DEVICE CLOSURE OF PATENT DUCTUS ARTERIOSUS (PDA)

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I CORE CONCEPTS AND ANATOMY

- **Definition:** Patent Ductus Arteriosus (PDA) is the persistent postnatal patency of the fetal arterial communication (derived from the left sixth embryonic aortic arch) connecting the roof of the main/proximal left pulmonary artery (LPA) just distal to the bifurcation with the anterior wall of the proximal descending thoracic aorta just distal to the origin of the left subclavian artery (the aortic isthmus).
- **The Krichenko Angiographic Classification (1989):** Standard morphological classification on lateral aortography that guides transcatheter device selection:
  - **Type A (Conical):** Most common (approx. 65 percent); well-defined aortic ampulla tapering to a discrete constriction at the pulmonary arterial insertion.
  - **Type B (Window):** Short, wide, window-like communication with constriction at the aortic end (often mimicking an aortopulmonary window).
  - **Type C (Tubular):** Tubular ductus throughout its length without any focal constriction.
  - **Type D (Complex):** Ductus with multiple constrictions and intervening aneurysms.
  - **Type E (Elongated):** Bizarre, elongated conical configuration with the constriction remote from the anterior edge of the trachea (classically seen in premature infants).

II RECOMMENDATIONS FOR CLOSURE (ESC 2020 ACHD / ACC-AHA 2018 GUIDELINES)

A Class I (Recommended)

- **Left Heart Volume Overload:** PDA closure is recommended in patients with evidence of Left Atrial (LA) and Left Ventricular (LV) enlargement / volume overload (Qp:Qs of 1.5:1 or greater) and no PAH (PVR less than 3 Wood Units), regardless of symptoms.
- **Clinical Symptoms or Prior Endarteritis:** Heart failure symptoms, failure to thrive in infants, or a prior episode of infective endarteritis.
- **Method of Choice:** Transcatheter device closure is the treatment of choice in adults and children when anatomically feasible (avoiding the calcified/friable ductal tissue risks of open surgery in adults).

B Class IIa (Should Be Considered)

- **Borderline PAH (PVR 3 to less than 5 Wood Units):** Closure should be considered in patients with PVR of 3 to less than 5 WU when a significant net left-to-right shunt (Qp:Qs greater than 1.5) persists.
- **Small Audible PDA:** Closure is reasonable for a small PDA with a continuous murmur and normal LV size to eliminate the lifetime risk of endarteritis.

C Class IIb (May Be Considered)

- **Severe PAH (PVR 5 Wood Units or Greater):** Closure may be considered in specialized centers only if targeted PAH therapy or vasoreactivity testing demonstrates a net left-to-right shunt (Qp:Qs greater than 1.5) with careful assessment during trial balloon occlusion of the PDA.

D Class III (Contraindicated / Harm)

- **Eisenmenger Syndrome:** PDA closure is strictly contraindicated in patients with Eisenmenger physiology (bidirectional or net right-to-left shunt with differential cyanosis and clubbing of the lower extremities/toes, or resting/exercise lower-limb desaturation).
- **Silent PDA:** Closure is not recommended for a tiny “silent” PDA detected only by echocardiography without an audible murmur.
- **Duct-Dependent Lesions:** Strictly contraindicated in duct-dependent congenital defects (e.g., interrupted aortic arch, critical coarctation, pulmonary atresia).

III THE INTERVENTIONAL TECHNIQUE (STANDARD ANTEGRADE PROTOCOL)

- **Vascular Access:** Percutaneous right femoral venous (typically 5F to 7F) and femoral arterial (4F or 5F) access under conscious sedation or general anesthesia. (In small or premature infants, a venous-only TTE-guided approach avoids femoral arterial thrombosis.)
- **Aortography and Sizing:** A pigtail catheter is positioned in the proximal descending aorta to perform a 90-degree lateral (and RAO 30-degree) descending aortogram, measuring the minimal ductal diameter (usually at the pulmonary end), the aortic ampulla diameter, and the ductal length (using the tracheal air shadow as an anatomical landmark).
- **Crossing the Ductus (Antegrade Approach):** The PDA is crossed either antegradely from the main pulmonary artery into the descending aorta using an end-hole catheter (Multipurpose or Judkins Right) and hydrophilic wire, or retrogradely from the aorta into the PA (snaring the wire in the PA to establish an arteriovenous rail if needed for large tubular ducts).
- **Device Sizing:** For the standard single-retention-disc Amplatzer Duct Occluder (ADO I), the pulmonary end of the device is selected to be at least 2 mm larger than the narrowest ductal diameter.
- **Stepwise Deployment:**
  - A long Mullins-type delivery sheath is advanced from the femoral vein across the right heart and PDA into the descending thoracic aorta.
  - The Aortic Retention Disc is unsheathed in the descending aorta and gently pulled back as a unit until it seats snugly within the aortic ampulla (confirmed by a slight tug and tracheal landmark alignment).
  - While maintaining gentle tension on the delivery cable, the sheath is retracted to deploy the cylindrical plug/body across the pulmonary orifice of the ductus.
- **Pre-Release Assessment:** Before unscrewing the delivery cable, perform a gentle stability check, check pullback/simultaneous pressure gradients across the aortic arch/isthmus, perform a control descending aortogram (confirming proper position and absence of aortic obstruction), and verify by echocardiography that there is no flow acceleration (greater than 2.0 m/s) in the Left Pulmonary Artery (LPA) or Descending Aorta.

PDA Morphology / Patient Profile	Preferred Transcatheter Device	Key Design Advantage
Type A Conical PDA (greater than 2 to 3 mm)	Amplatzer Duct Occluder I (ADO I) / Cocoon / Cera Duct Occluder	Single aortic retention skirt + tapered cylindrical body; >98% closure
Small PDA (less than 2.0 mm)	Detachable Coils (Flipper) or ADO II	Low profile, cost-effective for tiny ducts

PDA Morphology / Patient Profile	Preferred Transcatheter Device	Key Design Advantage
Type C Tubular / Elongated PDA	ADO II or Amplatzer Vascular Plug II (AVP II)	Symmetrical dual retention discs; delivered via 4F/5F sheath (arterial or venous)
Premature / ELBW Infants (700 g or greater)	Amplatzer Piccolo Occluder (formerly ADO II AS)	Ultra-low profile; implanted completely intraductally via venous-only TTE guidance
Very Large Adult / Hypertensive PDA	Muscular VSD Occluder or ASD Occluder	High radial strength and dual symmetrical discs prevent embolization into PA

IV THE EVIDENCE BASE AND LANDMARK DATA

- **Pivotal ADO I Trial (Pass et al., JACC 2004):** Multicenter pivotal trial demonstrating greater than 98 to 99 percent complete closure at 6 to 12 months with minimal major complications, establishing transcatheter occlusion as the standard of care over surgical ligation for patients weighing over 5 to 6 kg.
- **Premature Infant Trial (Amplatzer Piccolo Pivotal Trial, JACC Cardiovasc Interv 2020):** Demonstrated 99 percent implant success in 100 premature infants weighing 700 grams to 2 kg (95.5 percent across all 200 patients) using a transvenous, purely intraductal approach without femoral arterial access, avoiding the post-thoracotomy scoliosis, vocal cord paralysis (recurrent laryngeal nerve injury), and phrenic nerve injury associated with surgical PDA ligation.
- **Left Ventricular Remodeling:** Following closure of a large volume-overloading PDA, LV ejection fraction may transiently dip in the first 24 to 48 hours due to the sudden elimination of the low-resistance aortic runoff (acute afterload mismatch), followed by complete normalization of LV end-diastolic dimensions within 3 to 6 months.

V PROCEDURE-RELATED COMPLICATIONS

- **Device Embolization (less than 1 percent):** Embolization into the Pulmonary Artery (usually from device undersizing) or Descending Aorta (especially in hypertensive ducts); managed via percutaneous gooseneck snare retrieval through a larger sheath or surgical removal.
- **Iatrogenic Aortic Coarctation:** Protrusion of the aortic retention disc into the lumen of the descending aorta (highest risk in infants weighing less than 6 kg with short Type B/C ducts); a pullback gradient greater than 10 to 15 mmHg or Doppler velocity greater than 2.0 m/s with diastolic tail mandates device repositioning or retrieval before release.
- **Left Pulmonary Artery (LPA) Stenosis:** Protrusion of the pulmonary end of the device across the origin of the LPA (velocity greater than 2.0 m/s on TTE).
- **Intravascular Hemolysis:** Caused by a high-velocity residual jet shearing erythrocytes against the polyester fabric/nitinol mesh, presenting with hemoglobinuria (dark red/cola-colored urine) within 24 hours; mild cases resolve with hydration, while persistent severe hemolysis requires transcatheter coil/plug occlusion of the residual leak or device retrieval.

VI PRACTICAL CONSIDERATIONS IN THE INDIAN CLINICAL CONTEXT

- **Late-Presenting Adult PDA with Severe PAH:** In India, patients frequently present in adolescence or adulthood with a large PDA and severe Pulmonary Hypertension. Because the ductus enters distal to the left subclavian artery, simultaneous pulse oximetry on the right hand and foot is mandatory to detect differential cyanosis.
- **Trial Balloon / Device Occlusion Protocol in Borderline PAH:** In patients with severe PAH and a net left-to-right shunt, Indian tertiary centers perform a 15-to-20-minute trial occlusion of the PDA using a compliant sizing balloon or the occluder itself (attached to the delivery cable) while continuously recording simultaneous PA and Aortic pressures:
  - **Safe to Release:** If PA systolic/mean pressure drops by greater than 20 to 25 percent (or the PA/Aortic pressure ratio falls below 0.5) with no fall in systemic aortic pressure and no symptoms.
  - **Do Not Release (Retrieve Device):** If PA pressure rises or remains suprasystemic/systemic and aortic pressure falls, indicating irreversible PVR where the PDA is acting as a vital RV pop-off.
- **Exclusion of Active Endarteritis:** Any febrile patient with a PDA must have blood cultures and echocardiography (looking for vegetations in the main/left pulmonary artery at the site of jet impact) and complete antimicrobial eradication prior to elective device placement.

KEY REFERENCES

- **Krichenko A, Benson LN, Burrows P, et al.:** Angiographic classification of the isolated, persistently patent ductus arteriosus and implications for percutaneous catheter occlusion, *American Journal of Cardiology*, 1989.
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- **Sathanandam SK, Gutfinger D, O'Brien L, et al.:** Amplatzer Piccolo Occluder clinical trial for percutaneous closure of the patent ductus arteriosus in patients ≥700 grams, *JACC: Cardiovascular Interventions*, 2020.