Interventional left atrial appendage (LAA) occlusion has been shown to be non-inferior to warfarin therapy in terms of stroke prevention in randomized trials. Thus, the Watchman® device (Boston Scientific, Marlborough, MA, USA) was recently approved by the FDA for clinical use as an alternative to warfarin in the United States and it also found its way into the guidelines issued by the European Society of Cardiology. Therefore, a significant increase in the number of LAA occlusions can be expected not only in the United States but also world-wide. However, procedure related complications have been a major concern throughout the evolution of this technique; especially peri-procedural stroke has been a major contributor to rare but devastating adverse events. Since the underlying pathophysiological mechanism of procedural stroke is not yet elucidated, thorough investigation of embolic events are of utmost interest in order to improve procedural safety in interventional LAA occlusion.

A comparable challenge was recently encountered in the field of transcatheter aortic valve implantation (TAVI). In this area, the use of a cerebral protection device (Sentinel CPS®, Claret Medical Inc., Santa Rosa, CA, USA) has been shown to be safe and feasible. Moreover, the use of this particular device demonstrated retrieval of calcified and thrombotic cerebral emboli originating from the aortic valve and consecutive reduction of cerebral lesions as assessed by diffusion-weighted magnetic resonance imaging (DW-MRI). This finding is underlined by increasing evidence in literature, that not only major adverse events but also micro-embolic events that might contribute to adverse long-term effects like cognitive impairment.

We therefore investigated the feasibility and safety of cerebral embolic protection in the setting of interventional LAA occlusion procedures. We further hypothesized, that peri-procedural strokes in LAA occlusion are related to embolization of thrombotic and cardiac debris, which both could be alleviated by the use of the Sentinel® device. With this pilot investigation we aim to yield more insight into the pathomorphological correlate of cerebral embolization during interventional LAA occlusion.

**METHODS**

In five consecutive patients treated with interventional LAA occlusion, the Sentinel CPS® cerebral protection device was used. The LAA occlusion was performed in five consecutive patients, two with the Watchman® device and three with the Amulet® (St. Jude Medical Inc., St. Paul, MN, USA) device. All procedures were per-formed according to the instructions for use. Presence of LAA thrombus was ruled out before transseptal puncture by transesophageal echocardiography (TEE) in all patients. The protection device consists of two filters that are introduced via a 6 Fr right radial access and placed to cover the brachiocephalic trunk (proximal) as well as the left carotid artery (distal) (Figure 3). Filter placement was performed after transseptal puncture and administration of full-dose unfractionated heparin to maintain an activated clotting time > 250 seconds in order to mini-mize thrombus formation within the filter itself. After implantation of the LAA occlusion device the filters were removed, immediately fixated and their content underwent histopathologic examination at the CVPath Institute.

**RESULTS**

In all five patients, the delivery of the device was feasible via right radial access, utilizing a Graphix Standard 0.014” guidewire (Boston Scientific, Marlborough, MA, USA). Mean delivery time was 22.4 (± 9.3) minutes, mean additional contrast volume was 20 ml for visualizing the aortic branches. No adverse events with regard to the Sentinel® system or the radial access site occurred. A total of 10 filters (one proximal and one distal filter for each patient) were collected and underwent histopathologic analysis. Debris was found in all patients (9/10 filter-ten). Acute thrombus was found in 3 patients (2 Watchman®, 1 Amulet®), organizing thrombus in 4 patients (1 Watchman®, 3 Amulet®). One Amulet® patient had endocardial and another myocardial tissue in his filters. None of the filters included calcifications or other foreign material. The results per patient and device are shown in Table 1 and Figure 1, respectively. The maximal diameter of the collected material was 0.68 (±0.9) mm. No clinical apparent procedural complications occurred and no patient showed neurological abnormalities after the procedure or before discharge on the day after the implantation. All access sites remained without hematoma.

<table>
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<th>Pt.</th>
<th>Age</th>
<th>CHA2DS2-VASc Score</th>
<th>Implanted device</th>
<th>Any debris</th>
<th>Acute thrombus</th>
<th>Organized thrombus</th>
<th>Tissue</th>
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**CONCLUSION**

- The use of the Sentinel CPS system in LAA occlusion is safe and feasible
- Interventional LAA occlusion leads to embolization of thrombus material and cardiac tissue in all reported cases
- The clinical impact of these micromeboli remains uncertain but unfavorable long-term effects are likely
- Our data encourages further investigations on the clinical role of microemboli and on the question whether cerebral protection systems might reduce the risk of apparent procedural related strokes

**Table 1: Patient characteristics and summary of histomorphometric analysis per patient**

**Figures:**

- **Fig. 1:** Bar graphs illustrating the histomorphometric findings separately for the different device types
- **Fig. 2:** A: Proximal filter collected from patient #3 showing fragments of fibrocell rich and organized thrombi with smooth muscle cells infiltrating procoagulant matrix. B: Mucous fragments of parietal rich thrombi in patient #3. D: Endocardial tissue in #4.
- **Fig. 3:** A: Fluoroscopic view after implantation of the Amulet® device in patient #4 (*: Proximal filter; +: Distal filter; #: Deployed Amulet® device). B: Sentinel CPS® device.