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Catheter-based closure of the patent ductus arteriosus in lower weight infants

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ABSTRACT

Risks associated with drug therapy and surgical ligation have led health care providers to consider alternative strategies for patent ductus arteriosus (PDA) closure. Catheter-based PDA closure is the procedure of choice for ductal closure in adults, children, and infants ≥6 kg. Given evidence among older counterparts, interest in catheter-based closure of the PDA in lower weight (<6 kg) infants is growing. Among these smaller infants, the goals of this review are to: (1) provide an overview of the procedure; (2) review the types of PDA closure devices; (3) review the technical success (feasibility); (4) review the risks (safety profile); (5) discuss the quality of evidence on procedural efficacy; (6) consider areas for future research. The review provided herein suggests that catheter-based PDA closure is technically feasible, but the lack of comparative trials precludes determination of the optimal strategy for ductal closure in this subgroup of infants.

Introduction

Fundamental questions on the treatment of patent ductus arteriosus (PDA) in preterm infants remain unanswered.[1] Traditionally, surgical ligation has been used to provide definitive ductal closure, but surgery has risks, including vocal cord paralysis, post-operative cardiovascular dysfunction, and the potential for neurodevelopmental impairment.[2–5] While drug therapy (indomethacin, ibuprofen, acetaminophen) is effective in medically closing the ductus in some infants, side effects (renal gastrointestinal) and no long-term evidence of neurodevelopmental benefit, have led to growing uncertainty on the use of drug therapy.[6–11] These observations have led some health care providers to consider alternative strategies for PDA closure.[12–16]

Catheter-based PDA occlusion is among the safest of interventional cardiac procedures and is the procedure of choice for ductal closure in adults, children, and infants ≥6 kg.[17,18] Given success among more mature counterparts, coupled with the known risks of established treatments (surgical ligation, drug therapy), interest in the use of catheter-based closure of the PDA among lower weight (<6 kg) infants is growing.[12,14–16,19] Among this subgroup of infants, the goals of this review are to: (1) provide an overview

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of the procedure; (2) review the types of PDA closure devices; (3) review the technical success (feasibility); (4) review the risk (safety); (5) discuss the quality of evidence on the efficacy of the procedure; (6) consider areas for future research.

Procedural overview

In most cases, infants are transported to the catheterization suite and undergo general anesthesia.[12,16] Evidence of greater risk of vascular compromise in lower weight infants than in more mature counterparts has led to growing interest in approaches that avoid or limit arterial access in this subgroup of patients.[20,21] Recently, Zahn and colleagues described the use of transvenous access techniques that avoid direct arterial access without evidence of greater risk of device embolization or malposition.[13,22] Briefly, following femoral venous access, a coronary guidewire is advanced under fluoroscopic guidance through the right heart and across the PDA. A hydrophilic catheter or sheath is advanced over the guidewire into the descending aorta.[22] Decisions regarding the type of PDA device or coil are based on the angiographic classification of the PDA (Fig. 1).[23] The catheter is positioned across the PDA and into the aorta, wherein the chosen device is loaded, advanced to the distal tip of the catheter, and unsheathed and deployed across the PDA. Prior to release from the delivery cable, the left pulmonary artery (LPA) and descending aorta (DA) are evaluated by angiography and/or echocardiography and compared with the pre-procedural imaging. If there is evidence of device-related stenosis, the device is recaptured and either repositioned or removed and replaced with another device of a different size. If appropriately positioned, the device is released from the delivery cable (Fig. 2).

Following release, the LPA and DA are carefully evaluated for device-related stenosis. Infants are typically administered a single procedural dose of intravenous heparin (100 U/kg) unless contraindicated.[13] Repeat bolus doses of heparin can be provided to maintain activated clotting time (ACT) >250 seconds. Procedural time, defined as interval between femoral vessel are access to removal of the vascular sheath removal, is typically less than 1 hour. The timing and nature of follow-up (echocardiographic surveillance, ventilation-perfusion imaging) are highly variable in the literature.[24]

Types of PDA closure devices

At present, none of the PDA closure devices (described below) are approved by the US Federal Drug Administration (FDA) for lower weight infants.[24,25] While we have chosen to highlight two of the more common types of device used for PDA closure in premature infants, a number of additional devices are also available (e.g., Medtronic Microvascular Plug).

Amplatzer Vascular Plug II (AVP-II)

One device used for PDA closure in preterm infants is the Amplatzer Vascular Plug II (AVP II; Abbott, Chicago, IL).[13] This device is a self-expanding plug made of two layers of 144 braided nitinol wires (Fig. 3). The device has two outer disks and a central plug, all of which are the same diameter, and has an unconstrained length of 6 mm. In infants, the AVP II is well-visualized by fluoroscopy and transthoracic echocardiography, which allows for optimal placement in the catheterization suite under fluoroscopic and/or echo guidance. The 3, 4, and 6 mm diameter devices fit through a 4 Fr sheath and can be repositioned or removed if required. To achieve effective PDA closure as well as stable device position, the device size must be larger than the PDA diameter. Given the properties of nitinol wire, this will cause the deployed device

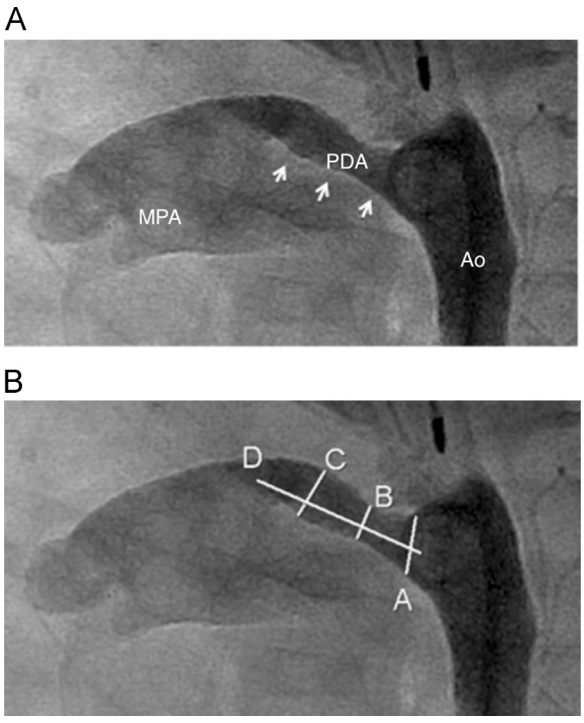

Fig. 1 – (A and B) Angiographic still frames in lateral projection of the patent ductus arteriosus and surrounding structures. (A) White arrows outline length of the PDA. Ao = aorta; MPA = main pulmonary artery. (B) Angiographic parameters used to define PDA classification and guide closure; A = Aortic ampulla; B = narrowest dimension; C = PDA size at insertion into pulmonary artery; D = PDA length.

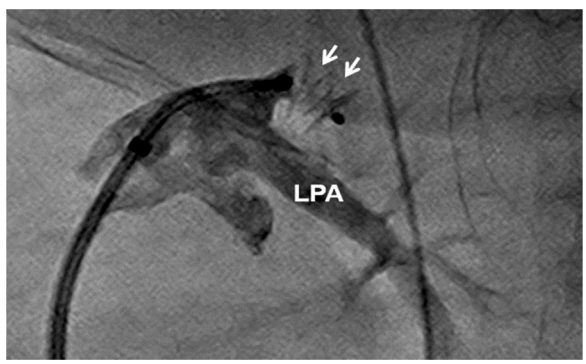

Fig. 2 – Angiographic still frames demonstrating catheter-based closure of PDA in a 1.2 kg premature infant. *Legend*: Angiogram in main pulmonary artery following deployment of the PDA device; white arrows outline the device in PDA without residual flow across the ductus. LPA = left pulmonary artery.