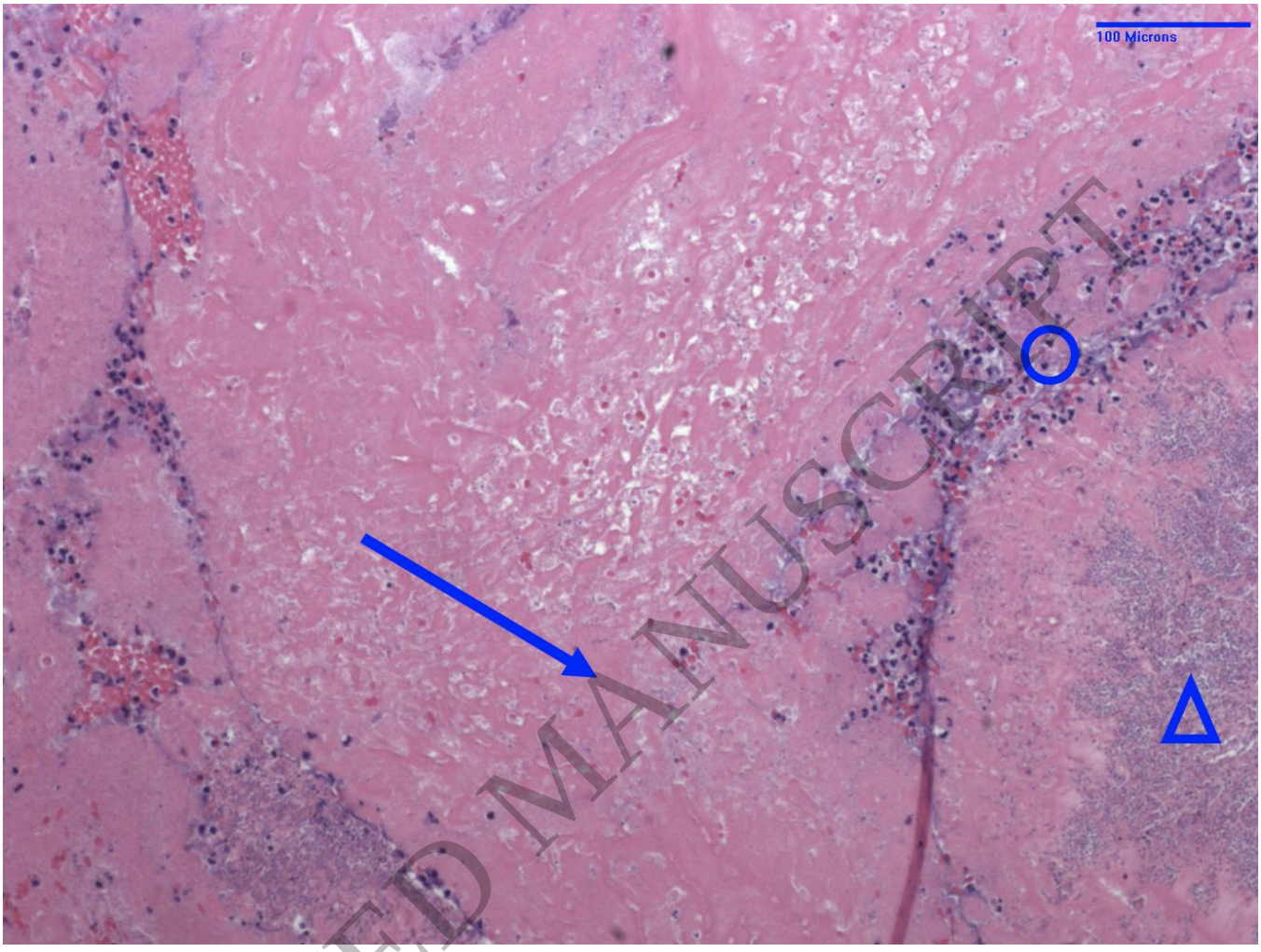

Figure 6

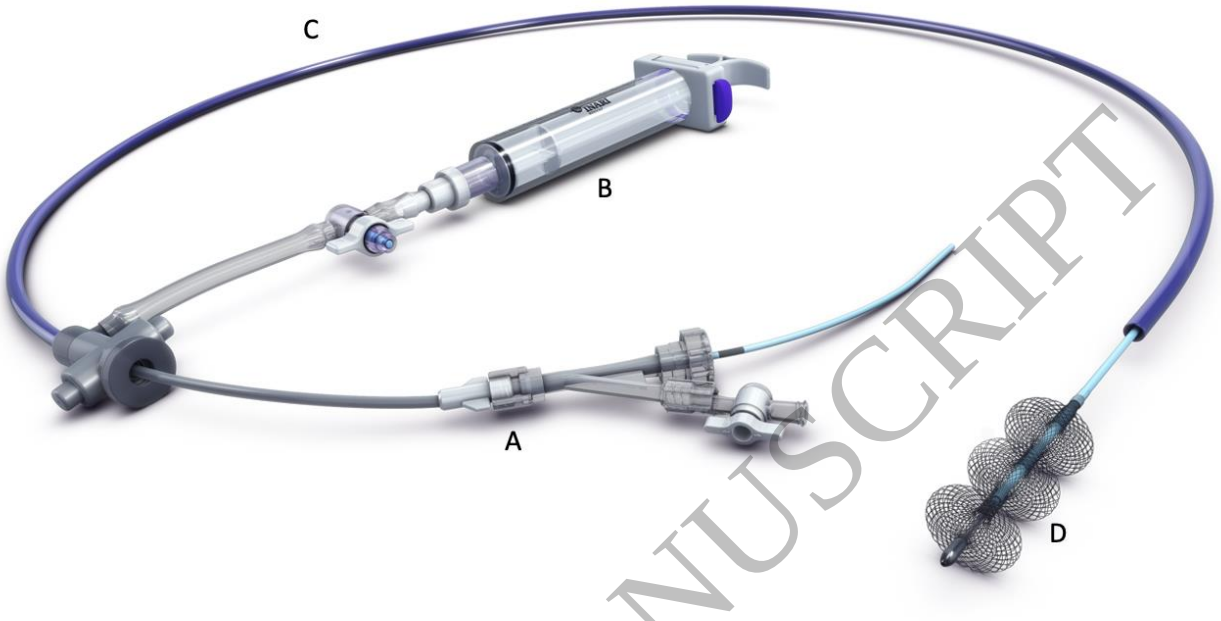

Figure 7