INTRODUCTION

Project Description

- Pulmonary embolism is the blockage of a pulmonary artery by a clot, resulting in loss of blood flow to the lungs.
- There are 600,000 cases annually resulting in nearly 60,000 fatalities\(^4\).
- First line treatment methods include medicine to break up clots, which can result in dangerous hemorrhaging.
- Pooled clinical success rate from catheter therapy is 86.5\%\(^2\).
- Advisor proposed the design of an improved catheter for quick and effective pulmonary embolism removal, which will have an even higher success rate.

Experimental Goals

The overall goal of the project is to design a catheter that can remove pulmonary embolisms safely and effectively.
- To research and evaluate current technology in embolism extraction.
- To synthesize a design that can be used percutaneously and safely.
- To produce a prototype of this design for demonstration purposes.

Experimental Hypothesis

A catheter-based solution for pulmonary embolism extraction using local thrombolytics and a clot trapping basket is feasible and will lead to reduced treatment times and better outcomes for patients with acute pulmonary embolisms in the first or second branches of pulmonary artery.

EXISTING METHODS

Current Treatments

Medications:
- Antiocoagulants (Heparins or Coumarins) - Prevent formation of new clots by inhibiting thrombin; Risk of bleeding and bruising\(^3\).
- Clot Dissolvers (Thrombolytics) – Aid in dissolution of clots by converting plasminogen to plasmin; 20% risk of sudden and severe bleeding\(^1\).

Surgical Options:
- Vein Filter – Filter placed in inferior vena cava prevents clots from reaching lungs\(^1\).
- Catheter Directed Therapy – Inserted into pulmonary artery; Used to manually break up and/or remove clot\(^3\); Existing devices not approved for this application\(^3\).
- Embolectomy – Surgical removal of the clot with forceps; High mortality and recurrence rates\(^3\).

DESIGN

Procedure Specifications

- The PE is located by an interventional radiologist using x-ray angiography.
- The guide wire is sent up through the femoral vein to the pulmonary artery containing the thrombus or clot.
- The device is then threaded along the guide wire past the thrombus.
- The “basket” is extended to the sides of the vessel wall.
- Tissue plasminogen activator (rtPA) is injected locally at 20mg/h to dissolve the thrombus.
- The Surgical coating on the “basket” attracts small pieces of the clot while the rest of the basket traps the larger pieces.
- Once the clot has been captured, the entire device is removed from the system along with thrombus.

Our Prototype

Figure 1. Catheter device with basket fully expanded and silicone sheath pulled back.

Figure 2. Catheter fully expanded with rtPA (black circles) eluding from the device.

Figure 3. Cross sectional view of catheter basket.

- Device is 2 meters in length and encased in biocompatible silicone tubing with a maximum diameter of 6 French.
- Stainless steel guide wire with a diameter of 0.75mm.
- Basket composed of six flexible titanium pieces that can be extended up to 15mm in diameter to act as a basket to trap the thrombus.
- rtPA is administered at 20mg/h from a syringe attached to distal end of device.

SOLUTION

Safety Considerations

- The use of thrombolytics, although traditionally well-tolerated, can have adverse effects in people prone to bleeding.
- The local elution should help reduce or eliminate these issues.
- Stress on the vessel wall from the basket’s pressure is mitigated by the use of multiple prongs as well as a double-sided design that reduces sharp edges.
- There should be little to no hemolysis, which reduces the risk of bradycardia and heart failure.
- Multiple backups increase the safety and effectiveness of this device.

Market Considerations and Benefits

- Easy to manufacture
- Inexpensive
- Raw material cost less than $50.00
- Disposable
- No large drive unit required
- Combines best features from current devices
- Increased patient safety
  - Biocompatibility of all materials used
  - Decreased procedure time
- Back-up protection not found in other devices
- Class III Device
- Requires PMA

References


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