Transcatheter Occlusion of Patent Ductus Arteriosus using a Canine Ductal Occluder in Dogs

F. Porciello, D. Caivano, M.E. Giorgi, P. Knafelz, M. Rishniw, N.S. Moise, A. Bufalari, A. Fruganti, and F. Birettoni

Background: Transcatheter occlusion of patent ductus arteriosus (PDA) is usually performed by fluoroscopy alone or together with transesophageal echocardiography (TEE). Transthoracic echocardiography (TTE) guidance has been used for deployment of Amplatz Canine Ductal Occluder (ACDO), but sometimes is limited by suboptimal acoustic windows. Transesophageal echocardiography can overcome such issues and provides higher image resolution at the level of the great vessels.

Objectives: To determine if TEE without fluoroscopy could be used to successfully perform ductal occlusion for the treatment of PDA in dogs.

Animals: Twenty client-owned dogs with PDA.

Methods: A prospective consecutive case series of PDA occlusion was performed using only TEE guidance. Dogs were positioned in right lateral recumbency and the TEE probe was positioned to visualize the descending aorta, PDA, and pulmonary artery. The guide wire, long introducer sheath, and ACDO were imaged by TEE to direct deployment.

Results: Ductal occlusion was performed successfully without need for fluoroscopy and without complications in 19 dogs. One dog required a second larger ACDO because of embolization of the first device 18 hours after positioning.

Conclusions and Clinical Importance: We have demonstrated that TEE monitoring without concurrent fluoroscopy can guide each step of transcatheter ACDO embolization thereby providing an alternate method of visualization for this procedure. Use of TEE alone can reduce radiation exposure or is an option when fluoroscopy is not available, and, therefore, should be evaluated in a larger case series to better assess procedural failure rates.

Key words: Canine; Congenital cardiac disease; Interventional cardiac procedures; PDA.

Transcatheter closure of persistent ductus arteriosus (PDA) is routinely performed in human and veterinary medicine. Although fluoroscopic guidance during a ductal occlusion is considered the standard, the recognition and application of alternative methods has merit worldwide. Transthoracic echocardiography (TTE) has been shown to be an effective substitute; however, transesophageal echocardiography offers better image quality.

Echocardiography should be considered as a viable method for guiding the transcatheter closure for several reasons. First, fluoroscopy is not available in all countries whereby the demand for treatment of dogs with a PDA is requested. Second, appropriate regulations for monitoring the radiation exposure may not be standardized to insure the safety of the veterinary personnel. Moreover, several studies have identified odds ratios of radiation-associated lens damage 3–4 times higher, or increased lifetime cancer risk, in interventional cardiologists than in cardiologists not involved in such procedures. In addition, a small study has observed a disproportionate number of left-hemisphere brain tumors (85%) in interventional cardiologists, presumably because of positioning of the image screens to the right of most interventionalists and consequent increased exposure of the left side of the head. In an effort to adhere to the principle of limiting radiation exposure to a level “as low as reasonably achievable” (ALARA), investigators have searched for alternative diagnostic procedures that do not involve ionizing radiation exposure—eg, ultrasonography or magnetic resonance imaging—or by educating personnel involved in the procedure. It is clear that reducing exposure to zero provides the best solution for adhering to the ALARA principle. In addition, recent international assessment has revealed greater exposure in junior staff cardiologists because of longer procedures—something that is likely applicable to veterinary cardiologists as well. Finally, while TEE

Abbreviations:
ACDO Amplatz Canine Ductal Occluder
PDA patent ductus arteriosus
TEE transesophageal echocardiography
TTE transthoracic echocardiography

From the Department of Veterinary Medicine, University of Perugia, Perugia, Italy (Porciello, Caivano, Giorgi, Bufalari, Birettoni); the Veterinary Hospital “Gregorio VII”, Rome, Italy (Knafelz); the Veterinary Information Network, Davis, CA (Rishniw); the Department of Clinical Sciences, College of Veterinary Medicine, Cornell University, Ithaca, NY (Moise); and the Department of Veterinary Medicine, University of Camerino, Matelica, Italy (Fruganti).

This study was performed at the Department of Veterinary Medicine, University of Perugia, Perugia, Italy; Veterinary Hospital “Gregorio VII”, Rome, Italy and Department of Veterinary Medicine, University of Camerino, Matelica, Italy.

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Corresponding author: F. Porciello, Department of Veterinary Medicine, University of Perugia, Via San Costanzo, 4 – 06126 Perugia, Italy; e-mail: francesco.porciello@unipg.it.

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equipment is expensive, most veterinary schools and veterinary cardiologists have echocardiographic capabilities and potential to add TEE, but do not necessarily have access to fluoroscopy (personal communications with representatives in Asia-Pacific countries, Brazil, China, Iran). In such situations, clinicians must resort to surgical occlusion of PDA.

Transesophageal echocardiography has proven useful in evaluating PDA morphology thereby guiding appropriate device selection,8,9 and TEE in combination with fluoroscopy, has been used to guide trans-catheter coil embolization and for deployment of Amplatz Canine Ductal Occluder (ACDO) in dogs.9,10 Recently, investigators examined the combined use of TEE and fluoroscopy to guide PDA occlusion using ACDO in 80 dogs.11 Using 2 screens (1 each for TEE and fluoroscopic imaging) to simultaneously monitor the procedures, they found that TEE provided complete monitoring of the entire procedure in 73/80 (91%) dogs.11 Furthermore, studies in humans illustrate the important role of TEE during interventional cardiovascular procedures in positioning of guide wires, catheters, and devices.12–16 The use of TEE reduces the duration of fluoroscopic time required to perform interventional procedures,9–11 and TEE has been used exclusively for PDA embolization in 3 pre-term infants on the neonatal intensive care unit.17 We recently described the use of TTE as the sole means of guiding, positioning, and deploying ACDO during PDA occlusion in dogs, but noted some limitations in the appropriate visualization of the PDA in dogs with suboptimal acoustic windows.1 However, TEE avoids the issue of suboptimal transthoracic acoustic windows and provides higher image resolution of cardiovascular anatomy and interventional devices.

Therefore, we hypothesized that TEE alone would permit successful visualization of cardiovascular structures and interventional devices and subsequent deployment of ACDO to occlude PDA.

Animals, Materials, and Methods

Twenty dogs consecutively identified with a PDA and recruited prospectively underwent PDA occlusion with an ACDO device from December 2011 to February 2014. All clients were informed of therapeutic options and formally consented to the therapeutic plan.

All dogs were diagnosed with PDA on the basis of physical examination, radiography, and TTE. A complete TTE study was performed with 1 of 3 echocardiographs (MyLab 30 Vet Gold, b MyLab Class C, b MyLab 70) using electronic sector-scanning transducers (frequency range: 2–11 MHz).

Ductal shape and minimal ductal diameter at the pulmonic ostium were assessed by TTE from right parasternal short-axis and left cranial parasternal views. All imaging studies were submitted for evaluation to a single cardiologist (FP) who then determined the ductal measurements and ACDO size for each dog.

Dogs were anesthetized by premedication with midazolam (0.2 mg/kg IV) and pentidine (5 mg/kg IV), induction with propofol (3–4 mg/kg IV) and maintenance, after endotracheal intubation, with sufentanil CRI (0.2–1 μg/kg/h) and isoflurane. Cefazolin (30 mg/kg SC) was administered before induction, repeated after 8 hours and continued for 5 days every 12 hours.

Dogs were placed in right lateral recumbency and 1 of the investigators performed a TEE study to confirm the PDA morphology and dimensions (Fig 1). A lubricated 14 mm TEE probe (TEE 022 Multiplane cardiac phased array probe) was advanced transorally to a midesophageal position with minimal force until a long-axis 4-chamber view was obtained (transverse plane). After viewing a long-axis 4-chamber transverse image, with the ultrasonic beam oriented approximately 80° from the sagittal plane, the probe was fully retroflexed and withdrawn to a cranial esophageal position to visualize the descending aorta in cross-section. The PDA was visualized by slightly straightening and turning the probe counterclockwise, and orienting the ultrasonic beam between 60° and 120°. Ductal shape was classified as type A, B, C, or D.
Percutaneous access was achieved as described previously. A 4-Fr introducer (Introducer set) was placed into the lumen of right femoral artery and a 0.035 inch, 180 cm atraumatic J-tip guide wire (Rosen wire) was then passed through the introducer into the artery, advanced along the aorta and guided through the PDA into the main pulmonary artery by TEE visualization. To facilitate wire entry into the PDA, the terminal 10 cm of the guide wire was bent to an angle of approximately 15°–30° before introduction into the artery. The J-tip of the guide wire was easily identified as a hyperechoic hook-shaped line in all the relevant vessels (aorta, PDA, pulmonary artery) (Fig 2A and Video S1 in section 1). In cases where the wire failed to enter the PDA and progressed cranially along the descending aorta beyond the aortic ostium of the PDA (Fig 2B and Video S1 in section 1), the wire was retracted until the tip reached the level of the aortic ostium of the PDA, and redirected into the ampulla by rotating the end of the wire with the help of a hemostat. The 4-Fr introducer was then removed and exchanged with a long (90 cm) 5-Fr, 6-Fr, or 7-Fr introducer sheath with an appropriate dilator (Delivery set for ACDO). Sheath size was matched to the selected ACDO.

The introducer sheath and dilator were advanced over the guide wire until the end of the sheath was visualized as a hyperechoic band advancing along the thinner line representing the guide wire (Fig 2C and Video S1 in section 2) in the pulmonary artery. The guide wire and the dilator were then removed and the ACDO was loaded into the sheath introducer through the hemostatic diaphragm of the ACDO loader. The sheath now appeared as 2 parallel hyperechoic lines (Fig 2D and Video S1 in section 3). The device was advanced with the delivery cable to the tip of the sheath until the flat distal disk was extruded and imaged within the main pulmonary artery. Air bubbles could be visualized within the pulmonary artery immediately before the distal disk appeared. During this phase, it was possible to distinguish the hyperechoic ACDO advancing inside the lumen of the sheath (Fig 3A and Video S1 in section 3). The flat distal disk appeared as a hyperechoic structure within the pulmonary artery with a small rounded tip protruding toward the lumen of the artery (Fig 3B). The partially deployed device, delivery system, and delivery cable were then retracted together as a single unit until the flat distal disk of the device was positioned against the pulmonic ostium of the PDA (Fig 3C and Video S1 in section 4). With the delivery cable firmly held in place, the sheath was

Fig 2. Transesophageal echocardiographic images recorded during PDA occlusion with ACDO. (A) The guide wire (arrow) can be seen crossing the PDA into the pulmonary artery and the J-tip is easily visualized in the main pulmonary artery (arrowhead). (B) A J-tip guide wire (arrow) can be seen progressing cranially along the descending aorta beyond the aortic ostium of the PDA. (C) The end of the introducer sheath (arrowhead) can be seen passing over the guide wire (arrow) through the PDA. (D) The introducer sheath, after guide wire and dilator removal, is easily visualized as 2 parallel lines (arrowheads). PDA, patent ductus arteriosus; Ao, descending aorta; MPA, main pulmonary artery; PV, pulmonic valve; LA, left atrium; MV, mitral valve; LV, left ventricle.
retracted to expose and deploy the device waist across the ductal ostium and the cupped proximal (ductal) disk within the ampulla of PDA. The entire deployment of the ACDO was monitored by TEE. After successful deployment, the proximal disk appeared as a hyperechoic cupped disk within the ampulla of the PDA (Fig 3D and Video S1 in section 5).

The decrease in ductal flow was visualized in real time by color flow Doppler TEE (Fig 4 and Video S1 in section 6). Appropriate positioning and stability of the device was then tested by gentle push-pull motions of the delivery cable and by direct visualization with TEE. Once stability was confirmed, the delivery cable was detached from device by counterclockwise rotation and the cable was removed from the sheath. Detachment of the delivery cable was visualized by TEE imaging (Fig 5 and Video S1 in section 7).

After sheath removal, constant moderate pressure was applied to the exit point of the sheath for 40 minutes.

All dogs were tranquilized with acepromazine (10 μg/kg IV) before recovering from anesthesia to avoid movements that might disrupt clotting at the vascular access sites. Thoracic radiography was not routinely performed postoperatively because TEE image quality was sufficient to allow a complete evaluation of the distention and the adequate placement of ACDO inside the PDA (Fig 6A,B and Video S1 in section 8). Thoracic radiography was planned to be performed only in case of ACDO dislodgment or other adverse events. The day after each procedure, a complete TTE study was performed in all dogs and was repeated 1, 6, and 12 months later.

The minimal ductal diameter (TTE and TEE), ACDO-waist size (TEE), and ACDO-waist-diameter-to-minimal-ductal-diameter (TEE) are reported as median with minimum and maximum values. The differences in TEE-derived and TTE-derived measurements of minimal ductal diameter were compared with a Wilcoxon Signed-Ranks test.

Results

Transarterial ductal occlusion using ACDO by sole TEE monitoring was attempted in 20 dogs (12 females and 8 males, with a median age of 13.3 months [range: 3–66 months] and weighing a median of 10.6 kg [range: 3.4–28 kg]) over the 27-month period. Breeds represented included 2 Doberman Pinschers, 1 Lagotto...
Romagnolo, 2 Border Collies, 1 Italian Greyhound, 2 German shepherd, 1 Shetland Sheepdog, 1 Labrador, 1 Miniature Poodle, and 9 mixed-breed dogs. The dogs were referred to the Veterinary Teaching Hospital of the Department of Veterinary Medicine of Perugia (n = 10 dogs), Camerino University (n = 4 dogs), or to the Gregorio VII Veterinary Hospital in Rome (n = 6 dogs), and procedures were performed at each institution.

In 19 dogs, TTE and TEE identified a PDA with a wide ampulla and narrow minimal ductal diameter at the pulmonic ostium, classified either as type IIa (n = 15) or IIb (n = 4). In 1 dog, the TTE image quality was insufficient to assess the ductal morphology, but was identified as type IIa with TEE. The minimal ductal diameter measured by TTE (median: 2.8; range: 1.3–4.8 mm) did not differ from that measured by TEE (median: 2.9; range: 1.6–5 mm) (P = .065). The largest absolute difference between any pair of measurements was 0.4 mm.

A preliminary selection of ACDO size, based on the measurement obtained from the TTE image, was made with a waist diameter 1.7-2.1 times the diameter of the pulmonic ostium of the PDA. The investigator (FP) changed the ACDO selected from TTE measurements in 2 dogs after obtaining the TEE measurement. The ACDO-waist diameter, based on the TEE measurements, had a median of 5.8 mm (range 3–10 mm), resulting in a median ratio of ACDO-waist-diameter-to-minimal-ductal-diameter of 1.9 (range, 1.66–2.1) in 19/20 dogs. In the 1 dog that embolized the initial ACDO, the ACDO-waist-diameter-to-minimal-ductal-diameter was 1.6 (6 mm diameter ACDO, 3.8 mm minimal ductal diameter); this ratio was increased to 2.4 in the second attempt, where we deployed a 9-mm ACDO.

Three dogs were receiving cardiac medications at time of presentation for congestive heart failure. Total procedural times ranged from 12 to 24 minutes. Procedural time was measured from the point at which we obtained vascular access to the removal of all catheters. Anesthesia time ranged from 55 to 67 minutes, and included the time spent compressing the access vascular site after introducer removal.

In 12 cases, the wire failed to enter the PDA when initially advanced within the aorta and progressed cranially along the descending aorta beyond the aortic ostium of the PDA (Fig 2B). Rotation of the guide wire with hemostats during echocardiographic monitoring allowed the J-tip of the Rosen wire to pass into the ampulla and through the pulmonic ostium of the ductus in all dogs in which entry failed at the first attempt. In 3 dogs with the smallest minimal ductal
diameter (1.6, 2, 2.4 mm), the Rosen wire required additional gentle pressure to pass through the ostium after redirection into the ampulla. In dogs with pulmonic ostium size >2.4 mm, we did not encounter difficulty in passing the wire through the pulmonic ostium.

All 20 dogs had successful PDA occlusion with no residual flow observed by color Doppler TEE before awakening. In 19/20 dogs, residual shunting, detected immediately after ACDO deployment, disappeared within 4–10 minutes (Fig 4). A TTE study performed 24 hours after each procedure demonstrated the correct position of the ACDO and absence of residual flow in these 19 dogs. In 1 dog, the heart rate suddenly increased from 60 bpm to 85 bpm and a precordial thrill as well as a continuous murmur in the left axilla were detected while it was sleeping in the intensive care unit, approximately 18 hours after the ACDO positioning. Thoracic radiography demonstrated ACDO dislodgment and embolization into the right caudal pulmonary artery (Fig 7). We successfully deployed a larger device (9 mm as compared with 6 mm size used initially) 42 days after the initial procedure (the 6-week delay was to accommodate the client). The dislodged device was left in situ. A complete TTE study was repeated after 1 month (on 20 dogs), 6 months (on 4

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**Fig 6.** Transesophageal echocardiographic images in long axis (A) and short axis (B) of the ACDO after the release. The quality of TEE images is adequate to evaluate the distension and placement of the flat distal disk (arrowhead) and proximal disk (arrow) of the device.

**Fig 7.** Right-lateral (A) and dorso-ventral (B) thoracic radiographs demonstrate ACDO embolization into the right caudal pulmonary artery.
dogs), and 12 months (on 10 dogs), confirming sustained complete occlusion. No complications necessitating abortion of the procedure were encountered in any patients. One dog developed a hematoma immediately after compression of the vascular access site, necessitating digital compression for a further 25 minutes followed by cooling with an ice pack for 1 hour. No further bleeding occurred and the dog recovered uneventfully.

Discussion

Our study demonstrates that TEE monitoring, without additional visualization provided by fluoroscopy, can guide each step of transcatheter ACDO embolization of PDAs, and provides evidence of TEE as an acceptable alternative when fluoroscopy is not available, or when there are concerns regarding radiation exposure. Although we have shown previously that TTE can be used during transcatheter PDA occlusion with ACDO, TEE overcame the problem of inadequate image quality in a minority of dogs in which ductal morphology and ACDO positioning could not be assessed sufficiently for safe deployment.1 In addition, TEE permitted multiplane imaging to best characterize the anatomy and size of the PDA.8,11

Importantly, although statistically not different, the minimal ductal diameter determined by TTE and TEE was dissimilar in 2 dogs such that the size of the ACDO that was selected changed. In this small case series, this constitutes 10% of the animals. Our results differ from those recently reported by Silva et al on a larger number of dogs, where investigators observed TTE measurements of the minimal ductal diameter to exceed those of TEE by 0.8 mm (with up to a 3.5 mm difference).11 Furthermore, in that study, the authors estimated that the ACDO size selected from TTE measurements would not have changed after examining TEE measurements in only 15% of dogs, but would have been larger by 1–3 sizes in 56/80 dogs, and smaller in 7/80 dogs, had TTE measurements been used to select the device.11 A possible explanation for the measurement difference between TTE and TEE when evaluated by various investigators is because of different echocardiographic methodology permitting the visualization of the ductus. In addition to technique, it is possible that in some cases, an elliptical shape of the ostium of the PDA (rather than a spherical shape) could lead to an underestimation of its actual size when the measurement is made across the minor axis of the ductus from a long-axis image of the ductus (Fig 8). This problem would be present regardless of the imaging modality (TEE, TTE, or fluoroscopy). However, multiplane TEE can document the elliptical morphology of the PDA ampulla in transverse section.8,9,11

As with our previous report of TTE-guided ACDO deployment,1 the guide wire, introducer sheath, and ACDO appeared hypechoic on TEE images and TEE guidance provided images of a quality sufficient to clearly monitor the procedures in real time. Correct positioning of all catheters and devices was possible with careful monitoring of the tips of the guide wires and catheters within the great vessels. Furthermore, immediate corrections to catheter or device positioning were possible. Because our technique completely avoids fluoroscopy, we omitted a step recommended by the manufacturers that advises the use of an angled tip selective catheter to perform the angiography and to facilitate the passage of the exchange wire across the PDA.

Although TEE image quality was adequate to complete PDA occlusion in all 20 dogs in this study, 7/80 dogs in a larger case series11 had insufficient TEE imaging to permit occlusion. The authors of that study indicated that imaging was not possible in 2 dogs, and that 5 additional dogs required fluoroscopic imaging because of TEE probe dislodgement and repositioning during the procedure. Therefore, in a small number of patients, TTE and TEE might not provide appropriate procedure monitoring, such that fluoroscopy might be required.

We performed percutaneous entry to the femoral artery, which allows access with minimal trauma to the tissues: the sizing-up technique for the placement of introducers (first 4-Fr and then 5-Fr, 6-Fr, or 7-Fr) allows for a gradual dilatation, decreases the amount of trauma to the vessel, and potentially reduces the incidence of hematoma formation. Although percutaneous arterial access in dogs is associated with high frequency of hemorrhage, complications of hemorrhage were not encountered in our serial cases except for 1 dog in which it was controlled by extending the compression time and applying an ice pack over the femoral artery. We decided to use cold-pack treatment because some authors claim that this treatment enhances vasoconstriction, a fundamental mechanism, together with the clot formation, in maintaining hemostasis after arterial vessel damage.19 In fact, cold-mediated vasoconstriction, in addition to the normal
physiologic vasoconstrictive response, has improved clinical outcomes of patients affected by femoral hematoma occurring after percutaneous coronary intervention. No dogs exhibited clinical signs of esophageal injury, although direct examination of the esophagus was not performed.

**Limitations**

The most important limitation of this study is the relatively small number of dogs included. A larger case series is warranted to confirm safety and effectiveness of TEE as the sole guidance for occlusion of PDA using the ACDO. The adverse event rate of our case series could be considered relatively high (10%); however, the 2 adverse events that we experienced (delayed ACDO dislodgement, femoral artery bleeding) were unrelated to the TEE guidance, as they have been reported in procedures performed with fluoroscopic guidance.20–22

One potential limitation of TEE and TTE guidance is the inability to monitor advancement of catheters and guide wires from the vascular access site to ductal aortic ostium. Fluoroscopic guidance permits the clinician to observe the course of these devices as they are passed into the region of interest. However, we had no complications associated with advancement of the catheters or wires to the point at which they could be detected by TEE. In addition, TEE-guided deployment offers advantages over TTE guidance of complete visualization of the thoracic ascending and descending aorta and, consequently allows more distal monitoring of the advancement of the guide wire and catheter than is achieved with TTE.

Another potential limitation could be the inability to introduce the TEE probe in very small dogs or those with laryngeal or esophageal diseases. As previously described, in some cases, we encountered a great resistance to the advancement of the TEE probe at the thoracic inlet. We overcame this issue by slightly retroflexing the probe followed by gentle forward motion. Once advanced, the probe was then returned to a straight position.

Fluoroscopic guidance permits the clinician to observe the pulmonary vasculature and lung fields. In the event of inappropriate ACDO deployment where the device dislodges into the pulmonary arteries, fluoroscopy can be used to guide a retrieval system to remove the device. However, some clinical investigators have shown that lodging of the small device in the distal pulmonary vasculature might not pose a risk, and therefore may not require retrieval. We sought to minimize the possibility of immediate dislodgment by testing the stability of the device while imaging the PDA, with gentle tugging and pushing before disconnecting the delivery cable. The back-and-forth maneuvering, however, may not provide an adequate assessment of the stability of the device, as suggested in a recent case report of delayed embolization and the case of delayed embolization described in our study. Direction of the thrust on the ACDO connected to the release cable may be different from that of the longitudinal axis of the ductus. In this case, the ACDO would be pushed toward the cranial wall of the ampulla rather than toward the ostium, reducing the validity of the test.

Other limitations for the use of TEE are the need for specialized (expensive) probes and personnel. All procedures were performed by 3 clinicians with experience in interventional procedures under TTE and TEE guidance; as such the required number of trained personnel may be a limitation.

**Conclusions**

We have demonstrated that TEE monitoring can guide each step of the transcatheater ACDO embolization procedure in dogs with PDA without requiring fluoroscopy, thereby avoiding radiation exposure, and it can be considered an alternative to TTE-based guidance. A larger cases series is indicated for validation of safety and effectiveness of TEE as the sole guidance for occlusion of PDA using the ACDO.

**Footnotes**

a Infiniti Medical, LLC, West Hollywood, CA  
b Esaote, Genova, Italy  
c Midazolam I.B.I; Hospira, Inc, Lake Forest, IL  
d Sufentanil; Hameln Pharmaceuticals, Hameld, Germany  
e Cefazolina; Teva Pharmaceutical Industries Ltd, Petach Tikva, Israel  
f Fentanyl; Esteve group, Barcelona, Spain  
g Prequillan; Fatro spa, Ozzano Emilia, Italy  
h Cefazolina; Teva Pharmaceutical Industries Ltd, Petach Tikva, Israel  
i Prequillan; Fatro spa, Ozzano Emilia, Italy

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Conflict of Interest Declaration: The investigators received no funding to perform this study. Authors disclose no conflict of interest.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Video S1. Transesophageal echo-guided occlusion of the PDA is shown in 8 sections (Quick Time, Codec AAC, H.264).