ORIGINAL RESEARCH

Cerebral Protection During Catheter Ablation of Ventricular Tachycardia in Patients With Ischemic Heart Disease

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***Background*—**Catheter ablation of ventricular tachycardia (VT) is associated with the risk of cerebral embolism. The origin of periprocedural brain embolism in the setting of VT ablation is often unknown and strategies to avoid it are sparse. The aim of this study was to assess the safety and feasibility of an endovascular 2-filter-based cerebral protection system (CPS) in left ventricular VT ablation procedures in patients with ischemic heart disease. Furthermore, histopathological correlates of periprocedural embolization were investigated.

***Methods and Results*—**In this pilot study, 11 patients with ischemic heart disease and sustained VT underwent left ventricular catheter ablation under CPS surveillance. The placement of the CPS was conducted before the ablation procedure via the right radial artery. The VT ablation procedure was performed via a combined transaortic and transseptal approach. All VTs were successfully ablated. Placement and retrieval of the CPS was successful and safe in all cases. No periprocedural complications related to the CPS were observed and no periprocedural transient ischemic attack or stroke occurred. Debris captured by the CPS was detected in all patients. Histology revealed that acute thrombus was the most common type of debris (91%), followed by arterial wall tissue (73%) and foreign material (55%). Less frequently found were myocardium (27%), calcification (9%), necrotic core (9%), and valve tissue (9%).

***Conclusions*—**Cerebral protection during VT ablation seems to be safe and feasible. Ablation procedures of VT are associated with embolization of embolic debris, which was found in every patient. **(*J Am Heart Assoc*. 2018;7:e009005. DOI: 10.1161/JAHA.118.009005.)**

Key Words: catheter ablation • histopathology • stroke prevention • ventricular tachycardia

Catheter ablation (CA) has evolved into an accepted treatment option for patients experiencing ventricular tachycardia (VT) related to ischemic heart disease.[1] Previous studies provided evidence for reduced rates of implantable cardioverter-defibrillator (ICD) shocks and prevention of electrical storm in patients after CA of VT as compared with medical treatment.[2,3] However, complication rates of CA are not negligible and include major complications such as myocardial rupture, coronary artery damage, and embolic stroke.[1] Periprocedural stroke is a devastating complication and the reported rates for periprocedural cerebrovascular events (including transient ischemic attack and embolic stroke) range from 0.8% to 1.8%.[2,4] Furthermore, 58% of patients undergoing routine VT ablation procedures show new cerebral ischemic lesions on postprocedural cerebral magnetic resonance imaging (CMRI).[5] Although these embolic events were initially thought to be subclinical, current investigations showed that they might have negative neurocognitive effects.[5,6] Strategies to avoid iatrogenic periprocedural cerebral emboli are sparse. Additionally, the source and type of the emboli are unknown.[5] The US Food and Drug Administration–approved Sentinel cerebral protection system (Sentinel CPS; Claret Medical Inc, Santa Rosa, CA) captures and removes debris dislodged during endovascular

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Clinical Perspective

What Is New?

- In a pilot trial of 11 patients using the Sentinel cerebral protection system during ventricular tachycardia ablation, cerebral protection was safe and embolic debris was identified in every patient.

What Are the Clinical Implications?

- Cerebral protection may be useful for preventing iatrogenic periprocedural stroke during ventricular tachycardia ablation.
- These findings support the performance of future randomized trials in larger cohorts.

procedures, preventing it from traveling to the brain. In patients undergoing transcatheter aortic valve replacement (TAVR), the CPS has demonstrated significantly higher stroke-free survival compared with unprotected TAVR.[7] Moreover, the device demonstrated retrieval of diverse tissue and material and subsequent reduction of cerebral lesions as assessed by CMRI.[8–10] In TAVR procedures, clinical studies revealed evidence of visible debris removed in up to 100% of cases; the device has also been studied in other endovascular procedures, such as interventional left atrial appendage (LAA) closure, transcatheter valve-in-valve procedures, and transcatheter mitral valve repair via MitraClip.[11–14] The aim of the present pilot study was to assess the safety and feasibility of the Sentinel CPS during VT ablation procedures in patients with ischemic heart disease and to provide insight into the histo-pathomorphologic correlates of periprocedural cerebral embolization.

Methods

The data, analytic methods, and study materials will not be made available to other researchers for purposes of reproducing the results or replicating the procedure.

Patient Population and Study Design

All patients referred to our institution (Asklepios Klinik St. Georg, Hamburg, Germany) with sustained VT suitable for VT ablation were screened. Patient selection followed our institutional standards and included patients at excessive risk for thromboembolic events (because of previously detected LAA or left ventricular [LV] thrombus, severe atherosclerosis, and calcification) during the ablation procedure. Inclusion criteria for this study were sustained monomorphic VT, prior coronary angiography to exclude acute ischemia as a trigger for VT, ischemic heart disease, and patients willing to take part in the study. Exclusion criteria were contraindications for anticoagulant and antiplatelet therapy, known hypersensitivity to nickel-titanium, arterial stenosis >70%, and severe kinking of either the left common carotid artery or the brachiocephalic trunk. All patients gave written informed consent and all patient information was anonymized. All data were assessed retrospectively. The study was approved by the local ethics board and has been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

Sentinel CPS

The Sentinel CPS is a dual-filter device designed to capture and remove any debris released during the intervention (Figure 1). The device consists of 2 polyurethane filter bags with 140-μm-diameter pores that are attached by nitinol loops to a 6F compatible catheter with a deflectable distal tip. The device is inserted over a 6F sheath via the right radial artery. The proximal filter is deployed in the brachiocephalic trunk, the distal filter in the left common carotid artery. It is noteworthy that the Sentinel CPS does not protect the left vertebral and subclavian arteries. The placement of the CPS was performed as previously described.[12–15] Briefly, before device placement, the anatomy of the aortic branches was visualized by angiography with a pigtail catheter placed in the ascending aorta. According to the CPS instructions, before the insertion of the system, a standard loading dose of 70 IU/kg heparin was initiated and activated clotting time (ACT) was measured every 30 minutes during the entire procedure. An ACT level of at least 300 s was mandatory before introduction of the CPS. Following insertion, the proximal filter was deployed in the brachiocephalic trunk. Afterwards the distal filter was deployed in the left common carotid artery.

Catheter Ablation Procedure

The mapping and ablation procedures were performed according to our institutional standards, which have been published earlier.[16] Transthoracic echocardiography was performed before each procedure to exclude LV thrombus. In patients with known atrial fibrillation, transesophageal echocardiography was performed to exclude left atrial (LA) thrombus. No other preprocedural imaging was performed.

The procedure was performed with patients under deep sedation with midazolam, fentanyl, and continuous infusion of propofol. An ACT level of at least 300 s was maintained throughout the procedure. Two diagnostic catheters were introduced via the right femoral vein and positioned in the coronary sinus (7F, Webster; Biosense Webster, Inc, Diamond Bar, CA) and the right ventricle (6F, Torqr; Medtronic, Inc,

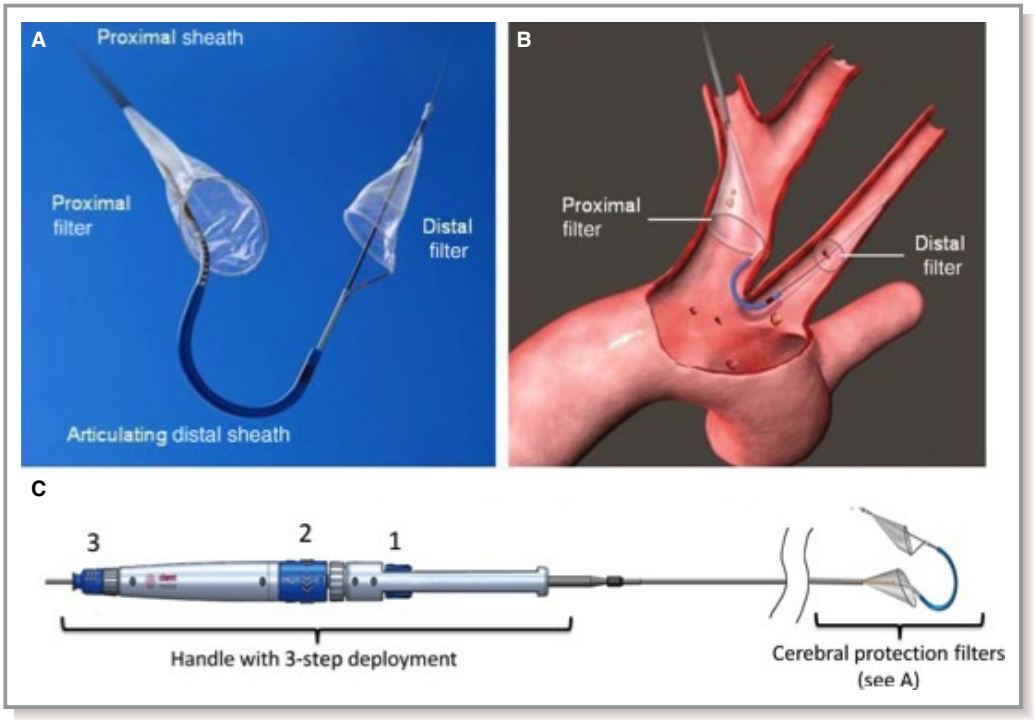

Figure 1. Sentinel cerebral protection system. A, The distal tip of the Sentinel cerebral protection system with its 2 filters (proximal and distal) and the articulating distal sheath. B, The proximal filter is positioned in the brachiocephalic trunk and the distal filter in the left common carotid artery. C, Full view of the Sentinel cerebral protection device with the handle, necessary for the deployment of the device, and the 2 filters at the distal tip.

Minneapolis, MN). For the antegrade approach, venous access was obtained via the right femoral vein and a single transseptal puncture was performed under fluoroscopic guidance using a modified Brockenbrough technique (71-cm Brockenbrough needle; BRK St. Jude Medical Inc, St. Paul, MN) and an 8.5F transseptal sheath (SL1, St. Jude Medical). The transseptal puncture was performed at the anterior–inferior portion of the fossa ovalis, as previously described.[17] In our experience, this approach facilitated access into the LV, particularly to cross the mitral valve. For the retrograde approach, a SR0 or SL1 sheath (St. Jude Medical) was advanced into the descending aorta via the right femoral artery. LV mapping was conducted utilizing a 3-dimensional electroanatomical mapping system (CARTO 3; Biosense Webster, Inc) and a 7.5F, 3.5-mm irrigated-tip catheter (NAVISTAR Thermocool; Biosense Webster, Inc). A low-voltage area was defined as a voltage of 1.5 mV. Radiofrequency current was delivered in the power-controlled mode with a maximum power of 40W and a flow rate of 17 to 30 mL/min. Programmed electrical stimulation was utilized to induce VT.

If hemodynamically stable VT could be induced, pacing was performed to entrain the VT and identify the critical isthmus during VT. For hemodynamically unstable VT, pace mapping was performed at different sites within the low-voltage area during sinus rhythm to identify the VT exit and potential critical isthmus. The procedural end point was the elimination of all fractionated or delayed potentials within the scar area and the noninducibility of any sustained VT via programmed electrical stimulation and burst pacing during a waiting period of at least 30 minutes.

Histopathologic Assessment of Captured Debris

After successful CA, the CPS was removed and the filters were visually screened for macroscopic thrombus attachment. Afterwards, they were immediately fixated in 10% neutral buffered formalin and underwent histopathologic examination at the CVPath Institute. A total of 22 filters (11 proximal and 11 distal) were analyzed. Each filter was assigned a CVPath case number and barcode and was digitally photographed before any physical alteration. The samples were carefully opened using scissor blades, and all contents were removed and filtered through a Falcon 40-μm nylon cell strainer. The material collected by the cell strainer was photographed again, then carefully folded and placed in a Shandon nylon biopsy bag (Fisher Scientific #6774009). The biopsy bag containing the sample was then transferred to an appropriately bar code–labeled biopsy cassette and submitted for processing. Samples were processed in a graded series of ethanol and xylene (Tissue-Tek VIP 6, Sakura) and embedded

in paraffin. Each paraffin block was serially cut at 4 to 5 μm, with 2 consecutive sections affixed per charged slide. Slides from each sample were stained with hematoxylin & eosin and Movat Pentachrome stain.

Each sample was evaluated for the presence of thrombus (acute versus organizing) and its composition, determined by including presence of platelets, red blood cells, inflammatory cells, necrotic core, foamy macrophages, calcification, valve tissue, arterial wall, collagenous tissue, foreign material, and myocardium. These values and all combinations were recorded and reported for both filters separately.

Postprocedural Assessments and Follow-Up

All patients underwent transthoracic echocardiography and interrogation of the ICD on the day after CA. Furthermore, ICD interrogation was performed at each hospital visit every 3 to 6 months. In addition, regular telephone interviews were performed. Additional outpatient visits were immediately initiated in case of symptoms or signs suggestive of recurrent arrhythmia.

Statistical Analysis

Continuous variables are described as mean and SD if normally distributed; otherwise the median and interquartile range (first and third quartile) are reported. Categorical data are described with absolute and relative frequencies. Differences between distal and proximal filters were evaluated using the McNemar's exact test for matched-pairs with small samples. All P values are 2-sided and a $P<0.05$ was considered statistically significant. All calculations were performed with SAS software (version 9.3; SAS Institute Inc, Cary, NC).

Results

Patients and Procedures

Between March 2016 and July 2017, 254 consecutive patients underwent CA of ventricular arrhythmias in our institution. A total of 11 patients with ischemic heart disease and sustained VT suitable for ablation were treated using the Sentinel CPS. Two patients were ruled out before placement of the CPS because of severe kinking and severe calcification of the brachiocephalic trunk. The patients' baseline characteristics are presented in Table 1. In 2 patients, preprocedural transthoracic echocardiography revealed LV thrombus within large anterior LV aneurysms. In a further patient with known atrial fibrillation, preprocedural transesophageal echocardiography found a LAA thrombus in spite of sufficient oral anticoagulation. Ablation of VT was urgently performed because of life-threatening electrical storms secondary to hemodynamically unstable VT storms in these patients.

Table 1. Baseline Characteristics and Procedural Details

Patients	11
Age, y	73 [65, 76]
Body mass index	27.5 [24.3, 29.0]
Male sex	11 (100)
Atrial fibrillation	6 (55)
Ischemic heart disease	11 (100)
Prior myocardial infarction	11 (100)
LV ejection fraction, %	30 [27, 37]
Prior implanted ICD	11 (100)
ICD implanted because of primary prophylaxis	5 (46)
LV aneurysm	7 (64)
Arterial hypertension	11 (100)
Diabetes mellitus type 2	2 (18)
Hyperlipidemia	9 (82)
Current smoking	4 (36)
Previous cardiac surgery	5 (46)
Indication for VT ablation: ICD-shock	9 (82)
Indication for VT ablation: ATP	2 (18)
VT storm	5 (46)
LV thrombus before the procedure	2 (18)
LAA thrombus before the procedure	1 (9)
LV volume, mL	280 [240, 320]
Periprocedural complications	1 (9)
Procedure time, min	185 [175, 215]
Fluoroscopy time, min	21 [19, 23]

Values are n, n (%), or median [first, third quartile]. ATP indicates antitachycardia pacing; ICD, implantable cardioverter-defibrillator; LAA, left atrial appendage; LV, left ventricle; VT, ventricular tachycardia.

The placement of the CPS proved to be safe and feasible in all cases. After placement of the CPS, LV mapping and VT ablation were conducted according to our institutional standards.[2,16,18] The median ACT was 310 s (interquartile range 295–327 s).

Antegrade and retrograde LV mapping was performed in all patients. The median LV volume was 280 (240, 320) mL. An anterior scar was detected in 7 patients (64%), while an inferior-basal scar was detected in 2 (18%). Two additional patients (18%) presented with an inferior-basal and lateral scar area. In the 11 patients, a total of 21 (1.0, 2.5) sustained monomorphic VTs were induced by programmed stimulation or catheter manipulation and were targeted by radiofrequency ablation. The procedural end point of elimination of all fractionated or delayed potentials within the scar area and noninducibility of any sustained VT was reached in all

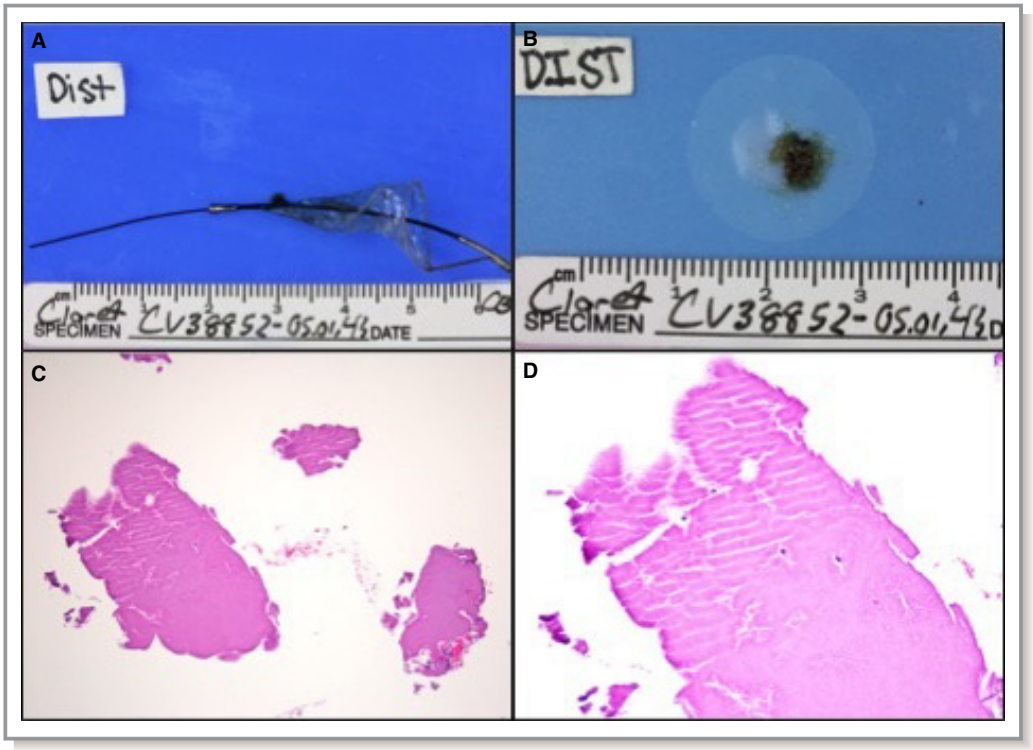

Figure 2. Macroscopic and microscopic view: acute thrombus. Gross images of the distal filter (A) and debris collected by the cell strainer (B), along with images of a hematoxylin and eosin–stained slide (C and D).

patients. The median radiofrequency ablation time was 45.7 minutes (interquartile range 42.3, 55.4 minutes).

One patient experienced periprocedural pericardial tamponade and was successfully treated by pericardiocentesis. No further periprocedural complications especially related to the CPS were observed and no periprocedural transient ischemic attack or stroke occurred. In total, 6 electrical cardioversions have been performed during the procedures (0.55/patient).

The retrieval of the CPS was safe and feasible in all cases. Procedure duration and fluoroscopy time were 185 (175, 215) minutes and 21 (19, 23) minutes, respectively. The investigation of the ICD 1 day after CA found no periprocedural complications. All patients were discharged safely. After a median follow-up of 9.0 (5.5, 11.5) months, 4 patients (36%) experienced recurrence of sustained VT, which required ICD shock (n=2) and antitachycardia pacing (n=2). One patient underwent a repeat VT ablation procedure without utilization of a CPS 17 months after the initial procedure. One patient died of heart failure 9 months after the VT ablation procedure. The last ICD investigation after 6 months had shown no recurrence of VT.

Histologic Findings

In the present study, the separate filters were analyzed to assess the type and quantity of debris material captured during the ablation procedure. The prespecified type of material that was relevant to capture included acute and organized thrombus, valve tissue, arterial wall tissue, calcification, foreign material, myocardium, and necrotic core. Of the 22 filters analyzed from the 11 patients, all 11 proximal and 11 distal filters were deployed properly.

In each individual patient, the predominant debris material captured was composed of acute platelet-rich thrombus (91%, Figure 2) mostly in the presence of other tissue (91%). This was followed by arterial wall (73%, Figure 3), foreign material (55%, Figure 4), and myocardium (27%). Valve tissue (Figure 5), calcification, and necrotic core were all observed at the same rate (9%). Organizing thrombus was not observed in any patient (Table 2).

In each proximal filter, acute platelet-rich thrombus was the predominant material captured (91%), followed by arterial wall (64%), foreign material (36%), myocardium (27%), and calcification (9%). Valve tissue and necrotic core were not observed in any proximal filter debris.

In each distal filter, acute platelet-rich thrombus was the predominant material captured (82%), followed by arterial wall (55%), foreign material (45%), valve tissue (9%), and necrotic core (9%). Calcification and myocardium were not observed in any distal filter. In the comparison of debris found in the proximal and distal filters, no significant differences were found (Table 3).

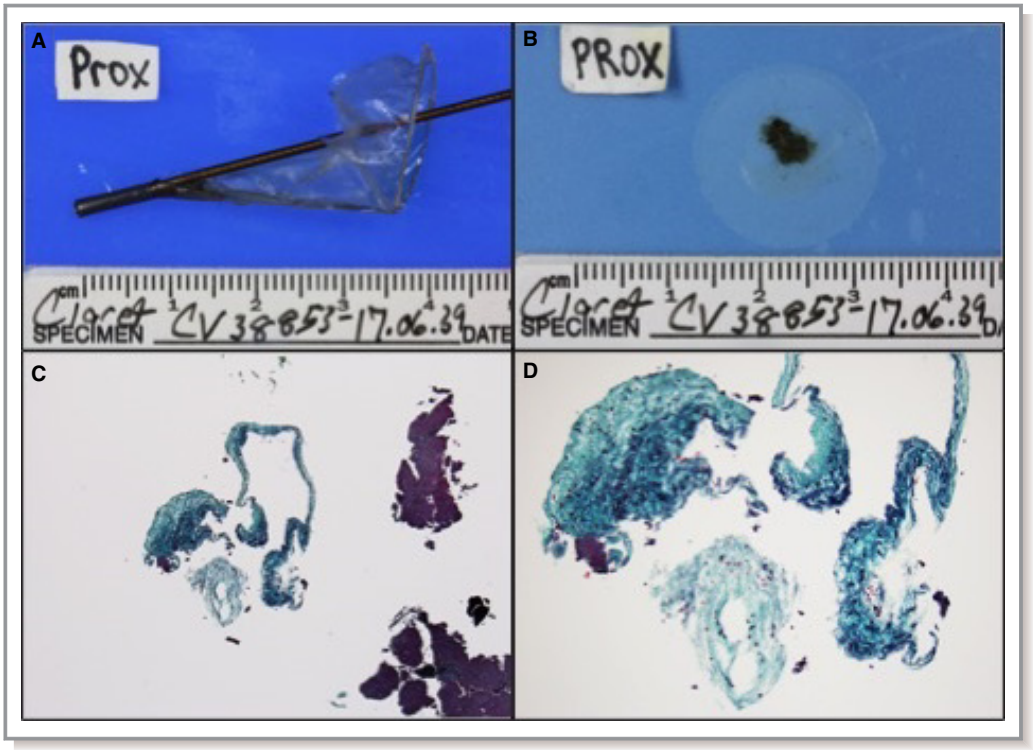

Figure 3. Macroscopic and microscopic view: arterial wall tissue. Gross images of the proximal filter (A) and debris collected by the cell strainer (B), along with images of a Movat pentachrome-stained slide (C and D).

Discussion

Embolic stroke is a devastating potential complication of any interventional endovascular procedure, and its prevention is a major issue of modern cardiovascular therapies.

The main findings of this first report on cerebral protection and debris capturing using a CPS during VT ablation procedures are as follows: (1) Application of the CPS during CA of VT seems to be feasible and safe; (2) Despite the presence of intracardiac thrombus formation in 3 patients, no periprocedural stroke or transient ischemic attack occurred; (3) The debris capture rate per patient (either proximal and/or distal filter) was 100%; (4) Acute thrombus was the most common type of debris (91%), despite sufficient ACT; and (5) Foreign material was found in 55% of filters.

Catheter Ablation and Cerebral Embolization

Catheter ablation of atrial and ventricular arrhythmias is increasingly performed in developed countries. In general, endovascular procedures bear the risk of periprocedural cerebral ischemic events. Embolic stroke, and subsequent decline in brain function, is a devastating periprocedural complication. Although the reported rates of clinically overt cerebrovascular events are relatively low (<2%),[2,4] 58% of patients undergoing routine VT ablation procedures exhibit new brain emboli in postprocedural CMRI.[5] Most of the CMRI-detected ischemic lesions remained clinically silent, but recent studies have shown that these lesions might be associated with neurocognitive impairment and the development of dementia.[19,20]

In the present study, the Sentinel CPS was used for cerebral protection during VT ablation procedures. This US Food and Drug Administration–approved device has shown device placement success rates of 99.6% during TAVR procedures and no major adverse device-related events.[7] In the present study, the deployment and retrieval of the CPS was performed without any complications and, except for 1 periprocedural pericardial tamponade not related to the CPS, no further complications occurred during the procedures, despite 3 patients showing preprocedural intracardiac thrombus formation. Therefore, our data suggest that this approach is safe and feasible.

Thrombotic Debris

Because of its thrombogenic nature, acute thrombus may originate at any part of endovascular catheters. Maleki et al reported 9% thrombus formation on transseptal sheaths despite adequate anticoagulation.[21] The thrombogenicity of guidewires during endovascular procedures has been described in vivo and in vitro.[22,23] For example, the rate of significant thrombus formation on guidewires used in routine

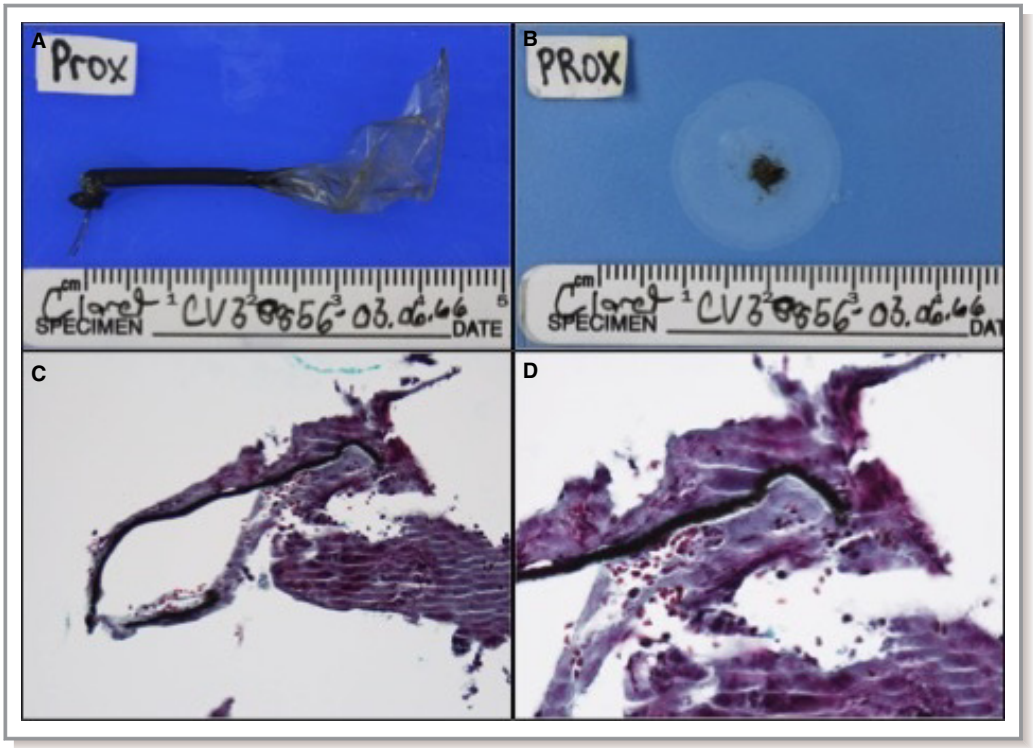

Figure 4. Macroscopic and microscopic view: foreign material and associated thrombus. Gross images of the proximal filter (A) and debris collected by the cell strainer (B), along with images of a Movat pentachrome-stained slide (C and D).

percutaneous coronary interventions was reported to be 48%.[24] Despite adequate periprocedural anticoagulation (ACT level >300 s), acute thrombus material was the most common type of debris in the present study, captured in >90% of the filters. In >90% of cases this thrombus material was attached to tissue and/or foreign material. The rate of acute thrombus material is in line with the data from other studies utilizing the Sentinel CPS in endovascular procedures (74%–100%).[10,12,14,15] The thrombogenicity of endovascular catheters cannot be avoided completely, yet an ACT level >300 s should be achieved in every left-sided procedure, especially in long-lasting procedures such as VT ablation.

Debris Originating From Arterial Walls

At 73%, arterial wall tissue was frequently found in the filters, accompanied by smaller amounts of calcified (9%) and necrotic core tissue (9%). All study patients experienced ischemic heart disease caused by atherosclerosis, which is not only found in the coronary arteries but also in the aorta and other arterial vessels. Therefore, the origin of this type of debris might be the manipulation of the ablation catheter within the aortic root, ascending aorta, and aortic arch, thereby injuring the atherosclerotic arterial wall, with subsequent embolization of arterial wall, and calcified and necrotic core tissue.

Calcific Debris

The observed rate of calcified debris in this study was relatively low (9%). Since calcification is 1 major reason for aortic stenosis, it is not surprising that the rate of calcified debris observed during TAVR and valve-in-valve procedures was reported to be much higher (46%–73%),[14,15] whereas for MitraClip and LAA closure procedures no calcified debris was found.[12,13]

Myocardial and Valve Tissue

The origin of myocardial (27%) and valve tissue (9%) might be the advancement and manipulation of the catheters into the left ventricle via the mitral valve. Interestingly, a much higher amount of valve tissue debris was found in CPS-guided MitraClip procedures (64%), most likely because of the repetitive "grasping" of the mitral leaflets during the procedure.[12]

Foreign Material

Apart from biological tissue, foreign material was found in the filters of more than half of the patients (55%). Although no further discrimination of foreign material was performed in this examination, we assume that the material most likely arose from hydrophilic polymer coatings used on guidewires,

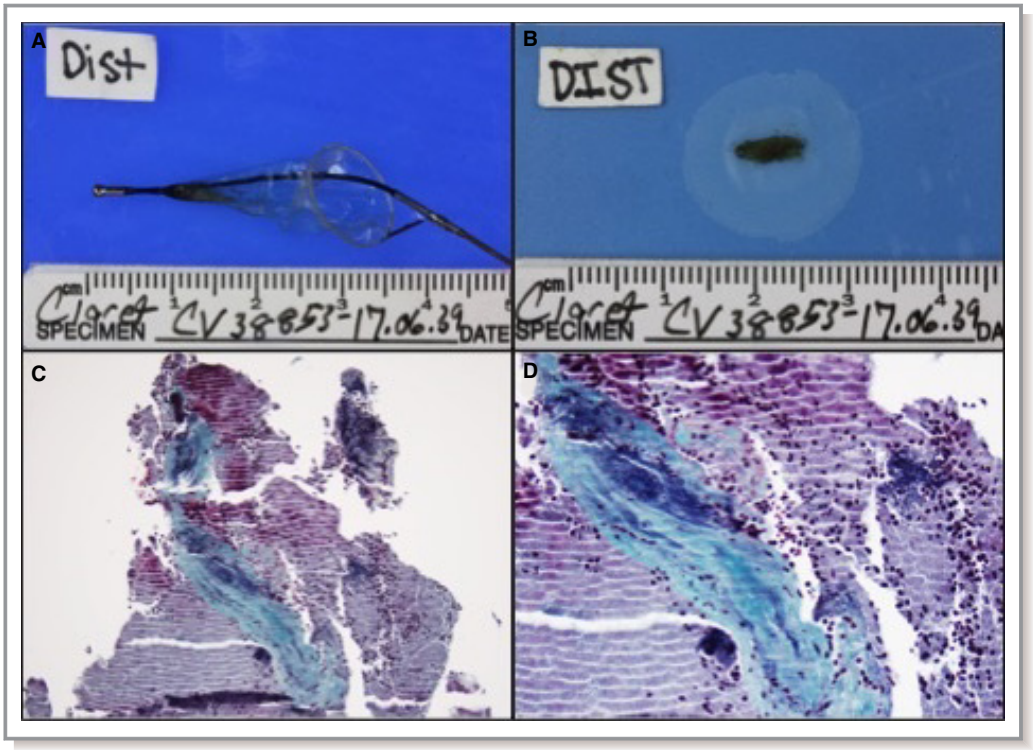

Figure 5. Macroscopic and microscopic view: valve tissue. Gross images of the distal filter (A) and debris collected by the cell strainer (B), along with images of a Movat pentachrome-stained slide (C and D).

catheters, and previously implanted ICD leads, which is consistent with previously identified materials in patients undergoing endovascular procedures.[22] A further source of foreign material might be the transseptal needle when advanced through the dilator and transseptal sheath for the antegrade approach, which has been shown to produce clinically relevant particles.[25] Because of thrombogenic effects of its surface, the presence of foreign material debris within the vascular system could induce acute thrombus formation, which was observed in the histologic analysis (Figure 4).

Obviously, the CPS itself could be a source of acute thrombus and foreign material. However, in animal studies, no thrombus was seen on the Sentinel CPS and no foreign material has been shown under high-magnification microscopy to originate from the filters even after manually scraping its surface.[12,14]

Mode of LV Mapping and Cerebral Debris

LV mapping can be achieved either via an antegrade transseptal approach, a retrograde transaortic approach, or a combination of both. In our experience, a complete LV map can only be achieved by a combination of both approaches.[16] A purely retrograde approach might produce less valve tissue debris and a purely antegrade transseptal approach might produce less arterial wall, necrotic core, and calcified tissue debris,[5] yet these hypotheses need to be proven in a larger study population with CPS and/or CMRI.

Clinical Relevance of Focal Cerebral Ischemia

Although the relevance of clinically silent periprocedural embolic lesions is unknown, the long-term consequences of these lesions might have negative neurocognitive effects such as premature dementia.[5,6,20] Most endovascular electrophysiological procedures such as CA of atrial fibrillation and, particularly, VT are associated with fairly long procedure durations compared with other interventional procedures (eg, coronary angiography, LAA closure, TAVR, and mitral valve repair with the MitraClip). Since increased dwell times of catheters will also increase the risk of embolization, prolonged procedure duration should be avoided. Since we observed captured debris in all patients, the devastating consequences of periprocedural iatrogenic stroke justify any attempt to prevent this complication. Our findings might influence the use of a CPS in selected patients with known periprocedural stroke risks such as expected long procedure duration, severe calcification within the aorta and aortic valve, or known LV or LA thrombi. Our findings should be considered as hypothesis-generating and require confirmation in larger patient cohorts.

Table 2. Data Summary of Debris Type Captured in Each Filter for Each Patient

Patient no.	Filter	Acute Thrombus	Acute Thrombus Attached to Tissue/Foreign Material	Organized Thrombus	Valve Tissue	Arterial Wall	Calcification	Foreign Material	Myocardium	Necrotic Core	Any Debris
1	Prox.	1	1	0	0	1	0	1	0	0	1
1	Dist.	1	1	0	0	1	0	0	0	0	1
2	Prox.	1	1	0	0	1	0	0	1	0	1
2	Dist.	1	1	0	0	0	0	1	0	0	1
3	Prox.	1	1	0	0	1	0	1	0	0	1
3	Dist.	1	1	0	0	1	0	1	0	0	1
4	Prox.	1	0	0	0	0	0	0	0	0	1
4	Dist.	1	1	0	0	0	0	1	0	0	1
5	Prox.	0	0	0	0	1	0	0	0	0	1
5	Dist.	0	0	0	0	1	0	0	0	0	1
6	Prox.	1	1	0	0	0	0	0	1	0	1
6	Dist.	0	0	0	0	1	0	0	0	0	1
7	Prox.	1	1	0	0	1	0	0	0	0	1
7	Dist.	1	0	0	0	0	0	0	0	0	1
8	Prox.	1	1	0	0	1	0	0	0	0	1
8	Dist.	1	1	0	1	1	0	0	0	0	1
9	Prox.	1	1	0	0	1	1	1	0	0	1
9	Dist.	1	1	0	0	1	0	1	0	1	1
10	Prox.	1	1	0	0	0	0	0	1	0	1
10	Dist.	1	0	0	0	0	0	0	0	0	1
11	Prox.	1	1	0	0	0	0	1	0	0	1
11	Dist.	1	1	0	0	0	0	1	0	0	1

0=absent; 1=present.

Limitations

The current pilot study represents a single-center experience with a limited number of patients. Therefore, it was not powered to judge on safety, feasibility, and identification of specific predictors of cerebral embolism. Additionally, no subgroup analysis comparing retrograde, antegrade, and combined approaches has been conducted. No CMRI or systematic assessment of neurocognitive function and no randomization have been performed.

Although the Sentinel CPS has demonstrated a reproducible excellent safety profile and a >92% procedural success rate for TAVR across multiple studies, every additional invasive

Table 3. Incidence of Debris Identified Per Patient, Per Proximal Filter, and Per Distal Filter as Well as Comparison of Proximal Versus Distal Filters

	Acute Thrombus	Acute Thrombus Attached to Tissue/Foreign Material	Organized Thrombus	Valve Tissue	Arterial Wall	Calcification	Foreign Material	Myocardium	Necrotic Core	Any Debris
Patients (n=11)	91%	91%	0%	9%	73%	9%	55%	27%	9%	100%
Prox. filter (n=11)	91%	82%	0%	0%	64%	9%	36%	27%	0%	100%
Dist. filter (n=11)	82%	64%	0%	9%	55%	0%	45%	0%	9%	100%
P value	1.00	0.617	n.a.	1.00	1.00	1.00	1.00	0.248	1.00	n.a.

No differences were found for the comparison of debris found in the proximal and distal filters. Statistical analysis has been performed via the McNemar's exact test. n.a. indicates not available.

intervention involves the risk of iatrogenic complications. Therefore, our data have to be seen in the context of hypothesis generation.

It remains unclear how much the filter system itself and its deployment contribute to our findings, since no data are available so far to answer this question.

The results may underestimate the incidence of cerebral embolization because the Sentinel CPS does not protect the left vertebral artery. However, this is the first analysis on utilizing a CPS in electrophysiological procedures, and the remarkable high incidence of debris found in the filters might offer future perspectives for preventing iatrogenic periprocedural stroke.

Conclusions

With increasing numbers of endocardial CA procedures, there is an increased potential for embolization of biological and foreign materials, with potentially severe subsequent complications such as periprocedural stroke. This is the first report assessing cerebral protection and debris capturing using the Sentinel CPS during endocardial VT ablation procedures. In this setting, the application of the CPS seems to be feasible and safe. With embolic debris found in every patient, this remarkable finding should alert all interventional electrophysiologists. It might lead to the development of more effective prevention of iatrogenic periprocedural stroke.

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