Verso:
Transcaval Docking Technology for Tricuspid Valves

EXECUTIVE SUMMARY

TEAM

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FUNDING
$59K GRA
$158K Biolocity Grant

INTELLECTUAL PROPERTY
US patent Issued

Technology available for licensing and partnership

STATUS
Prototype Development

SUMMARY

Verso, is a proprietary trans-caval docking platform technology, which enables millions of patients with "non-operable" isolated functional tricuspid valve regurgitation (FTR) be treated via a trans-catheter valve (THV) heterotopic approach. This unique Caval docking system provides a transferable technology solution for trans-catheter aortic heart valves to percutaneously treat FTR improving quality of life, survivability and reducing the frequency of hospital re-admissions and real cost savings.

TECHNOLOGY

The Caval Docking Technology allows a trans-catheter heart valve to be delivered, positioned and "docked" with precision at the junction of the IVC/SVC and RA to eliminate back flow of blood (regurgitation) through the TV reducing peripheral/abdominal edema, and hepatic congestion. The Verso technology eliminates the complexity of sizing and precise delivery of the THV, significantly reducing the learning curve for clinicians.

The inferior vena cava (IVC) internal diameter near the junction can vary in size from 11-40 mm (FTR patients on high end of range), thus sizing is a real procedural challenge for current trans-catheter heart valves as most reach a maximum diameter of 29mm. Therefore, valve diameter restricts access to 25% of inoperable tricuspid insufficiency patients using current valves. Creating a larger THV implies larger leaflets, increasing potential for thrombosis in low flow areas such as the IVC.
The Caval Dock will accommodate 29mm commercial valves into larger IVCs without creating potential for migration or leakage. Additionally, the distal end increases the axial length between the junction and hepatic veins. Finally, gaps in stent pattern will allow for hepatic flow without interference or obstruction. Using Coulter and GRA funds, first generation prototypes have been tested in vitro and in acute animal models.

The opportunity is compelling as our technology enables FDA/CE approved trans- catheter valve implantation to treat. The use of a docking system (Ease of deployment and increased tolerance for anatomical variability) expands the market for current THV technology from 25% to approximately 80% of the targeted population.

MARKET NEED

While tricuspid valve (TV) disease prevalence, disease progression and mortality are well known, it remains vastly undertreated. There are approximately 1.2 million functional Tricuspid Regurgitation (FTR) patients in the US alone, who represent a total available market (TAM) of > $1B. These patients are underserved by current technologies with only 5,000 patients treated annually. Clinical sequelae for patients are fatigue, decreased exercise tolerance, ascites, liver congestion, peripheral edema, abdominal fullness, and atrial fibrillation. In addition, heart failure patients with FTR have poor prognosis (death rate of 79%-64% at one year for patients with moderate or severe FTR respectively). Competitive technologies primarily try to address FTR at annular level (Annuloplasty) via an open surgery (significant residual FTR in 10-45% of patients post tricuspid repair). Some recent percutaneous techniques such as Millipede, 4-Tech Cardio, Forma, and Trialign have been developed, but have shown to be technically difficult to employ and have yielded an incomplete reduction of TR.

For more information on this technology email biolocity@gatech.edu or contact:
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