

Registry of AngioVac Procedures in Detail: The RAPID Registry

An overview of the largest prospective multicenter data set on the use, efficacy, and safety of the AngioVac system for removal of intravascular thrombi and right heart masses.

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Over the last few years, there is likely no area of vascular medicine more open to innovation and improvement in devices than venous thrombectomy. The goal of large-volume removal of intravascular thrombi or vegetative masses is to decrease the risk of pulmonary embolism, alleviate symptoms, and remove sources of infection. Several treatment strategies and device platforms exist but with a limited evidence base for efficacy and safety. The purpose of the RAPID registry was to collect information on the AngioVac system (AngioDynamics, Inc.; Figure 1) used in the removal of intravascular materials from the venous system. The RAPID registry prospectively collected data for 234 patients undergoing AngioVac procedures at 21 sites between March 2016 to August 2019. The registry included private practice, large academic centers, and large and small community hospitals with a diverse mix of practitioners such as cardiologists, electrophysiology cardiologists, cardiac surgeons, vascular surgeons, and interventional radiologists.

THE RAPID REGISTRY

Objective and Patient Population

The primary objective of the RAPID registry was to evaluate patterns of use and effectiveness and safety data with the use of the AngioVac system for various anatomic locations. The registry captured immediate functional and clinical outcome data for all patients who had the AngioVac cannula deployed into their venous system. A total of 234 patients were enrolled in the registry over a 3-year period, with an initial goal

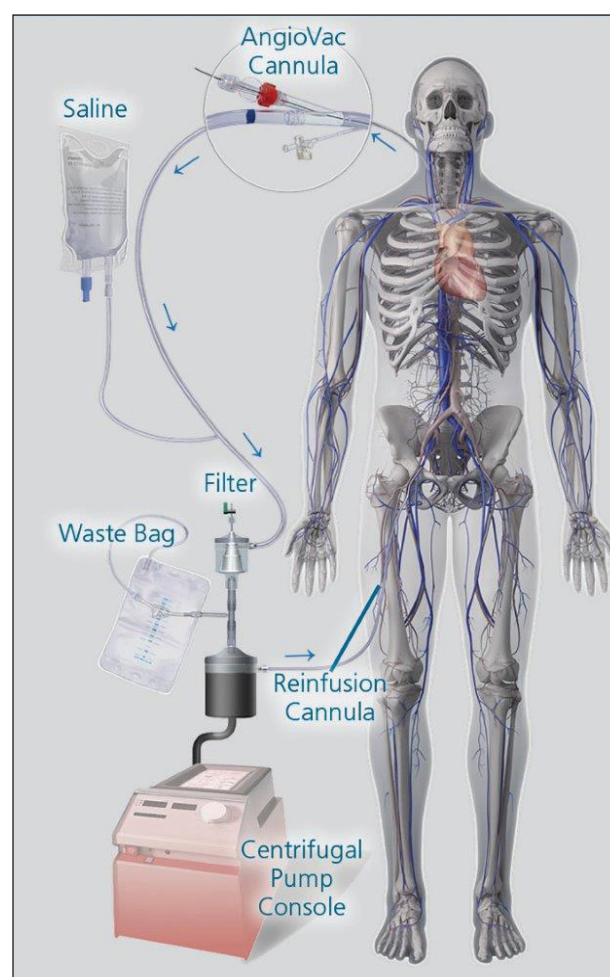


Figure 1. The AngioVac system.

of 200 patients. The registry had three main groups of patients; 113 were right heart mass patients, which included either thrombus or vegetation within the right atrium and to a much lesser extent within the right ventricle. The second largest group was the caval thrombectomy group with 84 patients, and the third group was catheter-associated thrombus with 20 patients. Also, five patients had pulmonary emboli* and 13 patients had a combination of the above procedures. The patient profile matched that of the United States as a whole and approximated the standard patient with venous thromboembolism. Mean age was 50 years, and patients had mean body mass index of 31 kg/m². About two-thirds of the patients had cancer or recent surgery.

Results

The registry had an efficacy threshold goal of removing over 70% of the clot. Efficacy was demonstrated in the majority of patients. Greater than 70% of clot/mass removal was achieved in 73.6% of caval thrombi, 58.5% of right heart mass, and 60% of catheter-related thrombi cases. Extracorporeal bypass time was < 1 hour for 176 (75.2%) procedures, with estimated blood loss of < 250 mL for 179 procedures (76.5%). The registry also reported 36 (13.2%) procedure-related adverse events, which included trauma to the cannula site, major or minor hemorrhage, distal embolization, arrhythmias, and cardiovascular perforations. There were three deaths reported, with one being procedure-related (secondary to massive pulmonary embolism).¹

SUMMARY

Overall, the RAPID registry validated the safety and efficacy of the AngioVac system for removing right heart mass, thrombi, catheter-related thrombi, and caval thrombi. The RAPID registry also demonstrated the versatility of the AngioVac system relative to treating patients with various clinical conditions, including caval thrombosis and right heart mass. Data collected

in this study may also be used to advance standards of care and facilitate the design of larger prospective studies. Further analysis of the RAPID registry data focusing on differing indications for use of the device and additional larger clinical trials will be performed to provide further evidence supporting the role of the AngioVac system in clinical practice. ■

1. Moriarty JM, et al. Endovascular removal of thrombus and right heart masses using the AngioVac system. Results of 234 patients from the prospective multicenter registry of AngioVac procedures in detail (RAPID). J Vasc Interv Radiol. Accepted for publication.

Results from the RAPID study were presented by Dr. John Moriarty at VIVA 2020, the Vascular Interventional Advances meeting.

All procedures in the RAPID database were performed with the Generation 2 cannula system.

*Indication for Use (AngioVac Cannula Generation 2): The AngioVac Cannula is indicated for use as a venous drainage cannula and for removal of fresh, soft thrombi or emboli during extracorporeal bypass for up to 6 hours.

Indications for Use (AngioVac Cannula Generation 2): The AngioVac Circuit is indicated for use in procedures requiring extracorporeal circulatory support for periods of up to six hours.

Refer to Directions for Use provided with the product for complete Instructions, Warnings, Precautions, Possible Adverse Effects and Contraindications. Observe all instructions for use prior to use. Failure to do so may result in patient complications.

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

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