MitraClip Mitral Valve Repair System

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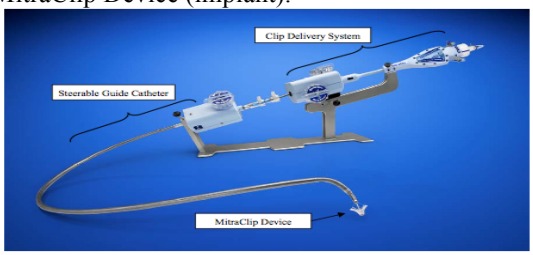
***Abstract*—Abbott Vascular has developed the MitraClip mitral valve repair system for the treatment of Mitral Regurgitation. This percutaneous system targets patients deemed high-risk for surgical complications.**

I.INTRODUCTION

Mitral Regurgitation (MR) occurs when the mitral valve fails to close tightly, due either to stretching or rupture of the chordae tendineae, or impacted valve function because of impaired ventricular wall motion and dilatation. The misfunction of the mitral valve allows blood to flow backward into the heart. Immediate symptoms of MR include tiredness and shortness of breath, but (untreated) can ultimately lead to limitation in activity, heart failure, and impaired hemodynamics. MR is graded on a severity scale of mild (1+) to severe (4+), with a severity of 3+ or 4+ being considered clinically significant. At least 250,000 patients a year are diagnosed with clinically significant Mitral Regurgitation (MR), making it the most common heart valve disease in the United States. The MitraClip serves to correct the mitral valve and treat MR in patients deemed too high risk for surgical complications in typical open mitral valve surgery.

II. METHODS

The MitraClip system (pictured below) is made up of two main components, the MitraClip Chip Delivery System (CDS) and the Steerable Guide Catheter (SGC). The CDS is broken into three parts: Delivery Catheter, Steerable Sleeve, and MitraClip Device (implant).



The Delivery Catheter and Steerable Sleeve plant the MitraChip, which is positioned into the appropriate location by the SGC. The SGC contains a handle made up of knobs and levers, which control the system, and is attached to a dilator. The MitraChip Device has two arms, which are able to open and close. The device is comprised of a (cardiac related) commonly used polyester fabric and metal alloys.

The MitraClip Device and Delivery Catheter enter the femoral vein through an incision in the groin (1cm), under general anesthesia. The SGC then directs the device through x-ray scans and ultrasound guidance. The device then enters the right atrium of the heart in order to pass into the left atrium just above the mitral valve, where the device is then implanted and detached from the Delivery Catheter. The two levers, or arms, of the device clamp the valve shut.

III. RESULTS

To date, in US prospective trials, more than 1,200 patients have been treated with the MitraClip system. Of those, more than 900 patients completed a follow up with a minimum of one year. The system has been approved in 40+ countries, with over 8,000 procedures having been completed worldwide. Patients treated with the system have a 30-day mortality rate of 4.8%, lower than the 18.2% usually expected for surgery. The implant success rate is 96%, and 86% of patients treated saw a reduction in the severity of MR to 2+ or less.

IV. DISCUSSION

MitraClip succeeds in being a minimally invasive procedure that addresses the need for a valve procedure that treats MR with reduced mortality compared to surgery. The downfall of the MitraClip system lies in its installation. There is high risk for health complications should the device be implanted even slightly incorrectly. The system has only been approved by the FDA's Circulatory System Devices Advisory Panel.

REFERENCES

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