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CASE REPORT

TriGuard Embolic Protection Device in percutaneous cardiac interventions with intracavitary cardiac thrombosis: A case series

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Abstract

Embolic cerebral protection devices are not routinely used in clinical practice during electrophysiological interventions. We report a case series of patients with intracardiac thrombosis undergoing a percutaneous left atrial appendage (LAA) closure and a ventricular tachycardia (VT) catheter ablation supported by TriGuard 3 Cerebral Embolic Protection Device.

KEYWORDS
electrophysiology - clinical, new technology

1 | INTRODUCTION

Intracardiac thrombosis is a non-infrequent finding in patient undergoing percutaneous cardiac interventions. In these clinical setting, most of the procedures have to be temporarily deferred until the resolution of thrombus. Very recently, among patients candidate to undergo left atrial appendage (LAA) closure, the disappointing results provided by VKA/DOAC attempts to dissolve LAA thrombus have promoted alternative strategies, such as LAA closure with distal debris protection.[1,2] Drug-resistant, recurrent, or incessant ventricular tachycardia (VT) represents a strong indication to prompt intervention; in up to 25%[3] of cases both a left ventricular thrombosis and LAA thrombus may be detected. Without distal protection, in case of clot mobilization, a high risk of intraprocedural stroke or non-cerebral ischemic event has to be considered. The introduction of arterial filters has proven safe in managing these clinical conditions: few reports in literature show the placement of an embolic cerebral protection device: TriGuard Embolic Protection Device[4] and Sentinel cerebral protection system.[5,6] We describe our experience using TriGuard 3 Embolic Protection Device in six patients undergoing percutaneous LAA closure (PLAAC) with LAA thrombus and in two patients undergoing a VT catheter ablation having a LAA thrombus and a left ventricular thrombosis, respectively.

Abbreviations: ACT, activated clotting time; ASA, acetylsalicylic acid; DOAC, direct-acting oral anticoagulants; ICE, intracardiac echocardiography; INR, international normalized ratio; LAA, left atrial appendage; MRI, magnetic resonance imaging; PLAAC, percutaneous left atrial appendage closure; TOE, transesophageal echocardiography; VKA, vitamin K antagonist; VT, ventricular tachycardia.

2 | MATERIALS AND METHODS

We have retrospectively analyzed data from eight cases. All of them underwent a percutaneous cardiac intervention in our center supported by TriGuard 3 Cerebral Embolic Protection Device (Keystone Heart Ltd, Caesarea, IL, USA). This device is a nitinol frame mesh filter positioned into the aortic arch to cover all three sovraaortic arteries. It is introduced through an 8Fr sheath over a 0.035″ guide wire inserted into the left femoral artery and it is positioned under fluoroscopy guidance in the ascending arch, distal to the innominate artery.[7,8] An angiography with a pig-tail catheter inserted via sheath can be performed to visualize the anatomy of the aorta and its branches. The filter is radiopaque and the terminal part of the sheath has a radiopaque marker, so the device can be easily repositioned under fluoroscopy without lengthening intraprocedural times nor requiring an additional contrast agent. The pore size of the mesh is of 115*145 μm,

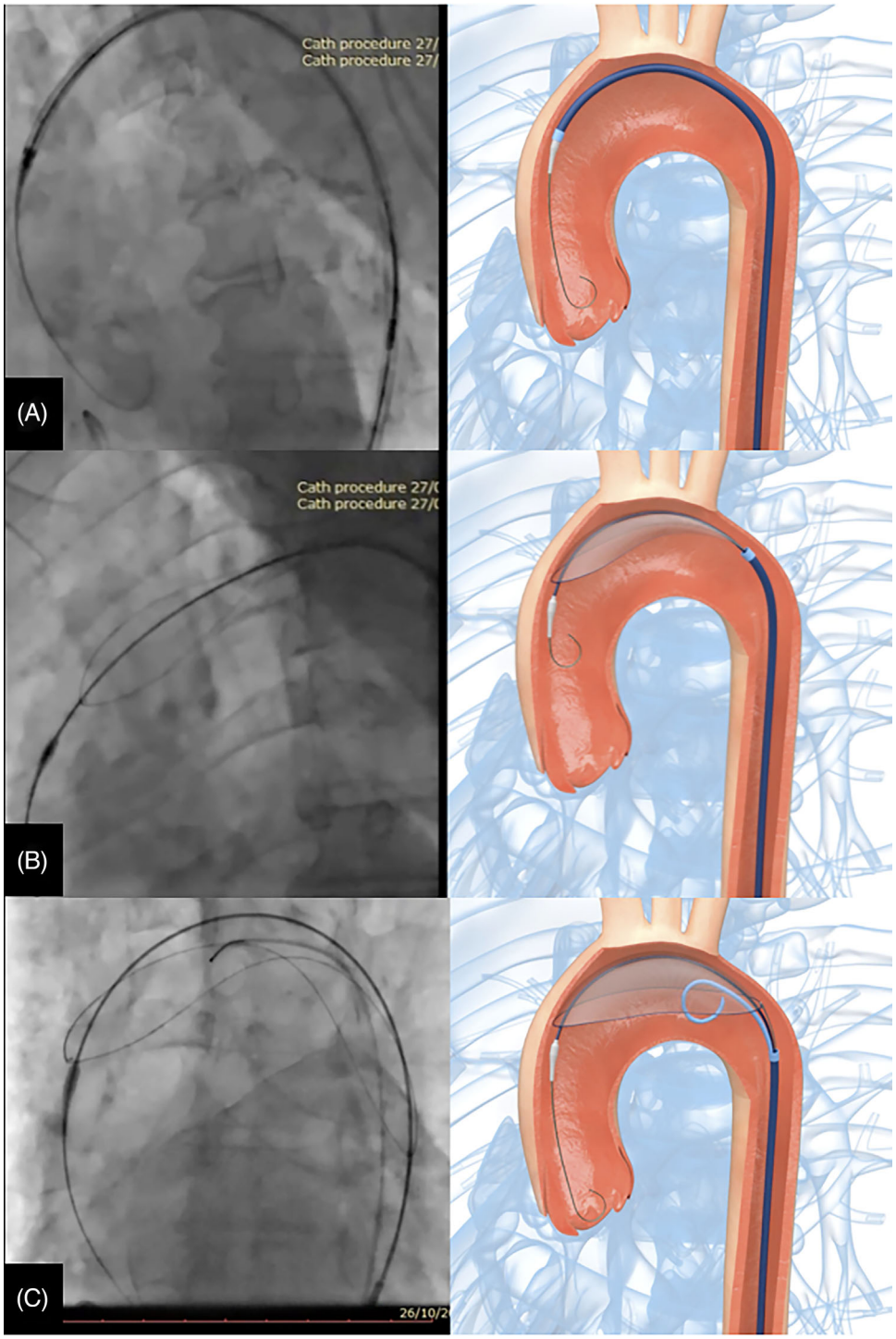


FIGURE 1 Different steps of TriGuard 3 placement. Images provided by courtesy of Keystone Heart Ltd. (A) Insertion. (B) Deployment. (C) Pigtail Insertion. [Color figure can be viewed at wileyonlinelibrary.com]

which allows the blood flow to the cerebral vessel; larger emboli are entrapped or diverted toward descending aorta.[7,8] Figure 1 illustrates procedural steps of TriGuard 3 placement.

The goal of using TriGuard 3 is the prevention of any thromboembolic event in the periprocedural setting with a low-risk of filter-related complications, such as vascular injury, dissection or perforation, particularly for aorta and sovra-aortic vessels.

2.1 | Case presentation

All eight patients had intracardiac thrombosis. Particularly, six of them underwent a PLAAC with thrombus (group 1) and two of them underwent a VT transcatheter ablation (group 2), with LAA and left ventricular thrombosis, respectively. Patients clinical features are reported in Table 1 for group 1 and in Table 2 for group 2.

TABLE 1 Clinical characteristics of patients who underwent a percutaneous left atrial appendage closure with thrombosis.

Patient	1	2	3	4	5	6
Sex	Female	Male	Male	Male	Male	Female
Age, years	77	44	68	40	73	81
Coronary artery disease	Yes	No	Yes	Yes	Yes	Yes
Arterial hypertension	Yes	No	Yes	Yes	Yes	Yes
Diabetes	No	No	Yes	Yes	Yes	No
Previous stroke	Ischemic	No	No	No	No	Ischemic
Renal failure	No	No	No	Yes	No	Yes
Left ventricular ejection fraction (%)	55	<35	<35	<35	<35	40
Atrial fibrillation	Permanent	Permanent	Persistent	Persistent	Persistent	Paroxysmal
CHA2DS2VASc	8	1	4	4	5	8
HAS-BLED	3	0	2	2	1	2
Antithrombotic therapy at the diagnosis of LAA thrombosis	ASA 100 mg/die + Coumadin (INR 2–3)	ASA 100 mg/die + Coumadin (INR 2–3)	Apixaban 5 mg bid	Apixaban 5 mg bid	Rivaroxaban 20 mg/die	Rivaroxaban 15 mg/die
Intensification of antithrombotic therapy before procedure	No	Yes, switch to ASA 100 mg/die + Pradaxa 150 mg bid (for 120 days)	Yes, switch to ASA 100 mg/die + Coumadin INR 2–3 (for 120 days)	Yes, switch to Coumadin INR 2–3 (for 45 days)	Yes, switch to Dabigatran 150 mg bid (for 60 days)	Yes, switch to Dabigatran 110 mg bid (for 15 days)
Antithrombotic therapy at the discharge	ASA 100 mg/die + Coumadin (INR 2–3)	ASA 100 mg/die + Pradaxa 150 mg bid	ASA 100 mg/die + Coumadin (INR 2–3)	Coumadin (INR 2–3)	Dabigatran 150 mg bid	Dabigatran 110 mg bid

TABLE 2 Clinical characteristics of patients in group 2.

Patient	7	8
Sex	Male	Male
Age, years	68	62
Coronary artery disease	No	Yes
Arterial hypertension	Yes	Yes
Diabetes	No	No
Previous stroke	No	No
Renal failure	Yes	No
Left ventricular ejection fraction (%)	<35	<35
Atrial fibrillation	Persistent	No
CHA2DS2VASc	5	3
HAS-BLED	3	0
Antithrombotic therapy at the discharge	Coumadin (INR 2–3)	Coumadin (INR 2–3)

In group-1 patients, LAA thrombosis was confirmed by a trans-esophageal echocardiogram (TOE) in four patients the thrombus was located in the distal third of LAA, whereas in the remaining two the thrombus extended to the middle third of the appendage.

All patients had been treated with anticoagulants at diagnosis and most of them underwent a further attempt to intensify anticoagulant therapy (also switching therapy), without success. Only patient number-1 remained on original treatment due to high HAS-BLED score. All the patients took intensified anticoagulant therapy for almost 45 days, save patient-7 which underwent an early PLAAC for recurrent cerebral ischemia. Baseline anti-thrombotic therapy and changes in therapy are reported in Table 1. The acute data and findings of percutaneous LAA closure procedures are described in Table 3.

In all but two patient the PLAAC procedure was guided by intracardiac echocardiography (ICE), by placing the ICE probe within left atrium as previously described by our group.[9] Left atrium was reached through trans-septal puncture and an activated clotting time (ACT) of more than 300 s was achieved in all patients. Auricolography was not performed due to embolization risk. All patients were implanted with Watchman FLX (Boston) and the device was successfully positioned in all patients without complications, using as much as possible a "one shot technique"; in only one patient the device had to be repositioned one time. The device sizing was obtained by matching ICE and previous TOE findings in terms of LAA landing zone and length. Figure 2 illustrates procedural steps of PLAAC. To avoid intraoperative thrombus dislodgement, a stepwise approach, largely based on continuous ICE monitoring has been followed (Figure 3). It consists of ICE guided trans-septal puncture and guidewire advancement within the left superior pulmonary vein; exchange with long delivery sheath; trans-septal crossing with the ICE probe, reaching the point allowing the best LAA view (usually at the LSPV ostium); LAA occluder sizing based

TABLE 3 Characteristics of percutaneous left atrial appendage closure procedures in group 1.

Patient	1	2	3	4	5	6
Cardiac rhythm	Atrial fibrillation	Atrial fibrillation	Atrial fibrillation	Atrial fibrillation	Atrial fibrillation	Sinus rhythm
Anesthesia	General anesthesia	Conscious sedation	General anesthesia	Conscious sedation	Conscious sedation	Conscious sedation
Imaging	Transesophageal echocardiogram	Intracardiac echocardiography	Transesophageal echocardiogram	Intracardiac echocardiography	Intracardiac echocardiography	Intracardiac echocardiography
Implanted device	Watchman FLX	Watchman FLX	Watchman FLX	Watchman FLX	Watchman FLX	Watchman FLX
Device size (mm)	27	27	35	31	27	24
Device deployment attempts	1	1	1	2	1	1
Auricolography	No	No	No	No	No	No
Skin-to-skin time (min)	90	60	70	120	100	60
Fluoroscopy time (min)	14.6	9.9	9	11.8	17	4
DAP (cGy*cm2)	3458	3700	670	8488	8928	436
Debris on filter	No	No	Yes	Yes	No	No

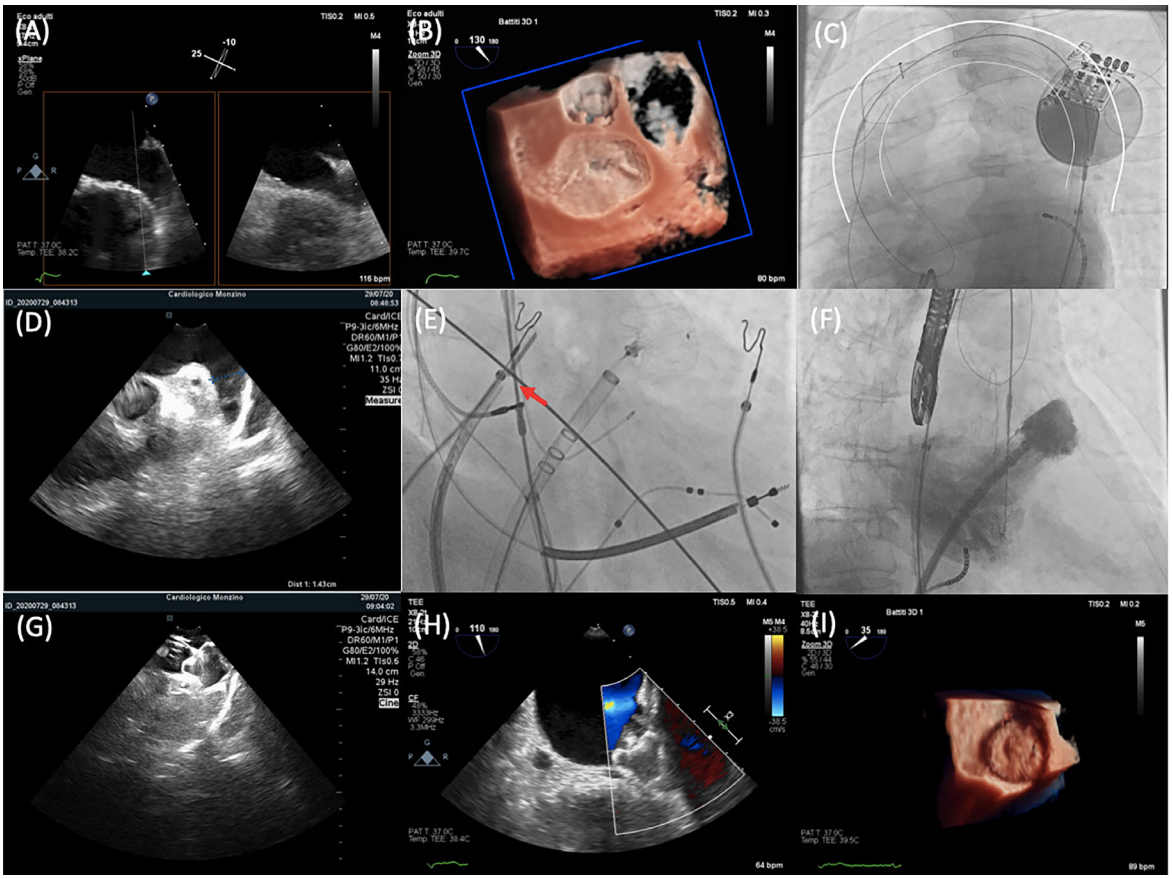


FIGURE 2 Representative images of percutaneous left atrial appendage (LAA) closure with Triguard. (A) Transesophageal echocardiography (TOE) study of LAA with 2D X-plane. (B) TOE study of LAA with 3D reconstructions. (C) Triguard is posizionated into the aortic arch (illustrated by white lines). (D) Intracardiac echocardiography (ICE) is used to obtain device size by measuring LAA. (E) Watchman FLX device delivery. The red arrow indicates ICE probe. (F) Final angiographic control of Watchman FLX device. (G) ICE control of Watchman FLX device. (H) TOE during follow-up reveals regular implantation of the device. Color-doppler do not show evidence of leak. (I) TOE with 3D reconstruction of LAA device. [Color figure can be viewed at wileyonlinelibrary.com]

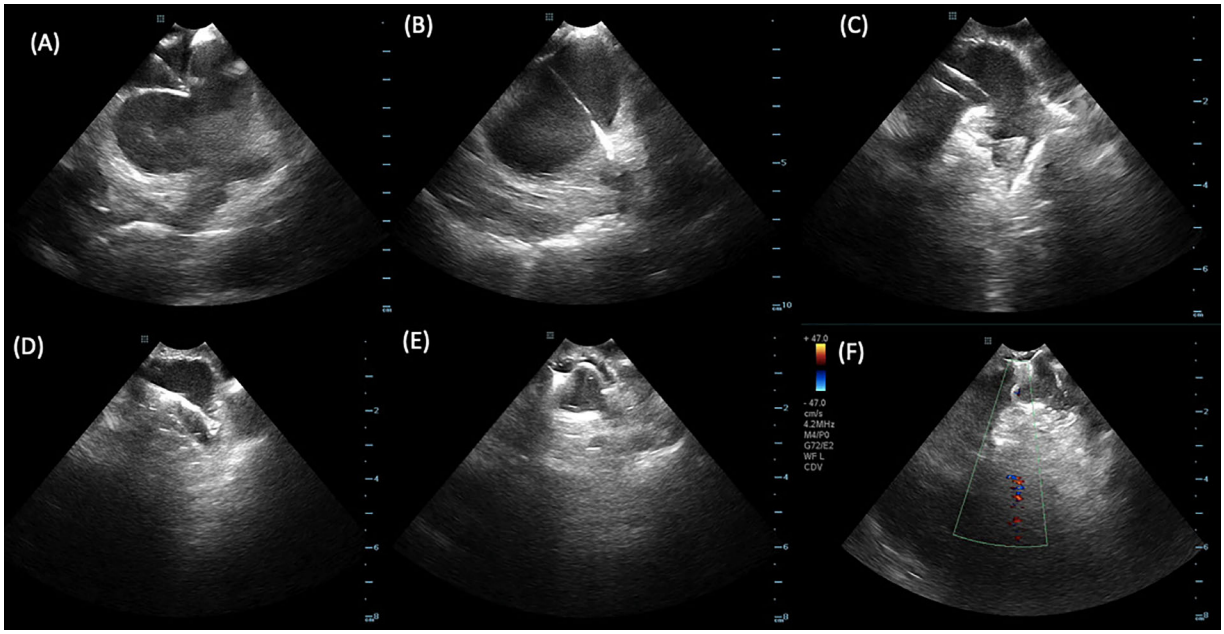
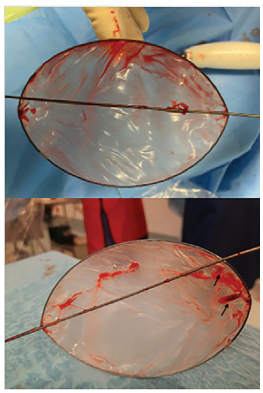


FIGURE 3 Step-by-step percutaneous left atrial appendage (LAA) closure with Watchman FLX device under intracardiac echocardiography (ICE). (A) Trans-septal puncture under ICE. (B) Guidewire positioning on the left superior pulmonary vein. (C) Delivery sheath is advanced into the left atrium. (D) Delivery sheath is placed into the proximal part of LAA. ICE probe is now into the left atrium to visualize better the LAA. (E) LAA occluder deploy. (F) The device has been opened and is now prepared for evaluation via tug test to confirm stability and color Doppler to exclude leaks. Subsequently, it will be released. [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 4 Characteristics of ventricular tachycardia catheter ablation procedures. On the right side, an image of two debris (arrows) on Triguard filter after VT catheter ablation in patient number-8. The maximum diameter of the largest was less than 1 mm.

Patient	7	8	
Cardiac rhythm	Ventricular tachycardia	Ventricular tachycardia	
Anesthesia	Conscious sedation	Conscious sedation	
Skin-to-skin time (min)	180	300	
Fluoroscopy time (min)	22.2	41.5	
DAP (cGy*cm2)	12778	5655	
Debris on filter	No	Yes	

on landing zone measurement and LAA occluder deploy under ICE monitoring.

Group-2 included patient number-7 with a LAA thrombosis and patient number-8 with a left ventricular thrombosis, at the left ventricular apex. Both patients had to undergo a left VT catheter ablation in the setting of electrical storm. In patient number-8 a special attention in catheter manipulation to avoid contact with the thrombus has been achieved thanks to ICE. The region-of-interest for ablation procedure (postero-lateral region) was relatively far from thrombus (left ventricular apex), nevertheless, two small clots debris was found in Triguard filter (image in Table 4). Characteristics of procedures are described in Table 4. Both patients took Coumadin and anticoagulant therapy has

not changed. All procedures were performed in conscious sedation; clinical VT termination was obtained in both patients.

As mentioned above, the goal of the combined procedures was the acute and delayed stroke (or any clinically overt thromboembolic event) prevention as well as the absence of filter-related complications. In both groups, no periprocedural stroke was observed as well as no complication associated with the device.

In group-1 a follow-up visit with TOE was performed after 45 days and no thromboembolic event was reported. TOE showed the regular implantation of the LAA device without evidence of device thrombosis or leak in all patients. A next follow-up visit at 6 months was made in both groups showing no evidence of thromboembolic or bleeding events. A change in anti-thrombotic therapy was observed in only two patients of group-1.

3 | DISCUSSION

To the best of our knowledge, this is the first report to describe a case series of PLAAC after the placement of TriGuard Cerebral Embolic Protection Device. Since LAA thrombus is usually a contraindication for LAA closure, patients should be informed that such intervention is not routinely performed (as not included in any recommendation). Despite the potential risk of thrombus dislodgement, the utilization of Watchman FLX device, as well as other similar devices, for LAAC in patients with thrombi remains a viable option, particularly when performed under ICE guidance and with appropriate catheter manipulation techniques to reduce the risk of embolism. A multicenter retrospective study demonstrated that the employment of the Amplatzer Amulet and Watchman FLX devices was viable and safe in the short-term.[10] A novel device the LAmbre as a two-part-device could potentially render it an optimal choice for LAAC in patients with thrombosis. This device incorporates a delivery sheath that does not extend to the distal LAA, thereby reducing the likelihood of embolism.[11,12]

In our setting, indication for LAA closure was on DOAC-recurrent stroke for patient number-1, whereas was an ultima ratio treatment option for the other patients. Our dates are consistent with an acute feasibility and safety of this procedure, without affecting the efficacy over the mid-term. There are also few reports in literature showing the placement of a cerebral protection device during a VT ablation.[13] We reported our experience with TriGuard filter in both clinical setting. Its strength is the possibility to cover all three sovraaortic arteries, so that no one cerebral artery is left unprotected. An alternative system as mentioned above is Sentinel cerebral protection system. It consists of two independent filters and it covers the brachio-cephalic artery and the left carotid artery, thus covering only two sovraaortic vessels. In contrast to TriGuard, it is introduced through the right radial artery. Limited data are reported in literature about TriGuard, whereas more data concerning Sentinel system are present. In particular, its use in PLAAC has been already proven effective.[5,6]

After the procedure, each filter was carefully removed and checked: we were able to find clot debris in two patients in group-1 and one patient in group-2 (image in Table 4). Subclinical micro-embolization was not systematically ruled out with magnetic resonance imaging (MRI) assessment; however, no clinical signs of distal embolization were observed.

In conclusion, the use of Triguard protection in patients with documented intracardiac thrombi undergoing percutaneous cardiac interventions is helpful in carrying out the procedure safely.

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DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no datasets were generated or analyzed during the current study.

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