Novel device for catheter directed thrombolysis and concurrent hemodynamic monitoring in the pulmonary arteries

Osman Ahmed MD[1] , Jonathan Paul, MD[2]

[1]Department of Radiology, Section of Vascular and Interventional Radiology, University of Chicago, Chicago, IL, USA; [2]Department of Medicine, Section of Interventional Cardiology, University of Chicago Medical Center, Chicago, IL, USA

Introduction

- Nearly 1 million patients a year suffer from venous thromboembolism (VTE) in the United States alone
- VTE is a spectrum of disease that includes both deep vein thrombosis (DVT) and pulmonary embolism (PE)
- PE is the at the latter end of the spectrum that can result in severe morbidity or mortality
- Catheter directed thrombolysis (CDT) is an endovascular method to infuse a low dose thrombolytic agent directly into the thrombus over time
- Current methods for CDT are limited by the necessity for multiple devices to navigate to the clot, small bore size of the infusion catheter, and undefined endpoints for lytic termination

Purpose

- Purpose: To evaluate the safety and feasibility of delivering a novel device capable of catheter directed thrombolysis (CDT) and concurrent hemodynamic monitoring in a porcine model.

Methods

Flow Medical is a start-up medical device company created through the University of Chicago Polsky Center for Entrepreneurship and Innovation by Drs. Jonathan Paul and Osman Ahmed. The company is in current development of a novel device capable of CDT and concurrent hemodynamic monitoring.

Design: An IACUC approved pilot study was conducted in two mixed breed pigs. Following intubation and general anesthesia, in each animal a novel device (Flow Medical; Chicago, IL) containing a multi-sidehole self-expanding and adjustable-length nitinol cage was placed in the right, left, and main pulmonary arteries. Functionality of proximal and distal hemodynamic monitoring ports integrated into the device were also assessed.

Interventional Technique: Micropuncture access was used to gain right common femoral venous access using modified Seldinger technique. A 10 Fr sheath was placed into the common femoral vein. The main, left, and right pulmonary arteries were selected with a JR-4 angiographic catheter following contrast injection. Over a stiff Amplatz guidewire, the novel device was advanced. The nitinol cage was exposed using a standard “pin-pull” technique. An anesthetist was present to monitor for any abnormal cardiac arrhythmias or hemodynamic changes. Fluid filled tubing was used at the end ports of the device to capture distal and proximal hemodynamic pressures within the pulmonary arteries.

Outcome assessment and definitions: Technical success was defined as the ability to place the device into the pulmonary artery over a .035” guidewire, expand its cage, and measure pulmonary arterial pressures. Procedure related complications including persistent cardiac arrhythmia, vessel perforation, and/or mortality were assessed.

Results

- Study objectives were technically successful in both animals. No procedure related complications occurred, with no arrythmia or hemodynamic changes noted. No radiographic evidence of vessel damage or hemorrhage was observed. Necropsy was NOT performed.
- In both animals, heparinized saline was successfully hand injected through the infusion ports without resistance. A distal and proximal (i.e. 15cm proximal to the distal tip) pulmonary arterial pressure was recorded in 1 animal. In the second animal, only a distal pressure could be obtained.

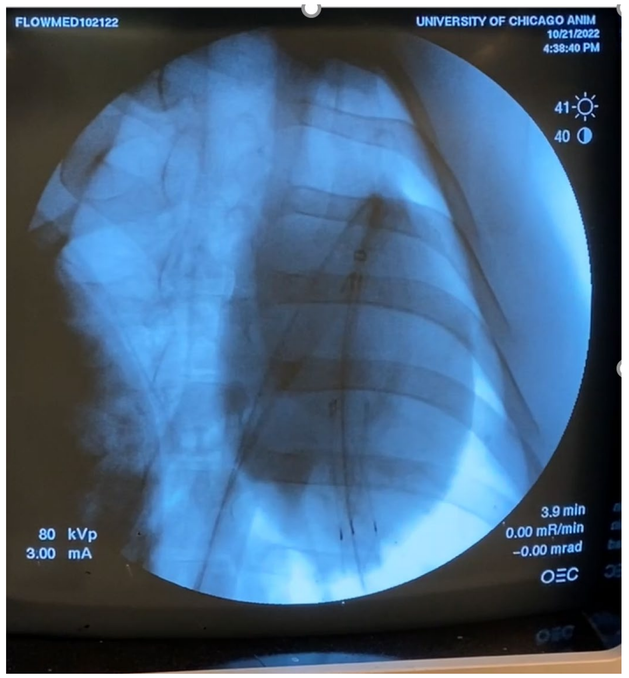

Figure 1. Device deployment in the left pulmonary artery

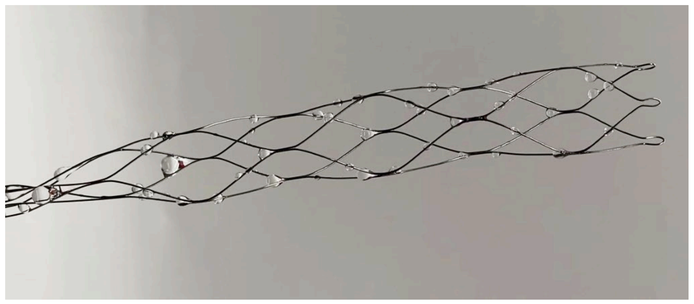

Figure 2. Adjustable, self-expanding nitinol cage to increase radial disperion of infused agents within the pulmonary arteries

Figure 3. On-table device handling and insertion

- Technical notes:
- The catheter was a 9 Fr design
- No “watermelon seeding” occurred during unsheathing of the nitinol cage
- The device was sheathed and re-sheathed without difficulty in the pulmonary arteries
- The device was removed unsheathed through the heart without any complication

Conclusions

- A novel device for concurrent catheter directed thrombolysis and hemodynamic monitoring in the pulmonary arteries was technically feasible and safe in this pilot porcine study. Future studies to establish safety and efficacy of this device are underway.