




# Can transcatheter PDA closure be performed in neonates $\leq 1000$ grams? The Memphis experience

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## Abstract

**Objective:** Advancements in transcatheter technology have now made it possible to safely close patent ductus arteriosus (PDA) in extremely low birth weight (ELBW) infants. The objective of this article is to describe our technique for transcatheter PDA closure (TCPC) in ELBW infants.

**Design:** The techniques employed are very specific to this population and are drastically different when compared to the procedure performed in patients weighing  $>5$  kg.

**Setting:** A multidisciplinary team approach should be taken to evaluate and manage ELBW infants in order to achieve success. It is important that specific techniques with venous-only approach outlined in this article be followed to achieve optimal results with low risk of complications.

**Patients:** To date, in Memphis, 55 ELBW infants have had successful TCPC at a weight of  $\leq 1000$  g with minimal procedure-related complications.

**Interventions:** It is important that specific techniques with venous-only approach outlined in this article be followed to achieve optimal results with low risk of complications.

**Outcome measures:** This procedure entails a steep learning curve and should be limited to specialized centers with expertise in these transcatheter procedures.

**Results:** There has been 100% procedural success of performing TCPC in children  $\leq 1000$  g. There have been only two procedure-related complications which happened to the first two patients,  $\leq 1000$  g, that we performed TCPC on.

**Conclusions:** It is feasible and probably safe to perform TCPC in children  $\leq 1000$  g. The techniques described in this article represent our institutional experience and have helped us improve clinical outcomes in ELBW infants.

## KEYWORDS

ADO II AS, AVP II, ELBW, MVP, PDA

## 1 | INTRODUCTION

Patent ductus arteriosus (PDA) is very common in extremely low birth weight (ELBW) neonates and can be found in  $\sim 42\%$  of infants weighing less than 1200 g.<sup>1-3</sup> Given the prematurity and comorbid factors, such

neonates are at high risks of morbidity and mortality. The PDA in this population is relatively larger and longer, also referred to as "fetal type PDA."<sup>4</sup> It is known that ELBW neonates with hemodynamically significant PDAs have higher incidence of chronic lung diseases, necrotizing enterocolitis, intraventricular hemorrhage, and increased risks of mortality.<sup>5</sup>

A PDA can be determined to be hemodynamically significant based on clinical and noninvasive trans-thoracic echocardiographic (TTE) evaluation. Salient echocardiographic features include size  $\geq 2$  mm diameter, left heart enlargement, and pan-diastolic flow reversal in the abdominal aorta. Medical therapy is not always effective and can cause adverse events. Surgical PDA ligation, although technically feasible in all neonates, can pose life-threatening risks like bleeding, pneumothorax, phrenic nerve palsy, vocal cord paralysis, and chylous effusion.<sup>6-8</sup>

Transcatheter PDA closure (TCPC) in older children ( $>5$  kg) has been performed for over half a century and is now the standard of care. However, it should be noted that performance of this procedure in an ELBW neonate entails use of specific techniques (Table 1) and devices for optimal results with low risk of complications.<sup>9,10</sup> In this article, we describe our approach toward evaluation and transcatheter closure of PDA in ELBW neonates.

## 2 | PATIENT SELECTION

All relevant patient details are discussed in a multidisciplinary team meeting comprising of the patient's neonatologists, cardiac surgeons, and cardiologists. Any hemodynamically significant PDAs would qualify for transcatheter closure except those with active infection, hemodynamic or respiratory instability that precludes transfer to the catheterization lab, intracardiac thrombus, severe renal dysfunction,

and those with continuous right to left shunting across the PDA. The PDA morphology does not preclude TCPC. The size of the patient in our experience is not a disqualifying factor. In fact, we prefer to perform this procedure when the patient is  $<1000$  grams. The reasons being (a) the smaller the patient, the longer the length of the PDA, which gives more room to implant the device, (b) the smaller/younger patients do not have pulmonary vascular disease, therefore, they tolerate the procedure better, and (c) the patients who have the procedure performed early in life seem to benefit the most from this procedure.

## 3 | PROCEDURE

The procedure is performed in the cardiac catheterization lab under general anesthesia using biplane fluoroscopy with the lowest frame rate of 3 frames per second. In Memphis, we have patients transferred for the procedure from multiple other hospitals (11 other institutes so far) that are between 0.5 and 500 miles away. Therefore, transporting the neonate from the neonatal intensive care unit (NICU) to the cardiac catheterization lab is never an issue. The neonate is transported from the NICU in the incubator, either using transport ventilator/oscillator or bag ventilation via an endotracheal tube. The patient is kept warm using heat lamps and a heating blanket with continuous temperature monitoring via an esophageal probe. The blood pressure cuff is placed around the left lower extremity and is cycled every 5 minutes. Transthoracic echocardiogram (TTE)

**TABLE 1** Ten important lessons learned from transcatheter patent ductus arteriosus closure in extremely low birth weight neonates

1. ELBW infants are very sensitive to thermal and hemodynamic changes and must be handled with extreme caution including insertion/manipulation of wires and catheters.
2. Ultrasound-guided femoral venous access should be obtained in ELBW infants. Arterial access can lead to complications and should be avoided. TTE guidance eliminates the need for arterial access and aortic angiogram.
3. TTE tends to underestimate the PDA length. Smaller the patient, longer the PDA. As the child gets older, the PDA tends to shorten. In children less than 1000 g, the median PDA length is at least 10 mm and the median PDA diameter is 3 mm.
4. Interventionalists interested in performing this procedure should follow a graded decrease in patient size, until a level of comfort performing transcatheter PDA closure in ELBW infants smaller than 1 kg can be achieved. This can help reduce complications.
5. Heparin bolus administration should be avoided in ELBW infants. Heparinized flushes can be used to prevent thrombosis within catheters.
6. The 4-French, 65-cm angled glide catheter (Terumo, Tokyo, Japan) and the 0.035" Wholey wire (Medtronic, Minneapolis, Minnesota) seem to be the best catheter and wire to use for ELBW infants. Avoiding wire-catheter mismatch is important to prevent injury to the blood vessels and to the tricuspid valve. Stiff delivery cables and catheters keep the tricuspid valve open and lead to decreased cardiac output during device delivery.
7. The PDA in ELBW infant is long and tubular resembling the fetal ductus, and typically 3 mm in diameter and 10 mm in length. Therefore, the MVP-5Q is pretty much one size fit all PDAs in ELBW infants with rare exceptions.
8. The device should be implanted entirely intraductal to prevent inadvertent stenosis of the left pulmonary artery or the distal aortic arch. Diskless devices such as the MVP can prevent this complication. PA angiogram and TTE can determine any inadvertent LPA stenosis caused by the device. To rule out and prevent aortic obstruction, the following are helpful:
  - a Keep a temperature probe in the esophagus. This will be in line with the aorta. Implanting the device anterior to the probe (as visualized on lateral fluoro) will prevent aortic obstruction by the device.
  - b Attach a blood pressure (BP) cuff in the left lower extremity. Obtaining a BP prior to and after device implantation can help rule out aortic obstruction.
  - c Palpation of the femoral arterial pulse pre- and post-device implantation.
  - d TTE can help determine aortic obstruction caused by the device.
9. Ideal timing for PDA closure in ELBW infants is within the first 4 weeks of age beyond which the benefit is limited. By 8 weeks, most ELBW infants with a large PDA show evidence of pulmonary hypertension.
10. Clinically apparent postligation syndrome seen with surgical PDA ligation is not encountered with device occlusion in ELBW infants.

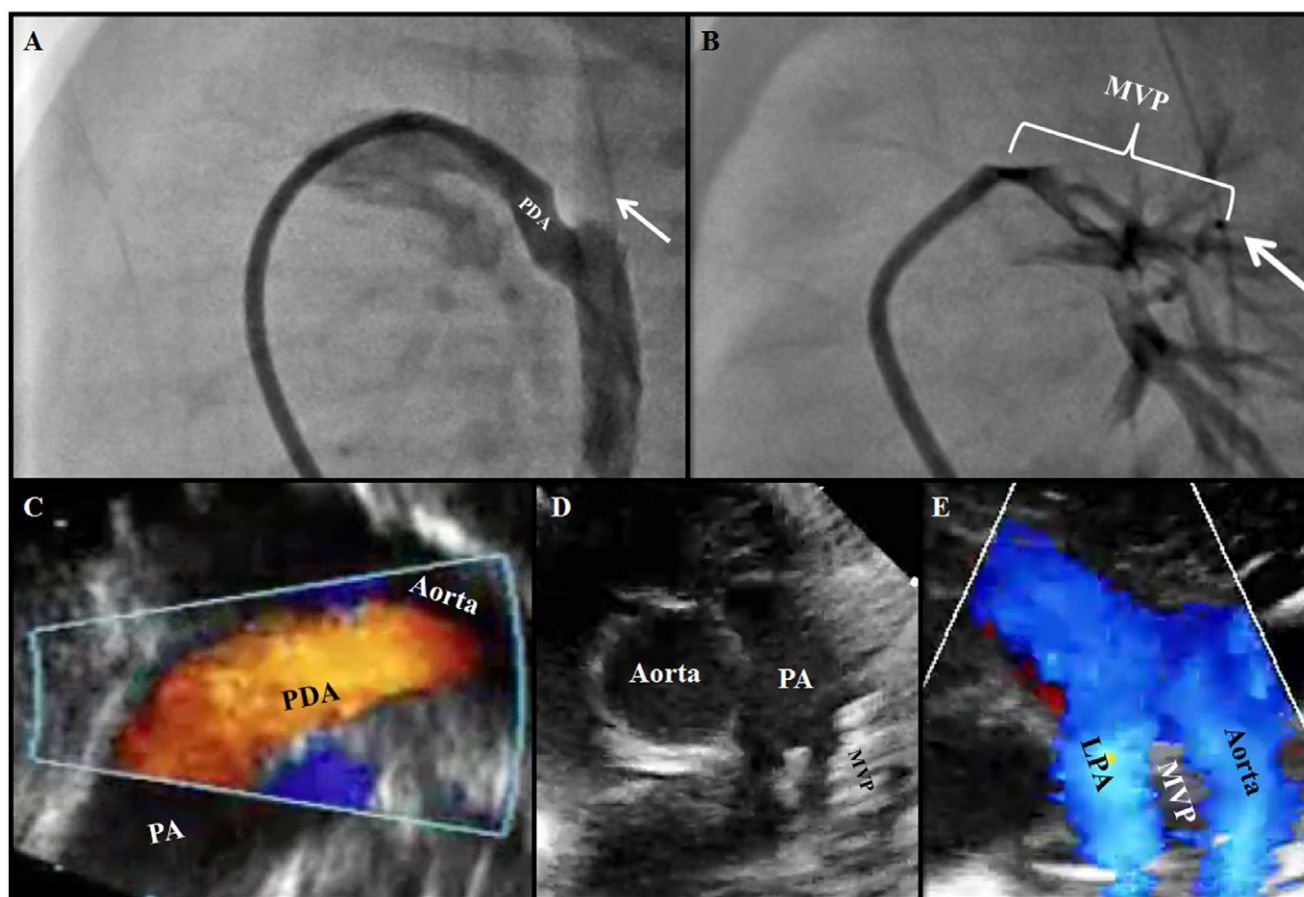
is performed by the operator standing at the head side of the table and a note is made in regard to the ideal windows for scanning during the procedure. Baseline measurements of the PDA diameters at the pulmonary and aortic ends, and the length of PDA are recorded. The systolic pulmonary artery (PA) pressure is estimated using peak pulmonary regurgitation velocity. A complete hemodynamic catheterization is not performed unless there is concern for pulmonary hypertension. Typically, pulmonary hypertension does not develop until the 2<sup>nd</sup> or 3<sup>rd</sup> months of life. Therefore, earlier PDA closure may be beneficial for these ELBW infants. Omission of hemodynamic measurements helps reduce procedural time and the amount of fluids administered to the patient to flush the catheters.

A 4-French 7-cm introducer sheath is placed in the right femoral vein under ultrasound guidance. Arterial access is not obtained as this group of patients is at high risk of arterial injury.<sup>11</sup> Heparinized saline flushes are sufficient to maintain activated clotting times between 200 and 250 seconds. Hence, a heparin bolus is not given. Prophylactic antibiotics are administered. Under fluoroscopic guidance, a 4-French angled glide catheter (Terumo) and a 0.035" Wholey wire (Medtronic) are used to cross the PDA antegrade into

the descending aorta. The wire is removed and a hand injection is performed using this catheter to delineate the size of the PDA. This angiogram is performed at 15 frames per second for accurate measurements and the largest dimensions are used for device selection (Figure 1A).

#### 4 | DEVICE SELECTION

Currently, there are no US FDA (United States Food and Drug Administration)-approved devices for the closure of PDA in the ELBW infants. However, with the experience we have accrued over the last decade, we commonly employ three devices in this population: microvascular plug (MVP; Medtronic), the Amplatzer ductal occluder II additional sizes (ADO II AS; Abbott, Lake Bluff, Illinois), and Amplatzer vascular plug II (AVP II, Abbott). In our center, we have performed PDA occlusions successfully on 55 ELBW infants less than 1000 g, with one failed attempt with the smallest patient weighing 600 g at the time of TCPC. There was one 900 g patient with a residual shunt noted on the postprocedure TTE following the



**FIGURE 1** Transcatheter PDA Closure in a 740 -g neonate using the MVP. (A) Lateral aortogram performed via an antegrade 4-French glide catheter through the PDA demonstrating a long, tubular, Type-F PDA. The arrow points to the esophageal temperature probe in line with the aorta. (B) Pulmonary angiogram post-PDA closure using the MVP. There is no PA stenosis. The arrow points to the distal radiopaque marker of the MVP lined up with the esophageal temperature probe. (C) Color post-procedure Doppler interrogation of the PDA prior to PDA closure. (D) 2D Echo demonstrating the MVP within the PDA with no branch PA stenosis. (E) Color Doppler interrogation post-PDA closure with the MVP. There is no residual PDA, no stenosis of the LPA or the aorta.

implantation of an MVP-7Q plug in a 6-mm PDA. The shunt was not visualized on follow-up TTE. The residual shunting was attributed to a small tear in the Gore-Tex membrane, which can happen due to repeated recapture and repositioning of the device. Otherwise, we have not encountered any other procedural complications. With increasing experience, there has been a gradual shortening of our procedural time: median 26 (range 8-44) minutes and fluoroscopic time 3.6 (range 2-13.3) minutes. Likewise, we have been able to reduce the total radiation dose to a median of 2.9 (1.8-7.5) mGy, and contrast dose 1.7 (1-3) ml/kg.

#### 4.1 | Microvascular plug

The MVP comprises of a nitinol framework covered partially by a polytetrafluoroethylene (PTFE) membrane at the proximal portion. Oversizing of the device to the target vessel anchors it in place and the PTFE covering leads to faster occlusion. The delivery wire is a 0.018'' nitinol pusher that is 180 cm long up to the detachment zone. There is a proximal and distal radiopaque marker. Mainly two sizes of the device are used in premature neonates: 5.3 mm (MVP-3Q) and 6.5 mm (MVP-5Q) which can be introduced through microcatheters of inner diameters 0.021'' and 0.027'', respectively. The unconstrained length is 12 mm for both the sizes, while the maximal constrained length is 15 and 16 mm for the MVP-3Q and MVP-5Q, respectively. The MVP-3Q is recommended for the target vessel whose diameter is between 1.5 and 3 mm and the MVP-5Q for 3-5-mm diameter PDA. The MVP-7Q is 9-mm unconstrained diameter and can be used for larger PDAs between 5- and 7-mm diameter via a 4-French catheter. In our series, the MVP-5Q is the most commonly used device size.

The device comes in a dispenser tube attached to a delivery wire. The device is prepared by immersing it into heparinized saline and withdrawing it into the loader catheter by pulling the delivery wire until the tip of the MVP is sheathed. The distal end of the introducer sheath is inserted into the hub of the 4-French glide catheter that has already been placed in the PDA through a Y-connector. After flushing the system, the hemostasis valve is tightened. The pusher wire is then advanced through the 4-French angle glide catheter until the distal platinum marker of the MVP is aligned with the distal part of the catheter. The hemostasis valve is then loosened and the device is unsheathed by slowly pulling back on the glide catheter while maintaining a constant forward pressure on the delivery wire. An angiogram is performed through the Y-adapter connected to the end of the glide catheter in a caudal angulation on the frontal and straight lateral projections to rule out any stenosis of the left pulmonary artery (Figure 1B). TTE is used to delineate any residual shunting and obstruction to the descending aorta or to the left pulmonary artery (Figure 1C and D). If repositioning of MVP is desired, the 4-French glide catheter is re-advanced over the delivery wire to recapture the device and the device can be redeployed in the same manner. Once a satisfactory position is achieved, the device can be detached using a torque device. It is recommended that a new device be used after more

than three attempts to reposition the MVP as this can cause a tear in the Gore-Tex membrane.

Though the MVP can be delivered through a microcatheter, the 4-French glide catheter is preferable, as it allows for an angiogram to be performed if necessary as well as to recapture the device prior to release or even after releasing the device using a snare. The MVP is not a very radiopaque device. Having the distal radiopaque marker to match the esophageal temperature probe on lateral fluoroscopy is a good technique to avoid excessive protrusion of the device into the aorta. Cycling of the BP cuff in the lower extremity, as well as palpation of the femoral arterial pressure can confirm good aortic flow. TTE can be used for confirmation. An angiogram performed via the Y-connector can help confirm that the device does not obstruct the pulmonary arteries. The MVP is a fairly long device. This is advantageous to cover the entire PDA length. The PDA is quite long in the ELBW infants and an inverse relationship is seen between the size of the patients and the length of the PDA.<sup>12</sup> Therefore, this device is suitable for very small patients.

Since the MVP does not have any retention discs, it avoids obstruction of the LPA or the aorta and may be more suited in the extremely small-sized patients. Oversizing the device by 1-2 mm greater than the PDA will eliminate the potential risk of embolization. These extremely small patients do not tolerate stiff wires across the tricuspid and pulmonary valves that are required to advance a delivery sheath for device deployment. The delivery cable of the MVP is less stiff compared to other devices and consequentially easier to maneuver through the heart in neonates weighing as small as 600 g. The MVP also has the advantage of being delivered through the same catheter that is used to cross the PDA, avoiding the need for a sheath exchange. There have been no other adverse events with the use of the MVP.

In our series, we have performed PDA occlusions with the MVP successfully on 65 ELBW infants between 600 grams and 1500 grams, 44 of whom were < 1 kg, with one failed attempt. The failure was secondary to the device not implanted properly. The device had displaced more proximal than expected causing mild left pulmonary artery (LPA) stenosis. Though this 700 grams patient was hemodynamically stable, we elected to retrieve the device. A 5 mm snare was used to capture the proximal radiopaque pin and the device was sheathed entirely into the 4-French glide catheter and retrieved without any complication. The PDA was occluded using an ADO-II AS device. There was one 900 grams patient with a residual shunt noted on the postprocedure TTE following the implantation of an MVP-7Q plug in a 6 mm PDA. The shunt was not visualized on follow-up TTE. The residual shunting was attributed to a small tear in the Gore-Tex membrane, which can happen due to repeated recapture and repositioning of the device. It is recommended that a new device be used after more than three attempts to reposition the MVP.

In our series of 146 ELBW infants with PDA closure at less than <2 kg, the median diameter of the PDA was 3.5 mm at the PA end, 4.2 mm at the aortic end and 10.6 mm in length based on angiographic measurement. Therefore, the MVP-5Q is almost a one size fits all for patients of this size. The procedure and fluoroscopic times

whilst using the MVP for PDA occlusions is a median of 24 (range 8-44) and 4 (range 1.4-7.8) minutes respectively.

## 4.2 | Amplatzer duct occluder II additional sizes

The ADO II AS is a self-expanding nitinol mesh occlusion device with a central waist and retention discs on both ends designed to minimize the protrusion into the aortic and pulmonary arteries. The retention discs on either side are 1-1.5 mm greater than the central device. The sizes are based on the central device which is available in three sizes. Therefore, the 3-mm device has discs 4 mm in size, the 4-mm device has discs that are 5.25 mm in size, and the 5-mm device has 6.5-mm disc sizes. It can be used for PDAs  $\leq 4$  mm in diameter and at least 6 mm in length. It can be placed through a 4-French delivery catheter via the venous approach in this population. Therefore, a catheter exchange is needed. We recommend using the 0.035" wholly wire for catheter exchange. In general, this wire is very atraumatic and is likely not to injure any valve structures or the PDA unlike lower caliber wires. Also, using a 0.035" wire reduces wire catheter mismatch preventing any adverse event due to that. The central waist fills up the ductal lumen and the retention discs are designed to deploy in the pulmonary and the aortic ends of the ductus arteriosus. However in ELBW infants, delivering the entire device intraductal could prevent any chance of inadvertent stenosis to the distal aortic arch or the LPA. This could also allow for relative undersizing of the device as it allows for the sizing to be based on the retention disc size rather than the central device. It comes preattached to a delivery cable whose distal tip is extremely flexible and is angiographically visible which helps in the precise placement of the device within the ductus. After device placement, a PA angiography can be performed through the Y-connector at the end of the deliver catheter. The aortic end can be checked using the principles described previously, including lining up the distal marker to the esophageal temperature probe, TTE, lower extremity noninvasive BP measurement prior to and post device occlusion of the PDA, and by palpation of the femoral arterial pulsations. There is an ongoing clinical trial in the United States to evaluate the safety and efficacy of this device for PDA closure.

## 4.3 | Amplatzer vascular plug II

The AVP II is a self-expanding nitinol plug composed of two layers of 144 braided nitinol wires constructed as two outer disks and a central plug of equal diameter. The diameter of the device chosen should be either 1-2 mm large or 20% larger than the target vessel. The 4-mm and the 6-mm AVP-II and can be delivered using a long 4-French sheath. It has excellent fluoroscopic and echocardiographic visibility.

The PDA is crossed as described above. Over a 0.025" wire parked in the descending aorta via the PDA, a 4-French hydrophilic sheath (Flexor, Cook Medical, Bloomington, Indiana) is advanced into the descending aorta. An appropriate size AVP-II is prepped and loaded into the introducer delivery catheter by pulling back on

the delivery wire under heparinized saline. The device introducer is hubbed into the long delivery sheath and the AVP-II is advanced to the tip of the sheath in the descending aorta. Once an appropriate position of the device is achieved in the PDA, it is unsheathed while exerting mild forward tension on the device to maintain it within the ductus arteriosus. If the device position is suboptimal, it can be recaptured by advancing the 4-French sheath over the delivery wire. Once a satisfactory position is achieved, the device is detached from the delivery wire followed by an angiogram and removal of the sheath.

The disadvantages of the AVP-II include the need for a sheath exchange, a relatively stiff delivery cable (which pop opens the tricuspid valve), and unavailability of a 5-mm device (generally the PDA is 3-4 mm diameter in  $<2$  kg neonates). This makes this device not ideal for ELBW infants. More recently, with the availability of the MVP and the ADO-II AS, we have only used the AVP-II in children  $>2$  kg. Out of the 117 PDA occlusions performed using the AVP-II at our center, only 22 were performed in children  $<2$  kg, and only 3 under 1 kg. In contrast, all 65 MVP used for PDA occlusions were performed in children  $<1.5$  kg, with 44 occlusions in children  $<1$  kg. The AVP-II was successful 94% of the times when attempted. There was a 5% incidence of LPA stenosis with the AVP-II exclusively when used in children  $<1.2$  kg. Though the retrieval of the AVP-II was necessary in only two patients in whom the device was successfully snared and sheathed into a long 4-French sheath, in both these patients (900 g and 1100 g in weight, respectively), the PDA went into spasm after retrieval and did not require further intervention. There was one device embolization in a 3-kg infant noted 4 hours after device implant that was successfully retrieved. The patient underwent surgical ligation of the PDA.

## 5 | FOLLOW-UP CARE

It is our practice to schedule PDA closure in ELBW neonates early in the day and to perform an echocardiogram and a chest x-ray, 6 hours postprocedure. This helps the team to be able to respond to any inadvertent complications in a timely manner. We have seen that the use of 4-Fr femoral venous sheaths in ELBW infants is safe and there is no need for follow-up vascular imaging unless clinically indicated. These patients are followed by the cardiology service on a weekly basis until hospital discharge. Follow-up echocardiographic evaluation is performed 30 days postclosure. In addition, we have instituted a multidisciplinary PDA clinic for longer term follow-up. All these patients are followed in the PDA clinic for a period of 3 years to assess for any longer term issues including pulmonary and neurodevelopmental outcomes.

## 6 | DISCUSSION

As for any new technology in medicine, there is a learning curve to this specialized procedure. Operators wishing to undertake PDA



closure in ELBW neonates should follow a graded approach by gradually gaining experience in larger premature neonates. It cannot be overemphasized that these ELBW neonates are extremely vulnerable and cannot tolerate any complications. Success is dependent on the collaboration between the neonatologists, cardiologists, pulmonologists, and cardiac surgeons. Important factors that determine the feasibility and success of a program planning to undertake such procedure include early referral for the procedure, experience in transporting these neonates to and from the catheterization lab, precise and accurate echocardiographic measurements, and speedy performance of the procedure. Long-term results are still unknown and are the focus of ongoing research. It is very important that these patients who undergo this procedure are followed carefully, so that long-term safety, benefits to patients, and outcomes can be clearly studied.

## 7 | CONCLUSIONS

ELBW neonates with hemodynamically significant PDAs are at significant risks of morbidity and mortality. Advancement in transcatheter technology and devices has now allowed us to safely close PDAs in ELBW neonates. This can be done with a venous-only approach. A multidisciplinary team involving neonatologists, pulmonologists, cardiologists, and surgeons is essential for the success of a program embarking on such procedures. The techniques described above represent our institutional experience and has helped us streamline the procedure.

## AUTHOR CONTRIBUTIONS

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