Device and Method for Protecting Against Coronary Artery Compression During Transcatheter Mitral Valve Annuloplasty

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Technology description

Summary

Catheter-based mitral valve regurgitation treatments that use a coronary sinus trajectory or coronary sinus implant can have unwanted effects because the coronary sinus and its branches have been found to cross the outer diameter of major coronary arteries in a majority of humans. As a result, pressure applied by any prosthetic device in the coronary sinus (such as tension on the annuloplasty device) can compress the underlying coronary artery and induce myocardial ischemia or infarction.
Available for licensing and commercial development are devices and methods that avoid constricting coronary artery branches during coronary sinus-based annuloplasty. These devices and methods protect coronary artery branches from constriction during trans-sinus mitral annuloplasty. The device protects a coronary vessel from compression during mitral annuloplasty in which an annuloplasty element, such as a tensioning device, extends at least partially through the coronary sinus over a coronary artery. The device is a surgically sterile bridge configured for placement within the coronary sinus at a location where the coronary sinus passes over a coronary artery, so that the protection device provides a support for a mitral annuloplasty element, such as a compressive prosthesis, including a tension element when it is placed under tension. The protection device has an arch of sufficient rigidity and dimensions to support the tensioning element over the coronary artery, redistribute tension away from an underlying coronary artery, and inhibit application of pressure to the underlying artery, for example when an annuloplasty tension element is placed under tension during mitral annuloplasty.
In particular, the protective device can be a support interposed in the coronary sinus between the annuloplasty device and the coronary artery. The device may be substantially tubular so that the tensioning element is contained within the protective device and supported in spaced relationship to the coronary artery. An arch may be configured to extend between a proximal end and a distal end that are substantially collinear with one another so that the ends form stabilizing members such as feet that retain the bridge in position over the coronary artery.
The device may be used in methods of improving the function of a mitral valve in a subject in which an annuloplasty element, for example an element that exerts compressive remodeling forces on the mitral

valve (such as a tensioning element), is introduced at least partially around the mitral valve, for example at least partially through the coronary sinus and over a coronary artery. The protective device is placed between the annuloplasty element and the coronary artery, with the annuloplasty element supported by the bridge of the device. Compressive remodeling forces are exerted by the annuloplasty device (for example by applying tension to alter the shape or configuration of the mitral valve annulus to reduce its circumference) while supporting the annuloplasty element on the bridge to inhibit application of pressure to the coronary artery. The function of the mitral valve in the patient is thereby improved without impairing coronary blood flow.

The annuloplasty element can be introduced at least partially around the mitral valve by advancing the annuloplasty element in an endovascular catheter through the vascular system to the heart and introducing the annuloplasty element and the protective device from the catheter into the coronary sinus through a coronary sinus ostium. In those embodiments in which the protective device includes an internal lumen, the annuloplasty element extends through the lumen of the protective device over the coronary artery so that the annuloplasty element is supported by the protective device. The protective device can be integrated directly into the annuloplasty element, such as a resilient or expandable device, or a tensioning element or tensioning material.

In other embodiments, this disclosure provides a method of improving function of a mitral valve in a subject who has mitral regurgitation by performing a mitral valve cerclage annuloplasty. In a particular disclosed example of the procedure, a guiding catheter is percutaneously inserted through the vasculature of a subject. The guiding catheter is introduced through the coronary sinus into the great cardiac vein, and a steerable microcatheter or other coaxial guiding catheter or steering device introduces a guidewire into a basal blood vessel such as the first septal coronary vein. From there the guidewire traverses under imaging guidance the septal myocardium or annulus fibrosis and reenters the right ventricle or right atrium. The guidewire is then retrieved using a vascular snare and the guiding catheter and guidewire are replaced with a tensioning system. The protective device is then introduced through the guiding catheter over or in tandem with the tensioning system so as to protect an underlying coronary artery when tension is introduced to perform the annuloplasty.

Application area

Cardiac valve repair
Interventional Cardiology
Cardiac Surgery

Institution

NIH - National Institutes of Health

联系我们

叶先生

电 话：021-65679356

手 机：13414935137

邮 箱：yeyingsheng@zf-ym.com