Heart Valve Docking System with Precision Positioning and Variable Sizing (#8408)

Increases eligibility for placement of transcatheter heart valves for up to 80% of patients with tricuspid regurgitation

This innovative anchoring stent is designed to enable treatment of functional tricuspid regurgitation (TR) in a larger patient population. Currently, size constraints prevent the use of transcatheter heart valves (THVs) in patients with tricuspid regurgitation in the native position, while heterotopic valve implantation can be performed in only 25% of patients. Using this anchoring stent, 80% of patients with TR would be eligible for treatment.

Developed by researchers at Georgia Tech, this technology includes a docking conduit—that is, a spacing stent with its distal and proximal sections joined through connecting beams. A stented anchoring conduit is used to secure a THV to the junction of the inferior vena cava (IVC) and/or superior vena cava (SVC) to the right atrium to reduce systemic pressure due to TR.

The distal end has an inner lumen design that conforms to the anchoring surfaces of a THV, in addition to radially extending petals that anchor elements to the vascular junction. The proximal and distal ends have different expansion diameters and/or radial expansion forces designed to enable them to conform to the venous wall of the SVC or IVC.

Benefits/Advantages

- **Versatile**: Enables the THV to function in up to 80% of patients while reducing the current risks of complications, such as embolization
- **Precise**: Allows a THV to be delivered, positioned, and docked at the junction of the IVC and/or SVC and at the right atrium junction
- **Secure in most any size junction**: Compensates for most size differences between the landing site and the size of the THV itself to allow for secure anchoring without the need to create a larger THV
- **Effective**: Reduces the chance of back flow of blood through the tricuspid valve into the venous system, diminishing peripheral and abdominal edema (bloating and pain) and hepatic congestion

Potential Commercial Applications

This technology has the potential to be used in the treatment of:

- Tricuspid regurgitation

- Mitral regurgitation

Background/Context for This Invention

Tricuspid regurgitation—which can cause fatigue, decreased exercise tolerance, ascites, liver congestion (hepatopathy), peripheral edema, abdominal fullness, and atrial fibrillation—is vastly undertreated. The tricuspid is the largest valve in the heart and has the most asymmetrical geometry, which makes placement of endovascular medical devices difficult.

Because of the technical challenges in the treatment of TR, only 25% of patients diagnosed with it in the heterotopic position are able to be treated with the standard approach. Presently, patients with TR in the native position cannot be treated. Current treatment consists of THV deployment in the junction of the IVC, SVC, or both and at the right atrium.

A problem lies in that most THVs only reach a maximum diameter of 29 mm, while the internal diameter near the IVC junction can vary in size from 11 to 40 mm. Undersizing the THV results in a potential migration that can occlude the hepatic veins or cause embolization into the right atrium. Creating a larger THV implies larger leaflets, increasing the potential for thrombosis in low-flow areas such as the IVC, so these patients would need to permanently take anti-coagulation drugs. Additionally, the variable distance (5 mm to 5 cm) between the junction and the hepatic veins further complicates deployment of currently available valves, increasing the risk of embolization into the atrium or the risk of hepatic vein obstruction.

Georgia Tech’s new technology is designed to expand THV treatment to a much larger group of patients.

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More Information

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Publications

Delivery steps for anchoring conduit and THV in the IVC-RA Junction: (A) delivery sheath is used for endovascular access in order to deliver devices to IVC-RA junction; (B) anchoring conduit is delivered and expanded into the junction; (C) a second delivery sheath is used to position the THV; D) THV is expanded into the distal section of the anchoring conduit.

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(A) Stented anchoring conduit in its expanded state, (B) anchoring conduit partially compressed within a delivery sheath, and (C) anchoring conduit with cloth/membrane on distal section

For more information about this technology, please visit:
https://licensing.research.gatech.edu/technology/heart-valve-docking-system-precision-positioning-and-variable-sizing