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ABSTRACT

Background: Cerebrovascular events that occur during structural and interventional procedures are a well known risk which is associated with increased mortality. The FDA has approved the use of the Sentinel device in TAVR. Hereby we report on our experience on the safety and efficacy of using Sentinel in a patient population undergoing non-TAVR transcatheter procedures.
Methods: Retrospective analysis of a single center experience with using the Sentinel device for non-TAVR transcatheter procedures.
Results: We identified 33 patients (average age was 73.8 years, 36.7% females, and 30% with history of a prior stroke) felt to be at high risk for cerebroembolic events that underwent Sentinel device placement. Sentinel placement was successful in all patients. Examples of high risk features included high atheroma burden in the aortic arch, left sided valve vegetations, intra-cardiac thrombi and severe left sided valve calcifications/thrombi. No patients developed periprocedural stroke or vascular complications.
Conclusion: Overall, the use of Sentinel for non-TAVR indications appears feasible and safe. The use of cerebral protection devices should be studied further in non-TAVR patients to establish its role and its benefits, especially with expanding the number of non-TAVR transcatheter interventions.

1. Introduction

Catheter-based cardiovascular interventions continue to evolve as new devices continue to expand the capabilities of interventional cardiologists and to improve patient safety. The potential for embolization of atheroma, vegetation of thrombus during catheter based cardiac interventions has long been recognized. Periprocedural stroke during transcatheter intervention is a rare but serious complication; it is associated with high mortality and impaired quality of life [1].

Over the past decade, transcatheter aortic valve replacement (TAVR) had emerged as a rapidly growing therapy for the treatment of aortic stenosis (AS). Cerebrovascular events that occur during TAVR are a well known risk which is associated with increased mortality. The vast majority of neurological events in TAVR occur in the peri-procedural period [2] and are thought to be related to cerebral embolization and hypoperfusion [3]. Studies suggest that the highest rate of embolism during TAVR is during valve positioning and deployment, and the second highest rate of embolism is during balloon aortic valvuloplasty [3]. Embolic protection devices (EPDs) were developed to help reduce the risk of cerebrovascular events during transcatheter procedures. In TAVR, the use of an FDA approved cerebral protection device (Sentinel CPS®, Boston Scientific, Marlborough, MA, USA) has demonstrated reduced cerebral lesions as assessed with magnetic resonance imaging (MRI) [4]. When performing TAVR with filter-based cerebral embolic protection (CEP) devices, embolic debris is captured in 90% to 95% of patients [5].

The lessons of TAVR can provide valuable insights and developments for other left sided cardiac procedures. The concept of trapping debris and preventing distal embolization is an intuitively appealing concept for other high risk procedures such as transcatheter mitral valve therapies as well as other procedures with high risk for cerebrovascular involvement.

We hereby report on our experience on the safety and efficacy of using embolic protection devices in a patient population undergoing transcatheter procedures felt to be at high risk for cerebrovascular embolic events.

2. Methods

A single-center, retrospective, observational study was performed with IRB approval. We identified 33 patients felt to be at high risk for cerebroembolic events. In which EPD was felt to be indicated to reduce

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peri-procedural stroke risk. High risk features identified included high atheroma burden in the aortic arch, left sided valve vegetations, intracardiac thrombi and severe left sided valve calcifications/thrombi.

3. Results

Average CHA_2DS_2VASC score was 5.2 ± 1.2 (indicating elevated peri-procedural stroke risk even in patients without atrial fibrillation [6]), average age was 73.8 years, 36.7% females, and 30% with history of a prior stroke. CEP with Sentinel™ CPSV® cerebral protection device was used in all patients. Patients' selection to receive a Sentinel cerebral protection device was based on clinical judgment regarding high risk of peri-procedural embolism, see Table 1. The procedures were performed according to the CEP instructions for use. All patients had available CT angiogram that was used to identify high-risk features that may preclude the use of the CEP device. CT planning for Sentinel is key in identifiying the size of the vessels (recommended vessel size of 9–15 mm for the right brachio-cephalic and 6.5–10 mm for the left carotid), anatomy of the neck vessels (whether a favorable angle, bovine arch or how much calcium) and potential stenosis. Throughout the procedure, unfractionated heparin was administered to maintain an activated clotting time > 250 s. After the transcatheter procedure, the filters were removed and their content underwent clinical examination.

All patients had successful placement of embolic protection device without procedural complications or difficulties. No patients developed periprocedural stroke or vascular complications.

4. Discussion

Due to the elevated risk of stroke in *endo*-vascular procedures, multiple EPDs were developed to help reduce this risk. In TAVR, the use of the FDA approved Sentinel has demonstrated reduced cerebral lesions as assessed with magnetic resonance imaging (MRI) [4] but is yet to show a clinical reduction in cerebro-vascular events. An ongoing trial is being performed to answer this very important question [PROTECTED TAVR trial (NCT04149535)]. Data for the use of EPDs is non-TAVR procedures is scarce and outcomes are not known. Recently, a multi-center European study demonstrated the efficacy and safety of using Sentinel in patients presenting with left atrial appendage thomrbus who are treated with trans-catheter left atrial appendage closure while using the Sentinel device [7]. Our paper adds to the growing non-randomized literature about the use of Sentinel for non-TAVR applications. More studies are needed to inform clinical practice and to whether or not Sentinel is associated with reduction in clinical endpoints.

Table 1
Rationale for use of cerebral embolic protection in non-TAVR procedures.

Procedure performed	Cases (%)	Rational for CEP use
Transcatheter mitral valve replacement	30.3	• Highly calcified valve leaflets • Concern for valve thrombus
Percutaneous balloon mitral valvuloplasty	21.2	• Heavily calcified leaflets
Percutaneous coronary intervention (with or without Impella)	18.2	• Large atheroma burden in aortic arch
Balloon aortic valvuloplasty	12.1	• Heavily calcified valve leaflets
Thrombus aspiration with Angiovac system	6.1	• Thrombus in transit • Large thrombus in aortic arch
Diagnostic coronary angiogram	6.1	• Large aortic arch thrombus • Aortic valve vegetations
Patent Foramen Ovale closure	3	• Deep venous thrombus with right to left shunt through PFO and concern for thrombus in transit
Transcatheter edge-to-edge repair with MitraClip system	3	• Deep venous thrombus with bidirectional shunt through PFO and concern for thrombus in transit

CEP = Cerebroembolic protection; PFO = patent formen ovale,

5. Limitations

This is a retrospective analysis and carries the risk of confounding. The lack of a control group is also a limitation. The decision to use CEP in these cases was entirely based on physicians qualitative estimation of stroke risk, which could be biased.

6. Conclusion and summary

High-risk catheter-based vascular and structural interventions carry significant risk of stroke related presumably to embolization of atheroma, vegetation or thrombus. In TAVR, the use of a cerebral protection device (Sentinel CPS®) has been proven to reduce cerebral lesions as assessed with magnetic resonance imaging (MRI). We hereby report a 30 patient single-center study where we used Sentinel for non-TAVR indications in selected high-risk individuals undergoing a variety of vascular and structural procedures.

Overall, the use of Sentinel for non-TAVR indications appears feasible and safe. We had no strokes in our 30-patient series. The use of cerebral protection devices should be studied further in non-TAVR patients to establish its role and its benefits, especially with expanding the number of non-TAVR transcatheter interventions.

Author statement

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