JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 9, NO. 2, 2016

ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER
http://dx.doi.org/10.1016/j.jcin.2015.09.039

# Cerebral Protection During MitraClip Implantation

## Initial Experience at 2 Centers

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## ABSTRACT

**OBJECTIVES** This study sought to assess the feasibility and safety of using a filter-based cerebral protection system (CPS) during MitraClip implantation and to report on the histopathologic analysis of the captured debris.

**BACKGROUND** Stroke is one of the serious adverse events associated with MitraClip therapy.

**METHODS** Between July 2014 and March 2015, 14 surgical high-risk patients (age 75 ± 7 years; 7 men; median logistic EuroSCORE 21%) underwent MitraClip implantation employing cerebral protection with a dual embolic filter system. All patients had severe mitral regurgitation of predominantly functional origin.

**RESULTS** All procedures were successfully completed for both CPS deployment/retrieval and MitraClip implantation. A total of 28 filters (2 from each patient) were analyzed. Microscopically, debris was identified in all 14 patients. The most common tissue types were acute thrombus and small fragments of foreign material, which were found in 12 patients (85.7%) each. Organizing thrombus was present in 4 patients (28.6%), valve tissue and/or superficial atrial wall tissue in 9 patients (64.3%), and fragments of myocardium in 2 patients (14.3%). No transient ischemic attacks, strokes, or deaths occurred peri-procedurally or during a median follow-up interval of 8.4 months.

**CONCLUSIONS** In this small study of patients undergoing MitraClip treatment with cerebral protection, embolic debris potentially conducive to cerebrovascular events was found in all patients. Debris was composed most often of acute thrombus, foreign material likely originating from the hydrophilic device coating, and valve/atrial wall tissue. Further studies are warranted to assess the impact of cerebral protection on the incidence of cerebrovascular events after MitraClip therapy. (J Am Coll Cardiol Intv 2016;9:171–9) © 2016 by the American College of Cardiology Foundation.

Mitral regurgitation (MR) is the second most common manifestation of valvular heart disease in adults (1). Since the first MitraClip (Abbott Vascular, Santa Clara, California) implantation in 2008, several studies have attested to the safety and effectiveness of this new percutaneous treatment option in patients with moderate-to-severe or severe MR (2–4). Current guidelines

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Manuscript received August 5, 2015; revised manuscript received September 14, 2015, accepted September 24, 2015.

**ABBREVIATIONS AND ACRONYMS**

**ACT** = activated clotting time

**CPS** = cerebral protection system

**IQR** = interquartile range

**MR** = mitral regurgitation

**MRI** = magnetic resonance imaging

**MVARC** = Mitral Valve Academic Research Consortium

**TAVR** = transcatheter aortic valve replacement

**TIA** = transient ischemic attack

consider the MitraClip system to be a treatment option for high-surgical-risk patients (evidence class IIb) (5,6). Occurrence of a stroke or a transient ischemic attack (TIA) is one of the potential complications during a MitraClip procedure. Incidences of 0.2% to 2.6% have been reported (2,3,7). Blazek et al. (8) showed that the MitraClip procedure resulted in new ischemic cerebral lesions on diffusion-weighted magnetic resonance imaging (MRI) in 23 (85.7%) of 27 patients studied.

SEE PAGE 180

Cerebral embolic protection devices for the prevention of cerebrovascular events have been introduced for transcatheter aortic valve replacement (TAVR) procedures (9). Van Mieghem et al. (10) reported on the histopathologic characteristics of debris captured and retrieved from a filter-based cerebral embolic protection device in 30 (75%) of 40 patients undergoing TAVR. The present study assessed the feasibility and safety of using a filter-based cerebral protection device during MitraClip implantation and reports on the histopathologic analysis of the debris captured.

## METHODS

**PATIENTS.** Between July 2014 and March 2015, a total of 14 surgical high-risk patients underwent a MitraClip procedure that employed cerebral protection with the dual-filter Sentinel system (Claret Medical, Santa Rosa, California) at 2 German sites (Hamburg [n = 10] and Aachen [n = 4]). The Hamburg patients were treated consecutively in 2 series of 6 and 4 patients; the Aachen patients were selected according to the patient's propensity for thromboembolic events due to echocardiographically detected thrombus material on pacemaker or defibrillator leads. Four patients (29%) had an internal cardiac defibrillator (2 of them as a cardiac resynchronization therapy) and 1 patient (7%) had a two-chamber pacemaker. No patient had a porcelain aorta. Pertinent baseline patient characteristics are given in Table 1.

All patients had severe MR of predominantly functional origin. Left ventricular function was impaired, with a mean ejection fraction of 37%, and all patients presented with reduced physical capacity (New York Heart Association functional class III or IV). A history of atrial fibrillation and prior stroke was present in 8 (57%) and 2 (14%) patients, respectively. No patient was found to have a thrombus in the left atrial appendage or the left ventricle. Nine patients

**TABLE 1 Baseline Patient Characteristics (N = 14)**

| | |
|---|---|
| Men | 7 (50) |
| Age, yrs | 75 ± 7 |
| Body mass index, kg/m$^2$ | 26 ± 4 |
| Logistic EuroSCORE, % | 21 (18–28) |
| NT-proBNP, pg/ml | 5,673 (1,603–12,160) |
| Left ventricle | |
| End-diastolic diameter, mm | 61 ± 9 |
| End-systolic diameter, mm | 48 ± 15 |
| Ejection fraction, % | 37 ± 16 |
| NYHA functional class | |
| III | 8 (57) |
| IV | 6 (43) |
| Arterial hypertension | 11/13 (85) |
| Hyperlipidemia | 9 (64) |
| Diabetes mellitus | 5 (36) |
| COPD | 5 (36) |
| Pulmonary hypertension | 7 (50) |
| Atrial fibrillation | 8 (57) |
| Chronic renal insufficiency | 7 (50) |
| Coronary artery disease | 7 (50) |
| Previous cardiac surgery | 2 (14) |
| Peripheral arterial disease | 3 (21) |
| Prior stroke | 2 (14) |
| MR etiology | |
| Degenerative | 3 (21) |
| Functional | 11 (79) |
| MR severity | |
| Severe | 14 (100) |

Values are n (%), mean ± SD, or median (interquartile range).

COPD = chronic obstructive pulmonary disease; EuroSCORE = European System for Cardiac Operative Risk Evaluation; MR = mitral regurgitation; NT-proBNP = N-terminal pro-brain natriuretic peptide; NYHA = New York Heart Association.

were on oral anticoagulation (phenprocoumon, n = 4; direct oral anticoagulants, n = 5) without interruption of the anticoagulation during the MitraClip intervention; 5 patients had dual antiplatelet therapy with aspirin and clopidogrel. Patients on dual antiplatelet therapy received a 300-mg loading dose of clopidogrel after the MitraClip procedure. Written informed consent was obtained from all patients.

**CEREBRAL PROTECTION DEVICE.** The Sentinel Cerebral Protection System (CPS) comprises 2 bag-like embolic filters attached back-to-back to the tip of a single 6-F compatible catheter, which is delivered from the right arm via radial or brachial artery access over a standard 0.014-inch coronary guidewire (Figure 1). The filter bags are made of polyurethane film with 140-μm laser-drilled holes, and each filter is mounted on a self-expanding nitinol wire loop. The system is advanced under fluoroscopic guidance such that the larger proximal filter (loop diameter: 9 to 15 mm) is deployed in the brachiocephalic trunk, and the smaller distal filter (loop diameter: 6.5 to 10 mm), which is in an