

# Overview of transcatheter patent ductus arteriosus closure in preterm infants

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## Abstract

Clinically significant patent ductus arteriosus (PDA) has been associated with significant morbidity in extremely low birth weight (ELBW) infants. Current management of ELBW infants with hemodynamically significant PDA includes supportive treatment, pharmacological therapy, and surgical ligation. All of these therapeutic options have their advantages and limitations. More recently, transcatheter PDA closure has been described as a viable option in this population. In this paper, we provide a comprehensive review of this emerging procedure.

## KEYWORDS

device occlusion, extremely low birth weight infant, patent ductus arteriosus

## 1 | INTRODUCTION

The ductus arteriosus is an essential fetal structure that closes spontaneously within the first week of life in the vast majority of healthy infants. However, the incidence of patent ductus arteriosus (PDA) reported by the National Institute of Child Health and Human Development (NICHD) Neonatal Research Network in preterm infants ranges from 20%-60% with an inverse relationship to birth weight.<sup>1</sup> In extremely low birth weight (ELBW) infants born prior to 24 weeks, the likelihood of spontaneous closure is less than 15%.<sup>2</sup> Nearly half of infants born less than 1000 g develop a hemodynamically significant PDA.<sup>3</sup> While there are structural differences in the PDA anatomy as classified by Krichenko, the predominant morphology in premature infants is the Fetal-type (F-type) PDA described as elongated and tubular with minimal tapering and tortuosity at the pulmonary end.<sup>4,5</sup>

Failure of ductal closure leads to a left to right shunt which can result in pulmonary overcirculation and left heart volume overload.<sup>6</sup> Additionally, delayed closure of the ductus arteriosus in ELBW infants has been associated with bronchopulmonary dysplasia, necrotizing enterocolitis, pulmonary hypertension, intraventricular hemorrhage, sepsis and infective endocarditis. The mortality risk in infants born before 29 weeks gestation increases 8-fold if PDA is present.<sup>7</sup>

Clinically or hemodynamically significant PDAs are currently treated with a combination of supportive approaches, pharmacotherapy, or surgical ligation. Indomethacin and ibuprofen, both nonselective cyclooxygenase (COX) inhibitors, have an estimated PDA closure rate of 50%-65% in ELBW infants. Given their vasoconstrictive properties, these medications have been associated with renal insufficiency and intestinal perforation.<sup>8,9</sup> Paracetamol (acetaminophen) is a new alternative to nonselective COX inhibitor pharmacotherapy with similar PDA closure rates and fewer reported side effects.<sup>10,11</sup> While there is little consensus regarding subsequent management, patients with clinically significant PDA who fail pharmacological therapy are currently treated with expectant management, including positive pressure ventilation, fluid restriction and diuresis, or ultimately referred for surgical ligation.<sup>12</sup> Despite advancements in surgical technique, surgical ductal ligation in ELBW infants has largely fallen out of favor due to a paucity of proven survival benefits and associated early and long-term morbidity.<sup>13,14</sup>

Transcatheter PDA closure was pioneered in 1967 by Porstmann et al.<sup>15</sup> The initial transcatheter PDA closure techniques utilized large arterial and venous delivery sheaths which limited its use in the pediatric population. Today, transcatheter PDA closure is the procedure of choice in adults, children, and larger infants.<sup>16</sup> However, this modality has not been routinely used in ELBW infants due to concerns regarding overall medical fragility, fear of increased incidence

of procedure-related adverse events, technical challenges involved in catheterizing extremely small patients and the absence of a suitable device for this application. Recently, however, there has been an emergence of several reports of successful transcatheter PDA closure in ELBW infants, which serves as the primary basis for this review.<sup>17</sup>

## 2 | TRANSCATHETER PDA OCCLUSION TECHNIQUES IN SMALLER PATIENTS: IS IT SAFE?

Transcatheter PDA closure is a minimally invasive procedure, which affords high success rates with few procedure-related complications. It is considered first-line therapy for PDA closure in children >6 kg. For the reasons discussed above, this technology has not been widely adopted for the ELBW population to date. There is data to suggest that ELBW and younger infants <30 days have increased procedure-related adverse events despite high PDA closure rates.<sup>17,18</sup> Therefore, operators are still looking to improve transcatheter PDA closure techniques and outcomes in smaller infants and children, particularly when the alternative treatment modalities are suboptimal.

The earliest case of PDA occlusion successfully performed in a low-birth weight infant was reported in 2001.<sup>19</sup> The procedure involved using a right saphenous vein cut down and antegrade PDA coil occlusion approach in an 1180 g infant. Small case series of PDA closure in preterm infants with a median procedure weight of 1100 g (range 930-1800 g) and 2200 g (range 1600-2600 g) were subsequently reported in 2007 and 2010.<sup>20,21</sup> Collectively, they showed that PDA coil occlusion using a transvenous femoral approach under fluoroscopy guidance in the catheterization suite was technically feasible and safe in a select cohort of preterm low birth weight infants. However, as noted by the authors, due to the relatively large size of the PDA in this population, the use of coils was limited to only about 10% of the population in need.

In 2011, Bentham et al. reported a novel echocardiographic guided technique to achieve percutaneous duct closure carried out in the NICU for three preterm infants with weights ranging from 1400 to 2185 g.<sup>22</sup> Femoral arterial access was used to place either coils or an Amplatzer ductal occluder (ADO II; Abbott Medical, Sylmar, California) device across the PDA. In an important breakthrough, transthoracic echocardiographic imaging was utilized instead of fluoroscopy to guide the procedure and evaluate device placement, residual shunt and surrounding arteries. This allowed for the procedure to be performed at the bedside, thereby avoiding significant risks associated with transportation of critically ill infants. Additionally, it allowed for multiple treatment teams to coordinate care in one location and eliminated procedure-related contrast and radiation exposure risks. Unfortunately, this approach, which utilizes femoral arterial access without fluoroscopy, placed these infants at risk for limb ischemia and has limited management options for complications such as device embolization.

More recently, several European studies have demonstrated the safety and efficacy of the newer Amplatzer Ductal Occluder in Additional Sizes (ADO II-AS) in smaller patients. Baspinar et al. reported on 69 infants weighing <6 kg at the time of the procedure.<sup>23</sup> This included 16 premature infants (mean weight of  $1.7 \pm 0.3$  kg) and 13 ELBW patients, with an implant success rate of 81.2% for premature infants and 94.3% for those <6 kg. Major complications included three device embolizations and one death. Importantly, patient age was found to be an important risk factor for major complication. In this cohort, weight was not a significant contributor to outcome. Sungurs et al. investigated a similar series of 60 children, including 9 infants  $\leq 3$  kg.<sup>24</sup> PDA closure with the ADO II-AS device was successful in 8/9 (88.8%) infants. One infant weighing 2.2 kg had a significant residual shunt that required removal of the device and surgical ligation. Complete occlusion was achieved in all successfully implanted patients within 24 hours in the original cohort and no complications were reported at a median follow-up of 12 months. Similarly, Kenny et al. reported on the use of the ADO II-AS device in 17 patients with a median weight of 5.7 kg (range 1.7-17.4 kg).<sup>25</sup> The two smallest infants <2000 g underwent femoral arterial access with retrograde PDA closure under echocardiography guidance as described by Bentham et al.<sup>22</sup> The smallest 1700 g infant had unsuccessful percutaneous access requiring femoral arterial cutdown and subsequently developed transiently diminished pulses. Notably, the remaining 15 cases, including 7 infants with weight range 2-5.65 kg, underwent the procedure in a catheterization suite using both femoral venous and arterial access. Device delivery was successful with complete shunt occlusion in 13 cases at the end of the procedure. One patient had device embolization to the left pulmonary artery requiring surgical removal. At four months follow-up, there was complete ductal closure in all 16 remaining patients.

Subsequently, our group described a transvenous antegrade technique utilizing echocardiography with limited fluoroscopy guidance at the bedside in 24 ELBW infants.<sup>26,27</sup> Patients with hemodynamically significant PDA who failed medical management and had a ductal length greater than 6 mm were considered candidates for this procedure regardless of size or degree of illness. Due to limited availability of alternative devices in the United States at the time, all patients were treated with the Amplatzer Vascular Plug II (AVP II). This device is available in 3 mm, 4 mm, and 6 mm diameters and is 6 mm in length (ergo the criteria for minimum ductal length of 6 mm). Femoral venous access alone was utilized in 96% (23/24) of patients. Device size was chosen to be 1 mm larger than the narrowest PDA diameter. Low dose digital single-plane fluoroscopy (either in the catheterization laboratory or using a C-arm at the bedside) was utilized to guide catheter and wire placement through the right heart, thereby facilitating placement of a soft guide wire down the descending aorta via the PDA. Echocardiography was then primarily used to guide device placement, paying close attention to the possible development of left pulmonary artery (LPA) or aortic obstruction, as well as evaluate for residual ductal shunting prior to device release. In cases where Doppler flow systolic peak gradient >15 mm Hg or persistent

antegrade diastolic flow was seen in either the LPA or aorta, the device was recollected and repositioned or removed. Using this approach, implantation success rate was 88% (21/24) in this group of ELBW infants with a median weight of 1249 g (755-2380 g). Complete occlusion was achieved in all patients by the end of the procedure. Devices were removed in the three unsuccessful cases due to concern for LPA stenosis and these infants underwent uncomplicated surgical ligation. Procedural complications were recognized in 3 patients, 2 of whom were remedied with catheter techniques in the same procedure (both with significant descending aortic obstruction which was noted immediately after device release and was corrected with device repositioning). One patient with a large 6 mm device developed LPA stenosis secondary to device encroachment and compression of the LPA. This infant underwent LPA stent placement several weeks after the procedure with a good result. When compared to a historical surgical ligation control group, it appeared that this group of ELBW infants had a significantly lower incidence of cardiorespiratory compromise (so-called postligation syndrome).<sup>28</sup> There was one late death (3 months post procedure) unrelated to the procedure. At follow-up of 11 months, no patients had developed vascular occlusion (i.e. LPA or aortic stenosis) or recurrent ductal flow.<sup>4</sup>

More recent reports of PDA closure using Medtronic Micro Vascular Plug (MVP) in preterm infants has shown similar promising results in ELBW infants weighing less than 2000 g.<sup>29,30</sup> Sathanandam et al. described a successful, echocardiography guided, antegrade PDA occlusion approach, via femoral venous access in 12 patients with a median weight of 1210 g (range 700-3500 g). Using femoral arterial access, the retrograde PDA occlusion technique was attempted in two additional patients >2 kg, which was unsuccessful in one patient with a short and wide ductus arteriosus. Complete duct occlusion was achieved postprocedure in 13 of 14 (93%) patients. One patient had a small residual shunt, which resolved on follow-up. There were no reported procedure-related complications at a median follow-up of 11 months.

A meta-analysis of percutaneous PDA closure in infants was performed in 2017 comparing 38 studies and 635 procedures.<sup>17</sup> Of

these, 19% of patients weighed <3 kg ( $n = 103$ ) and 48% ( $n = 255$ ) weighed 3-6 kg at the time of the procedure. The technical success rate was 92.2% and the overall clinical adverse events rate was 10.1%. Most adverse events (78.3%, 47/60) were of moderate severity. There were rare major and catastrophic adverse events (1.6%, 10/635 and <0.5%, 3/635, respectively). However, clinical adverse events in the <6 kg subgroup was 2-3 times higher than those observed in larger patients (14.0% vs. 4.8%). There was no difference in PDA occlusion rates based on patient age or size. Outcomes for both technical success and adverse events improved over time.<sup>17</sup> Similarly, data from the IMproving Pediatric and Adult Congenital Treatment (IMPACT) registry involved 747 attempted transcatheter PDA closures in infants <6 kg across 73 hospitals. Approximately 35% of infants weighed <4 kg ( $n = 264$ ) and 2.5% weighed <2 kg ( $n = 19$ ). The authors reported a high technical success rate of 94%, regardless of weight and age. Major adverse events were noted in 12.6% of the cases. Infants younger than 30 days had greater risk of major adverse events (relative risk 3.3, confidence interval 1.46-7.64).<sup>18</sup>

The risks and benefits of percutaneous PDA closure continue to evolve with new devices and techniques. Though the transcatheter reported outcomes in preterm infants are promising, they have not been directly compared with surgical outcomes in prospective trials. Recent retrospective studies comparing percutaneous PDA closure versus surgical ligation showed that preterm infants with transcatheter PDA occlusion have faster improvement in respiratory function.<sup>31,32</sup> Patients undergoing surgical ligation at the same time period, and reportedly with similar characteristics, had higher overall morbidity including a high incidence of recurrent laryngeal nerve palsy (17%). The authors concluded that transcatheter closure of PDA in select low birth weight and preterm infants is a safe and reliable alternative to surgical ligation.<sup>32</sup>

### 3 | DEVICE CONSIDERATIONS

Appropriate device selection based on PDA morphology and imaging assessment before and during deployment have proven essential to the success of transcatheter PDA closure in ELBW infants. Few

**TABLE 1** Characteristics of devices commonly used for ductus arteriosus occlusion in preterm and small infants. Coils are not included

Device				
Name	ADO II	ADO II-AS	AVP II	MVP
Disk size (mm)	9-12	4-6.5	3-2	-
Waist size (mm)	3-6	3-5	3-22	5.3-13
Length (mm)	4-6	2-6	6-18	12-18
Sheath size (Fr)	4-5 Fr	4 Fr	4-7 Fr	Microcatheter 4-5 Fr
FDA approval	2013	In trial	2007	2015

Abbreviations: ADO, Amplatzer Duct Occluder; ADO II-AS, Amplatzer Duct Occluder II Additional Sizes; AVP, amplatzer vascular plug; FDA, food and drug administration; MVP, micro vascular plug.

devices are particularly suited for PDA closure in small and preterm infants. Table 1 provides a summary of commercially available devices in the United States that are used with some frequency in preterm and small infants for PDA closure.

The ADO II device is a self-expanding device comprised of two layers of Nitinol shaped in two symmetrical retention disks and a smaller central waist frame. It has a bigger disk to waist ratio and is therefore not particularly well suited for PDA closure in ELBW infants as the large disks can cause LPA or aortic obstruction.

The ADO II-AS device commonly used outside the United States is currently under investigation in the United States. The ADO II-AS is available in a variety of small diameters and lengths (2-6 mm) when compared with the ADO II. The ADO II-AS design modification is an improvement on the AVP II and the ADO II for shorter fetal ductal variants because the disks on the device are only slightly larger than its waist. It has a softer delivery cable than other Amplatzer self-expanding devices, which allows for much more predictable release of the device and increased application to the anatomic variants of PDA in premature infants.

The AVP II is a self-expanding, multilayered, nitinol device with a symmetric frame. Its disk diameter is similar to its waist diameter. It is available in small diameters suitable for this population, but the 6-mm length may result in risk for LPA or aortic occlusion as seen in our experience described.

The Medtronic Micro Vascular Plug (MVP) is a nitinol cage-like framework covered by a polytetrafluoroethylene (PTFE) membrane which lacks retention disks, making it suitable for tubular PDA of premature infants. It is designed for immediate vessel occlusion and predictable deployment. Its two smaller diameter devices, MVP-3Q and MVP-5Q, have a unique microcatheter delivery sheath, which is desirable for small infants. Initial results with this device in the ELBW population have been encouraging.

The use of both generic, off-label and PDA-specific devices continues to expand the capabilities for treating PDAs in small and premature infants. The design and ultimate regulatory approval of devices specifically suited for closure of PDA in ELBW infants will help expedite their widespread use and likely improve clinical outcomes in this at-risk, in-need patient population.

#### 4 | FUTURE DIRECTIONS: IMPLICATIONS FOR RESEARCH AND MANAGEMENT GUIDELINE

Transcatheter closure of hemodynamically significant PDAs would intuitively appear to be advantageous in ELBW infants. We have developed and refined an echocardiographic guided, antegrade femoral venous approach, which can be performed at the bedside with little or no contrast and minimal radiation exposure. Multiple centers are now reporting excellent short-term results with a variety of devices in this setting, but as of this overview we still await approval for a device specifically suited for this unique population in the United States. Early results from the US ADO II-AS multicenter

clinical trial are encouraging. We are cautiously optimistic that this device will receive FDA approval for premature infant PDA closure, and other devices such as the MVP will soon follow. Ongoing modifications in device design and techniques may ultimately make this a routine bedside procedure performed in the neonatal intensive care unit. Once these devices are routinely available, carefully designed prospective randomized trials will be necessary to determine whether this novel therapy should be the new standard of care.

#### 5 | CONCLUSION AND RECOMMENDATIONS

Transcatheter PDA closure in preterm ELBW infants is now technically feasible with high ductal occlusion rates and acceptable complication rates. Despite the early enthusiasm for this new procedure, prospective studies comparing the results of transcatheter PDA closure with conservative management, pharmacological treatment, and surgical ligation are needed to gain a better understanding of the role for this therapy in the ELBW infant with PDA.

#### CONFLICT OF INTEREST STATEMENT

Dr Zahn is a consultant for Abbott Medical, Medtronic, and Edwards Lifesciences. He is the national principal investigator for the ADO II AS clinical study. Dr Almeida-Jones is a co-investigator for the ADO II AS clinical study.

#### AUTHOR CONTRIBUTIONS

Myriam Almeida-Jones, Nai Yu Tang, Aneela Reedy, and Evan Zahn contributed to drafting and critical revision of article, as well as approval of the final version.

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