Safety of an esophageal deviator for atrial fibrillation catheter ablation

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BACKGROUND Esophageal thermal injury is a complication of atrial fibrillation (AF) ablation, and it can be avoided by esophageal deviation during left atrial posterior wall radiofrequency catheter ablation.

OBJECTIVE This study aimed to evaluate the safety of a nitinol-based mechanical esophageal displacement device (MEDD) and its performance.

METHODS This preclinical safety study was conducted on 20 pigs, with 10 undergoing radiofrequency AF ablation using the MEDD and 10 serving as a control group under anticoagulation but without radiofrequency application. Esophageal traumatic injuries were classified from 0 to 4 and were grouped as absent (grade 0), minor (grade 1 or 2), moderate (grade 3), or major risk lesions (grade 4) by anatomopathological study. Grades 1 and 2 were considered acceptable. Fluoroscopy was used to measure displacement.

RESULTS Five (25%) pigs developed traumatic lesions, 4 with grade 1 and 1 with grade 2 (2-mm superficial ulcer). There was no difference in lesion occurrence between the radiofrequency and control groups (30% and 20%, respectively; $P = .43$). Under rightward displacement, the right edge moved 23.9 (interquartile range [IQR] 21.3–26.3) mm and the left edge moved 16.3 (IQR 13.8–18.4) mm ($P < .001$) from baseline. Under leftward displacement, the right edge moved 13.5 (IQR 10.9–15.3) mm and the left edge moved 16.5 (IQR 12.3–18.5) mm ($P = .07$). A perforation to the pharyngeal diverticulum occurred in 1 pig, related to an accidental extubation.

CONCLUSION In pigs, the MEDD demonstrated safety in relation to esophageal tissue, and successful deviation. Esophageal traumatic injuries were acceptable, but improper manipulation led to pharyngeal lesion.

KEYWORDS Atrial fibrillation; Catheter ablation; Complication; Esophageal injury; Esophageal deviator; Safety

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Introduction

Catheter ablation has become the most effective strategy in the treatment of atrial fibrillation (AF).[1] Compared with antiarrhythmic drugs, AF ablation has shown better outcomes with regard to symptom control and AF burden reduction.[2] In heart failure patients, AF ablation also reduces hospitalization and mortality.[3]

Although catheter ablation has a safe profile, rare major complications have been reported.[1] Esophageal thermal injury (ETI) leading to atrioesophageal fistula is the most feared complication due to high morbidity and mortality (55%).[4] The incidence of atrioesophageal fistula is very low, ranging from 0.02 to 0.11%,[1] and has been reported in all available energy sources used in clinical practice.[4] Esophageal perforations can be treated by endoscopic or surgical approaches.[4] In contrast, endoscopically detected ETI occurs in approximately 11% of AF ablations, and almost all of these recover within a few weeks.[5]

Many strategies to prevent ETI have been used in clinical practice, even though their value remains uncertain, and these strategies include reducing the power settings of radiofrequency (RF) in the left atrial posterior wall (LAPW), monitoring the esophageal temperature, and using proton pump inhibitors.[1] Devices have also been developed for esophageal deviation[6–12] and active cooling,[13,14] and these aim to protect the esophagus.

In particular, esophageal deviation uses different materials to deviate the esophagus. Although these deviators have been used to protect the esophagus from thermal injury, they are used with caution due to the potential for traumatic damage.[6]

The aim of the study was to evaluate the safety of a mechanical esophageal displacement device (MEDD) in a swine model using a histopathological study. We also evaluated the performance of the deviator using these study conditions.

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KEY FINDINGS

- The nitinol mechanical esophageal displacement device was considered safe to the esophagus in a swine model.
- The device demonstrated successful displacement of the swine esophagus.
- Proper device usage is crucial to prevent harm to pharyngeal structures.

Methods

Device

The MEDD consists of a preshaped nitinol deviator that was developed in our institution in 2016 (Figure 1A), and it is a prototype similar to the EsoSure deviator (Northeast Scientific, Waterbury, CT).[12] The device was designed by the Arrhythmia Unit and Bioengineering Lab in Heart Institute (InCor), University of São Paulo Medical School (São Paulo, Brazil), in partnership with the Aeronautics Institute of Technology (São José dos Campos, Brazil). The nitinol material is flexible in cold water (0°C), allowing it to be molded into a rectilinear shape, and in environments at a mammalian body temperature (35–37°C), it assumes a stiff preshaped S-shaped curvature, resembling a mandolin (Figure 1B). The nitinol rod is isolated by a silicone covering. The device has a single thermocouple esophageal temperature probe (Dixtal Biomédica, São Paulo, Brazil) attached to the mid portion of the curve on the concave side of the device and can deliver contrast medium via a separate lumen.

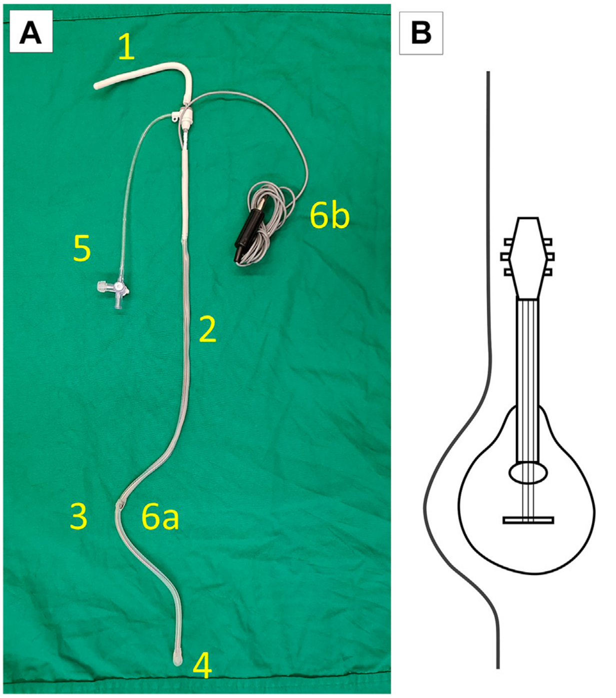

Figure 1 **A:** The esophageal displacement device used in the study: (1) handling rod; (2) nitinol rod covered by vulcanized silicone (proximal portion); (3) bending of the nitinol rod; (4) silicone tip; (5) access port for infusion of contrast through the device lumen; (6a) thermometer sensor; (6b) thermometer cable. **B:** Comparison with a mandolin.

Preclinical study

This study was approved by the Ethical Committee on Animal Use of the University of São Paulo, in accordance with the Guide for the Care and Use of Laboratory Animals. It was performed at the Experimental Lab at the Heart Institute (São Paulo, Brazil). The study consisted of 20 Landrace pigs weighing 25 to 35 kg that underwent MEDD insertion under general anesthesia and anticoagulation using a pulmonary vein isolation protocol (Figure 2). We performed pulmonary vein and left atrial (LA) 3-dimensional (3D) maps plus RF ablation in 10 pigs (MEDD-RF group) and only a 3D map without RF ablation in the other 10 pigs (MEDD only) in an alternating sequence. We aimed to exclude potential ETI in the MEDD-only group.

Procedure

All swine were premedicated, intubated, and mechanically ventilated with isoflurane (1%–3%) after overnight fasting. Veterinarians performed an oroesophageal intubation using a 9.0 endotracheal tube for the insertion of a MEDD through it. The patches of an electroanatomical mapping system (NavX EnSite; Abbott, St. Paul, MN) were positioned on the shaved bodies of the pigs. The pigs were in a straight supine position to visualize that the spinous processes were perfectly aligned.

We performed a puncture of the right jugular vein to insert a decapolar catheter (Inquiry; Abbott, St. Paul, MN) in the coronary sinus through a 7F sheet and a double puncture of the right femoral vein to insert 2 long 8F sheets (SL1 Swartz; Abbott, St. Paul, MN). We then performed transseptal punctures using a transseptal needle (Cook Medical, Bloomington, IN), placed a circular decapolar catheter (Abbott, St. Paul, MN) and an 8-mm therapeutic catheter (Abbott, St. Paul, MN) in the LA under a heparin infusion protocol (with an active clotting time of 300–350 seconds), followed by the creation of the 3D anatomical map of the LA and pulmonary veins.

The next step was to perform the iodinated contrast esophagogram at the basal position using an anteroposterior fluoroscopic view by passing a nasogastric tube through an orotracheal cannula directed to the esophagus (oroesophageal cannula). Then, a left atriogram was performed using the anteroposterior and lateral views to study the anatomical relationships, with the arterial phase registering the aortogram.

Before insertion of the MEDD, it was cooled and shaped into a rectilinear fashion. Then, it was inserted into the esophageal lumen through the oroesophageal cannula with an angle of rotation of its shaft aimed at achieving a rightward deviation. After a thermal balance was obtained, the MEDD assumed the S shape and was adjusted to achieve maximum rightward deviation at the level of the pulmonary vein ostia. Finally, a rightward esophagogram was obtained (Supplemental Video 1).

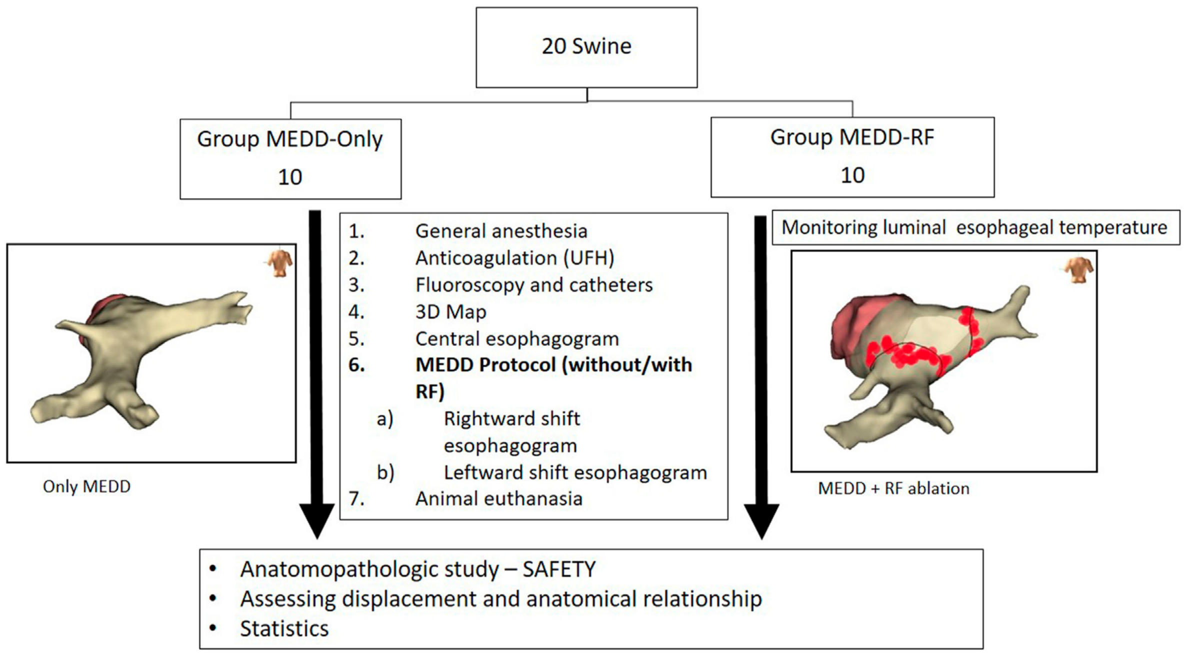

Figure 2 Experimental study design. 3D = 3-dimensional; MEDD = mechanical esophageal displacement device; MEDD-Only = mechanical esophageal displacement device only; MEDD-RF = mechanical esophageal displacement device with radiofrequency ablation; RF = radiofrequency; UFH = unfractionated heparin.

In the MEDD-RF group, we performed wide antral circumferential ablations of the left pulmonary veins using power settings of 55°C and 50 W anteriorly and 30 W on the LAPW. The luminal esophageal temperature (LET) was monitored during RF ablation.

After acquiring the set of lesions, the MEDD was removed, cooled again, and reinserted using the same sequence, but with the angle rotated 180° during the second insertion, aiming for a leftward deviation at the same level. Finally, a leftward esophagogram was obtained. In the MEDD-RF group, wide antral circumferential ablation was performed under LET monitoring. After that, we removed the MEDD and the esophageal tube from the esophagus. We also removed the catheters from the sheets. The total time for esophageal displacement was approximately 10 to 30 minutes for each side, with a longer duration observed in the pigs in the MEDD-RF group.

Euthanasia protocol

After catheter removal, the animals were euthanized. The pigs were in a deep surgical plane of anesthesia. An injection of potassium chloride, 75 to 150 mg/kg, was administered intravenously to induce cardiac arrest and death. This method is compatible with the American Veterinary Medical Association Guidelines on Euthanasia. After euthanasia, the thoracic cavities of the animals were opened by sternotomy, and we removed the esophagus, larynx, and laryngopharynx en bloc. These tissues were placed in formaldehyde and sent to pathology for pathological evaluation.

Assessing the esophageal injuries

After proper fixation in formaldehyde, the esophagus was opened in the longitudinal direction, and the mucosa and adventitia were directly inspected for any evidence of traumatic injury, as well as any ETIs in the MEDD-RF group. The retrocardiac segment of the esophagus was identified during the dissection, and according to a pre-established protocol, 3 esophageal samples, represented by 5-mm segmental rings, were taken: the first sample was taken just above the cranial edge of the heart (A1), the second sample was taken retrocardiac at the midpoint (A2), and the third sample was taken just below the caudal edge of the heart (A3). Any other esophageal segments that demonstrated any visible changes were also collected as suspicious extra samples.

The samples were processed for conventional histological study and stained with hematoxylin and eosin. The slides were microscopically inspected to find any histopathological signs of trauma or thermal injury. An expected characteristic of ETI is a gradient of injury along the esophageal wall, with a greater degree of damage in the adventitia compared with the inner layers. This is in contrast to the gradient of injury expected in traumatic injury, which typically involves damage from the lumen to the outer layers.

A score was created to grade the traumatic esophageal lesions from 0 to 4 using macro- and microscopy data: grade 0, no lesions; grade 1a, subepithelial cleavage and vascular congestion; grade 1b, erosion (lack continuity of the epithelium with exposure of the lamina propria) and mild hematoma; grade 2, superficial esophageal ulcer (up to the submucosal layer) and moderate hematoma; grade 3, deep

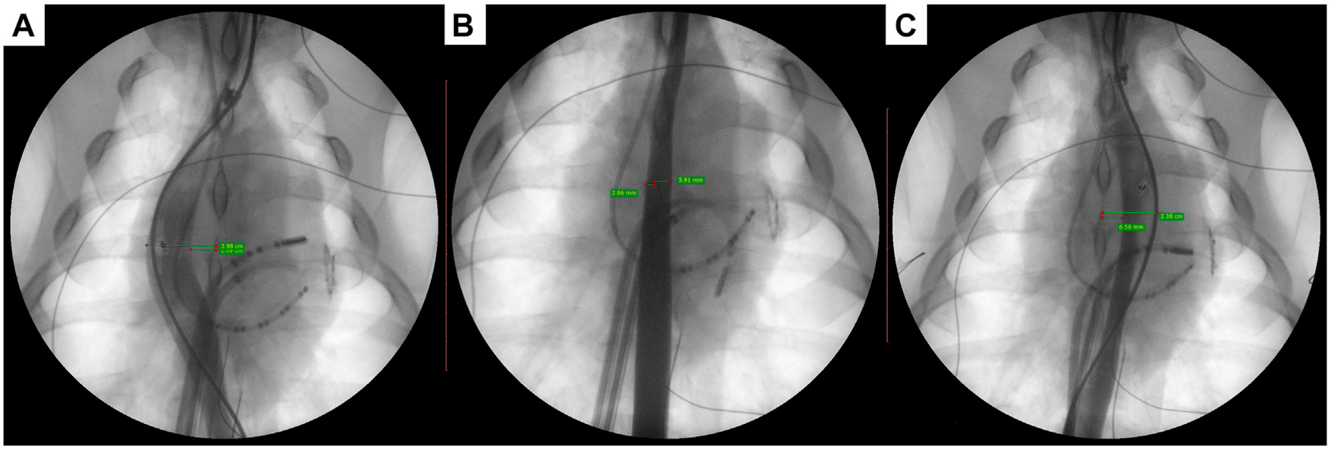

Figure 3 Anteroposterior fluoroscopic view of the esophagogram. **A:** Shifted to the right. **B:** Central. **C:** Shifted to the left.

esophageal ulcer (up to the muscularis propria) and severe hematoma; and grade 4, esophageal perforation.

Grade 1a, 1b, and 2 injuries were classified as low risk; grade 3 was moderate risk; and grade 4 was graded as a high-risk injury. Low-risk traumatic injuries were considered acceptable events, considering the low probability that they would progress to esophageal perforation.

MEDD safety was defined as the absence of traumatic esophageal injuries or the presence of acceptable traumatic injuries.

Assessing esophageal displacement

In the anteroposterior fluoroscopic view, esophagograms were obtained in 3 positions (Figure 3): central (Figure 3A), shifted to the right (Figure 3B), and shifted to the left (Figure 3C). The reference used to measure the displacement of the esophageal edges was at the level of the ostia of the pulmonary veins.

The measurements were performed using the RadiAnt DICOM Viewer program (Medixant, Poznan, Poland) after appropriate calibration.

The right and left edges of the contrasted esophageal lumen were positioned in a Cartesian coordinate system in which the abscissa was the laterolateral axis at the level of the pulmonary vein ostia, which was perpendicular to the median sagittal plane represented by the central line connecting the spinous processes of the porcine spine. This was the zero point.

Thus, the positions of each esophageal edge in the 3 esophagograms were obtained, which enabled the analysis of the shift of the edges in the laterolateral axis, considering that the convexity of the MEDD maintained the contact by pushing only the side that was related to the deviation, while the other edge was passively trailed.

Assessing the LA-esophagus anatomical relationship

The anatomical relationship between the LA, esophagus, and aorta was evaluated through LA and aortogram imaging, as well as by gross pathology examination.

Statistics

We used the Shapiro-Wilk test for continuous variables, which were expressed as the mean ± SD if they met the normality criteria or the median and interquartile range (IQR) if they did not. The Wilcoxon signed rank test was used to compare the data related to edge displacement. The chi-square test was used to compare the categorical data. A P value $<.05$ was used to demonstrate statistical significance. For statistical analysis, we used SPSS version 25.0 (IBM Corporation, Armonk, NY).

Results

Anatomopathological study

All pigs underwent the procedure with all of the steps of the protocol as allocated for the study groups. The median weight of the pigs was 32 (IQR 30–35) kg.

Safety assessment

Traumatic esophageal lesions were found in 5 (25%) pigs: 2 of them (10%) were visualized macroscopically and 3 (15%) were identifiable only under microscopy. All identified lesions were considered acceptable. The pigs were classified based on the highest degree of traumatic injury, with 3 classified as grade 1a, 1 as grade 1b, and 1 as grade 2. There was no evidence of thermal injury in the MEDD-RF group. There was no difference in the occurrence of injuries between the MEDD-RF and MEDD-only groups (30% and 20%, respectively; P = .43) (Table 1). Four of the 10 suspicious extra samples corresponded to intact and large esophageal vessels in histopathology.

Detailed assessment of the traumatic injuries

The traumatic esophageal injuries found in the anatomopathological study are reported in Table 2 and are presented in Figures 4 and 5.

Assessing esophageal displacement

The median retrocardiac esophageal diameter found on the central esophagogram was 10.9 (IQR 8.4–12.8) mm. Under

Table 1 Proportion of esophageal traumatic injuries found and analyzed after stratifying by study group

	Total (N = 20)	MEDD-RF (n = 10)	MEDD only (n = 10)	*P**
Grade 0	15 (75)	7 (70)	8 (80)	.43†
Grade 1	4 (20)	2 (20)	2 (20)	
Grade 2	1 (5)	1 (10)	0	
Grade 3	0	0	0	
Grade 4	0	0	0	

Values are n (%).
MEDD = mechanical esophageal displacement device; MEDD-RF = mechanical esophageal displacement device with radiofrequency.
*Likelihood ratio chi-square test.

rightward displacement, the pushed right edge shifted 23.9 (IQR 21.3–26.3) mm and the trailing left edge shifted 16.3 (IQR 13.8–18.4) mm ($P < .001$) in relation to the basal position of the central esophagus. Under leftward displacement, the trailed right edge shifted 13.5 (IQR 10.9–15.3) mm and the pushed left edge shifted 16.5 (IQR 12.3–18.5) mm ($P = .07$). The pushed edges shifted more than the trailed edges, which is what was expected in an elastic structure.

From another point of view, when comparing the lateral displacement inside the mediastinum, the rightward deviation was greater than the leftward deviation for the pushed edges ($P < .001$) and the trailing edges ($P = .004$), as seen in Table 3.

Assessing the LA-esophagus anatomical relationship

The LA was always found in the left hemithorax and to the left of the esophagus. In the left lateral view, the median distance that was measured between the LAPW and the esophagus was 29.1 (IQR 26.1–31.8) mm, which represented the absence of contiguity between these structures in the porcine thorax. In fact, no increase in the LET was observed in the MEDD-RF group during any RF ablation point.

Pigs have smaller atria relative to their cardiac mass.[15] We noticed that the majority of LA volume in pigs is represented by the LA appendage, and the arrangement of porcine pulmonary veins differs from that in humans. The right veins form a single long trunk that crosses the midline, while the inferior left vein is the largest and caudally directed, with an angle of almost 90° to the superior left vein, as described in the swine anatomy atlas.[16]

Although the tissue constitution of the porcine esophagus is similar to that of the human esophagus, it has a craniocaudal arrangement.[16] Specifically, the aortogram and gross pathology examinations confirmed that the descending thoracic

Table 2 The traumatic injuries in the anatomopathological study and the swine classification

		Anatomopathological study			
			Microscopy		
Swine	Group	Macroscopy	Description	Lesion grade	Swine grade
5	MEDD only	Normal (figure 4A)	A1: subepithelial cleavage corresponding to 42% of the circumference (Figure 5A)	1a	1a
6	MEDD-RF	Mild hematoma in the adventitia in the proximal portion of the esophagus (Figure 4B)	A1: polymorphonuclear perivascular infiltrate and leukocyte marginalization in an area of edema (Figure 5B)	1a	1b
			E1: recent mild adventitial hemorrhage	1b	
			E2: recent mild adventitial hemorrhage (Figure 5C)	1b	
8	MEDD-RF	A 2 mm superficial ulcer at the level of the cranial edge of the heart (Figure 4C)	A1: Superficial ulcer with subepithelial and periglandular neutrophilic infiltrate, mucus shedding, mild hematoma (Figure 5D)	2	2
			A2: subepithelial cleavage corresponding to 6% of the circumference (Figure 5E)	1a	
13	MEDD only	Normal	A3: subepithelial cleavage corresponding to 4% of the circumference (Figure 5F)	1a	1a
14	MEDD-RF	Normal	A2: subepithelial cleavage corresponding to 3% of the circumference	1a	1a

MEDD = mechanical esophageal displacement device; MEDD-RF = mechanical esophageal displacement device with radiofrequency.

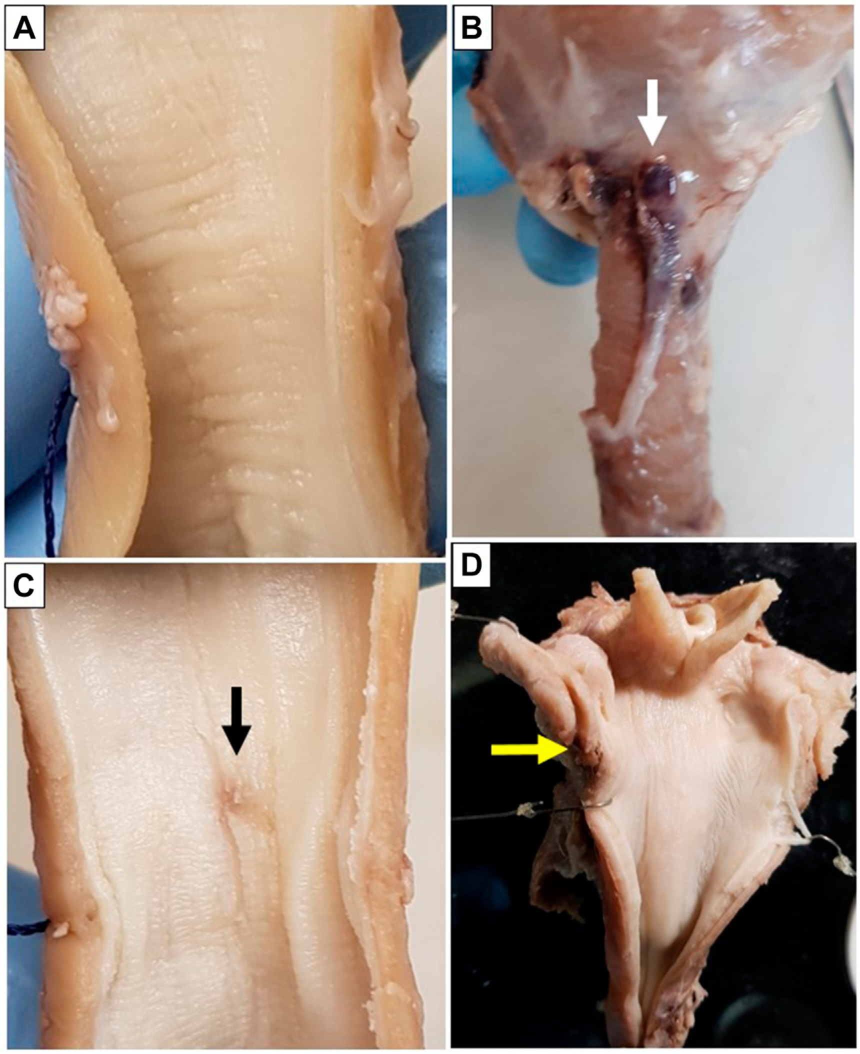

Figure 4 Macroscopy of the esophagus. **A:** Swine 5, normal. **B:** Swine 6, hematoma in the adventitia (white arrow). **C:** Swine 8, superficial ulcer (black arrow). **D:** Swine 10, perforation of the pharyngeal diverticulum (yellow arrow).

aorta is positioned to the left of the esophagus, contributing to a greater rightward displacement compared with the leftward displacement.

Adverse events in the experiments

Intercurrences occurred in 2 experiments. In pig 5, there was a pericardial tamponade related to an accidental transeptal puncture. Relief pericardiocentesis was performed, and then all of the protocol stages in this animal were performed successfully.

An accidental extubation occurred in pig number 10 due to accidental traction of the cannula. For orotracheal reintubation, it was necessary to remove the oroesophageal cannula. However, the veterinarian reinserted this cannula incorrectly, and the reinsertion of the deviator led to the perforation of the pharyngeal diverticulum, a swine anatomical structure (Figure 4D). The team noticed this and a correct insertion was performed.

Discussion

Evidence in esophageal deviators

This is the first study in animals that assessed the safety of a mechanical deviator using a histopathological study to evaluate trauma to the esophagus and adjacent structures.

Many esophageal deviators have been tested in the last 2 decades using available tools not designed to this role and devices specifically designed to be MEDD during AF ablation.

Herweg and colleagues[10] demonstrated successful esophageal deviations without injury using transesophageal echocardiography. Chugh and colleagues[11] employed an esophagogastroduodenoscopy (EGD) probe for deviation without complications.

In a pilot study, Koruth and colleagues[6] used a stylet through a chest tube for esophageal deviation, but this led to esophageal trauma in 63% of cases, including moderate injuries and an esophageal ulcer. The traumatic esophageal injuries found in this study aroused interest in our group for the

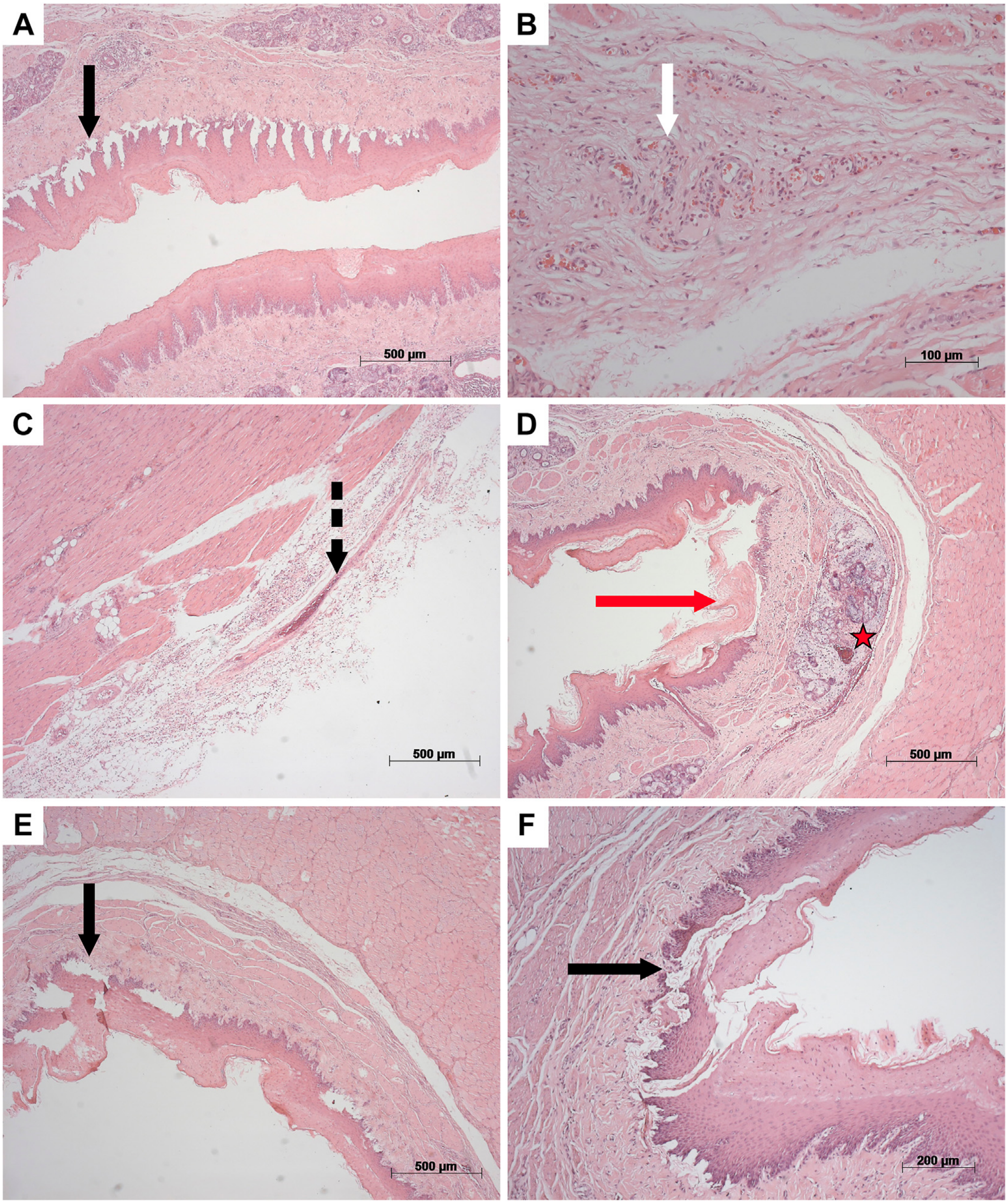

Figure 5 Histopathological study. **A:** Subepithelial cleavage (black arrow) in swine 5. **B:** PMN infiltrate (white arrow) in swine 6. **C:** Recent mild adventitia hematoma (dotted arrow) in swine 6. **D:** Superficial ulcer (red arrow) and periglandular neutrophilic infiltrate (red star) in swine 8. **E, F:** Subepithelial cleavage (black arrows) in swine 8 and 13.

development of a safe MEDD. The same group further evaluated the technique in 114 patients, revealing an inverse correlation between deviation magnitude and increase in the LET. However, some patients experienced significant oropharyngeal discomfort due to stylet manipulation.[7]

Pachón Mateos and colleagues[9] evaluated a transesophageal echocardiography probe for deviation in 704 patients, showing good efficacy and safety. Among the 8 patients undergoing EGD for esophageal symptoms, minimal bleeding from superficial linear lesions occurred in 2 cases.[9]

Few mechanical esophageal displacement devices have been developed for clinical use, such as the DV8 Balloon Retractor (Manual Surgical Sciences, Minneapolis, MN), which demonstrated effective esophageal deviation, although 2 pharyngeal bleeding events were observed.[8] Another device, the preshaped nitinol esophageal deviator EsoSure, showed successful deviation with lower LET increase during RF ablation compared with the control group.[12] However, some patients experienced transient odynophagia.[12] Additionally, a recently described esophageal retractor

Table 3 Analysis of the displacement of the pushed and trailing esophageal edges when comparing the rightward displacement and the leftward displacement

	Rightward displacement	Leftward displacement	*P**
Pushed edges			
Scenario	Right edge pushed right	Left edge pushed left	
Shift, mm	23.9 (21.3–26.3)	16.5 (12.3–18.5)	<.001
Trailing edges			
Scenario	Left edge trailed to the right	Right edge trailed to the left	
Shift, mm	16.3 (13.8–18.4)	13.5 (10.9–15.3)	.004

Values are median (interquartile range).
*Wilcoxon signed rank test.

utilizing vacuum suction and mechanical deflection demonstrated promising safety performance in a small case series.[17]

Methodology

Traumatic injury classification was based on consensus from pathologists and surgeons, as well as from references for various esophageal lesions.[18,19] We considered an unacceptable lesion a deep ulcer or a more invasive injury using the experience acquired from performing routine EGDs postablation in our service. These criteria were later supported by studies identifying thermal deep ulcers as precursors of esophageal perforation.[20]

The MEDD developed by our institution shares nitinol technology with EsoSure but differs in several aspects. First, the MEDD has a unique mandolin shape, while EsoSure is sinusoidal. Second, our MEDD is covered by silicone and inserted through an oroesophageal tube, while EsoSure uses an orogastric tube. Third, changing the deviation side of our MEDD requires removal and reinsertion, whereas EsoSure is movable inside the orogastric tube. Last, the Heart Institute's MEDD has a thermometer and an infusion port for contrast.

When designing the MEDD, we considered that a rightward deviation of the esophagus could provide enough distance from the left pulmonary veins for isolation and avoid thermal injury in the human esophagus. Similarly, a leftward deviation could avoid ETI during isolation of the right pulmonary veins. However, the MEDD would need to be disposed inside the esophagus in 2 opposite angles of rotation of its shaft to achieve this.

We hypothesized that the least traumatic method to change the side of deviation would involve removing and reinserting the MEDD, as described previously. However, we did not test the rotation of the S-shaped MEDD by 180° inside the esophagus, and we do not know if the main risk of traumatic injury is during insertion or withdrawal of the MEDD.

Findings

Our study found acceptable esophageal trauma from the MEDD. The observed esophageal lesions included a small superficial ulcer and a mild hematoma, the most severe among the identified injuries, contrasting with subepithelial cleavage in 3 other pigs. Another experimental study reported serosal ecchymosis in 1 pig and 1 canine from a group of dogs and pigs with LA ablations performed using EsoSure.[21]

We also encountered a perforation of the pharyngoesophageal diverticulum, which could have had important clinical implications due to its severity. This complication that occurred outside of the study protocol cannot be considered irrelevant. Despite this single adverse event, we considered that the use of MEDD had a very short learning curve.

Regarding shift measurements, we observed a displacement of the trailing edges by 13 to 16 mm, deemed satisfactory and consistent with the swine model utilized in our study. Although the literature lacks exact displacement studies, some suggest a safe distance of at least 20 mm between the trailing esophageal edge and the ablation line in humans.[7,12] Unfortunately, in the swine model, this measurement could not be performed due to the distance between the structures.

Limitations

The pig anatomy limits accurate replication of the LA-esophagus relationship during AF ablation in humans due to a greater esophagus-to-LA distance in pigs (approximately 29 mm) compared with humans (often <5 mm).[22] Additionally, the lower weight of the pigs poses a limitation, as it differs from the weight of an adult human.

Moreover, the absence of swine EGD prior to the experiment hindered the identification of previous peptic lesions. Uncertainty about the clinical significance of subepithelial cleavage existed, as it could be an artifact induced during organ harvesting or a previous unrelated injury. Another limitation was the absence of a group subjected to pulmonary vein isolation without using the MEDD.

As a preclinical study, our safety assessment cannot directly translate into clinical safety for this device. A dedicated clinical trial is needed for a comprehensive evaluation of safety and efficacy.

Clinical Implications

Our study enhances understanding of MEDD biomechanics and gastrointestinal interactions. The results endorse the esophageal safety concept of using MEDDs designed for this purpose while acknowledging possible trauma to pharyngeal structures.[7,8,12]

This study sheds light on unresolved issues in thermal energy sources for AF ablation, even with high expectations for the results of randomized clinical trials involving pulsed-field ablation. Our findings may facilitate better understanding and utilization of the esophageal deviators.

Conclusion

In the swine model, the application of a nitinol preshaped esophageal deviator using this specific protocol demonstrated the device's safety in relation to esophageal tissue, meeting the pre-established safety criteria. The resulting traumatic injuries to the esophagus were deemed acceptable, with most of these lesions only detectable under careful microscopic examination. However, it is essential to handle the device correctly, as improper manipulation was associated with a serious complication to pharyngeal tissue, highlighting the potential for harm. The device achieved a satisfactory deviation of the esophagus, which was consistent with the swine model used. However, further evaluation of its efficacy needs to be addressed through a clinical trial.

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Ethics Statement: This study was approved by the Ethical Committee on Animal Use of the University of São Paulo, in accordance with the Guide for the Care and Use of Laboratory Animals.

References

1. Calkins H, Hindricks G, Cappato R, et al. 2017 HRS/EHRA/ECAS/APHRS/SOLAECE Expert Consensus Statement on catheter and surgical ablation of atrial fibrillation. Heart Rhythm 2017;14:e275–e444.
2. Asad ZUA, Yousif A, Khan MS, Al-Khatib SM, Stavrakis S. Catheter ablation versus medical therapy for atrial fibrillation: a systematic review and meta-analysis of randomized controlled trials. Circ Arrhythm Electrophysiol 2019;12:e007414.
3. Marrouche NF, Kheirkhahan M, Brachmann J. Catheter ablation for atrial fibrillation with heart failure. N Engl J Med 2018;379:490–492.
4. Han HC, Ha FJ, Sanders P, et al. Atrioesophageal fistula: clinical presentation, procedural characteristics, diagnostic investigations, and treatment outcomes. Circ Arrhythm Electrophysiol 2017;10:e005579.
5. Ha FJ, Han HC, Sanders P, et al. Prevalence and prevention of oesophageal injury during atrial fibrillation ablation: a systematic review and meta-analysis. Europace 2019;21:80–90.
6. Koruth JS, Reddy VY, Miller MA, et al. Mechanical esophageal displacement during catheter ablation for atrial fibrillation. J Cardiovasc Electrophysiol 2012;23:147–154.
7. Palaniswamy C, Koruth JS, Mittnacht AJ, et al. The extent of mechanical esophageal deviation to avoid esophageal heating during catheter ablation of atrial fibrillation. J Am Coll Cardiol EP 2017;3:1146–1154.
8. Bhardwaj R, Naniwadekar A, Whang W, et al. Esophageal deviation during atrial fibrillation ablation: clinical experience with a dedicated esophageal balloon retractor. J Am Coll Cardiol EP 2018;4:1020–1030.
9. Pachón Mateos JC, Mateos EI, Pena TG, et al. Simplified method for esophagus protection during radiofrequency catheter ablation of atrial fibrillation–prospective study of 704 cases. Rev Bras Cir Cardiovasc 2015;30:139–147.
10. Herweg B, Johnson N, Postler G, et al. Mechanical esophageal deflection during ablation of atrial fibrillation. Pacing Clin Electrophysiol 2006;29:957–961.
11. Chugh A, Rubenstein J, Good E, et al. Mechanical displacement of the esophagus in patients undergoing left atrial ablation of atrial fibrillation. Heart Rhythm 2009;6:319–322.
12. Parikh V, Swarup V, Hantla J, et al. Feasibility, safety, and efficacy of a novel preshaped nitinol esophageal deviator to successfully deflect the esophagus and ablate left atrium without esophageal temperature rise during atrial fibrillation ablation: the DEFLECT GUT study. Heart Rhythm 2018;15:1321–1327.
13. Leung LW, Gallagher MM, Santangeli P, et al. Esophageal cooling for protection during left atrial ablation: a systematic review and meta-analysis. J Interv Card Electrophysiol 2020;59:347–355.
14. Leung LWM, Bajpai A, Zuberi Z, et al. Randomized comparison of oesophageal protection with a temperature control device: results of the impact study. Europace 2021;23:205–215.
15. Shah A, Goerlich CE, Pasrija C, et al. Anatomical differences between human and pig hearts and their relevance for cardiac xenotransplantation surgical technique. J Am Coll Cardiol Case Rep 2022;4:1049–1052.
16. McCrackin MA, Swindle MM. Gastrointestinal procedures. In: Swindle MM, Smith AC, eds. Swine in the Laboratory: Surgery, Anesthesia, Imaging, and Experimental Techniques, 3rd ed. Boca Raton, FL: CRC Press; 2016. p. 105–134.
17. Aguinaga L, Palazzo A, Bravo A, et al. Esophageal deviation with vacuum suction and mechanical deflection during ablation of atrial fibrillation: first in man evaluation. J Cardiovasc Electrophysiol 2021;32:67–70.
18. Sakata Y, Tsuruoka N, Shimoda R, et al. Comparison of clinical characteristics of patients with acute esophageal mucosal lesion and those with severe reflux esophagitis. Digestion 2019;99:275–282.
19. Ain QU, Jamil M, Safian HA, et al. Assessing the degree of acute esophageal injury secondary to corrosive intake: insights from a public sector hospitals of a developing country. Cureus 2020;12:e10858.
20. Yarlagadda B, Deneke T, Turagam M, et al. Temporal relationships between esophageal injury type and progression in patients undergoing atrial fibrillation catheter ablation. Heart Rhythm 2019;16:204–212.
21. Wang S, Matthew JS, Lehmann I, et al. The feasibility and safety of a novel displacement device in protecting the esophagus during radiofrequency ablation of left atrial targets. Heart Rhythm 2017;14:S514–S563.
22. Sanchez-Quintana D, Cabrera JA, et al. Anatomic relations between the esophagus and left atrium and relevance for ablation of atrial fibrillation. Circulation 2005;112:1400–1405.