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ORIGINAL STUDIES

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Use of the Medtronic Microvascular Plug 7Q for transcatheter closure of large patent ductus arteriosus in infants weighing less than 2.5 kg

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Abstract

Background: The sole Food and Drug Administration-approved device for transcatheter closure of the patent arterial duct in premature infants is indicated for patent ductus arteriosus (PDAs) ≤ 4 mm in diameter. We report a two-center experience with transcatheter closure of large PDAs (>4 mm) in infants weighing <2.5 kg using the Microvascular Plug 7Q (MVP-7Q) device.

Methods: This is a retrospective review of departmental databases and medical charts to define patient cohort and report demographic, procedural, and follow-up data.

Results: Twenty-two patients (12 male) with a median gestational age and birthweight of 25.5 weeks (interquartile range [IQR] = 24–28) and 800 g (572–1075), respectively, underwent attempted PDA occlusion with the MVP-7Q using a transvenous approach. The median age and weight at the time of PDA occlusion was 32 days (IQR = 24–28) and 1100 g (IQR = 960–1700), respectively. The median PDA length was 12 mm (IQR = 11–12.65). The median PDA diameters at the aortic and pulmonary ends were 5.1 (IQR = 4.9–5.5) and 4.8 mm (IQR = 4.6–5.3), respectively. Successful device occlusion was achieved in 20 patients (91%). There were two failed attempts: One due to inappropriate sizing, and the other secondary to left pulmonary artery stenosis. There were no procedural complications and no residual shunting on follow-up.

Conclusions: The MVP-7Q is safe and effective for transcatheter closure of large (>4 mm) PDAs in infants <2.5 kg. The lack of retention disks may help with avoiding impingement on surrounding vessels.

KEYWORDS

coil/device/transcatheter, congenital heart disease, embolization, endovascular, intervention, pediatrics

1 | INTRODUCTION

Historically, transcatheter patent ductus arteriosus (PDA) closure was avoided in very-low-birth-weight infants due to concerns regarding aortic obstruction and femoral arterial compromise, particularly with first- and second-generation occlusion devices. However, several lower profile devices have been recently developed that have facilitated greater engagement with transcatheter PDA closure in premature infants.[1–3] There is a growing body of evidence outlining the safety and efficacy of transcatheter PDA closure in this cohort.[4–6] To date, only the Amplatzer Piccolo Occluder (Abbott Structural Heart), is Food and Drug Administration (FDA) approved for preterm infants weighing ≥700 g.[7] However, this device is only suitable for PDA diameters measuring up to 4 mm and therefore up to 20% of hemodynamically relevant PDA's may be too large for closure with this device.[2,3,7]

The MicroVascular Plug (MVP; Medtronic) is FDA approved and CE marked for vascular embolization.[8] The PDA morphology in extremely premature infants is long and tubular and resembles its fetal counterpart (F-type PDA).[9] The MVP device is an ovoid-shaped, self-expanding device without retention discs and its use has been previously reported in the transcatheter occlusion of PDAs in premature infants.[10,11] Of the four available sizes, the MVP-7Q is suitable for occlusion of vessels up to 7 mm in diameter and is deliverable through a 4-Fr catheter. Therefore the MVP-7Q is an attractive option for transcatheter PDA closure in premature infants with large PDA's. The aim of this study is to describe early experience with the MVP-7Q for the occlusion of large PDAs (>4 mm) in infants <2.5 kg.

2 | METHODS

A retrospective review from two large tertiary referral centers over a 36-month period was performed. Patients from Children's Health Ireland at Crumlin were identified from a dedicated National Institute of Cardiology Outcomes Research database. In Le Bonheur Children's Hospital, the electronic medical record was queried to identify patients retrospectively. Infants weighing <2.5 kg at the time of the procedure, with a large PDA (minimum diameter > 4 mm), with attempted occlusion using the MVP-7Q device were included in this study.

Demographic details including patient age, gender, weight, and body surface area at the time of the procedure were collected. The gestational age at birth, age at procedure, birthweight, procedure weight, procedure time, PDA diameter at the aortic and pulmonary ends, PDA length, contrast volume, fluoroscopy time, radiation dose exposure, and associated comorbidities were recorded. Left ventricular chamber size was also assessed using *z*-scores.[12]

Procedural success was defined as successful PDA device occlusion with the MVP-7Q when the patient left the cardiac catheterization lab. Any significant procedure-related complications are included.

2.1 | Statistics

We used IBM SPSS Statistics for Windows, version 26 (IBM Corp.) for data analysis. Continuous variables were reported as mean and standard deviation or median and interquartile range (IQR). Categorical variables are reported as frequency percentages. In Children's Hospital Ireland at Crumlin and in accordance with the General Data Protection Regulation guidelines, Research Ethics approval for data sharing was obtained for this retrospective study. In Le Bonheur Children's Hospital), Institutional Review Board approval from the University of Tennessee Health Science Centre was obtained.

2.2 | Device description

The MVP-7Q consists of a self-expanding nitinol frame with the proximal half covered in polytetrafluoroethylene (PTFE; Figure 1). The unconstrained diameter of the device is 9.2 mm and it is

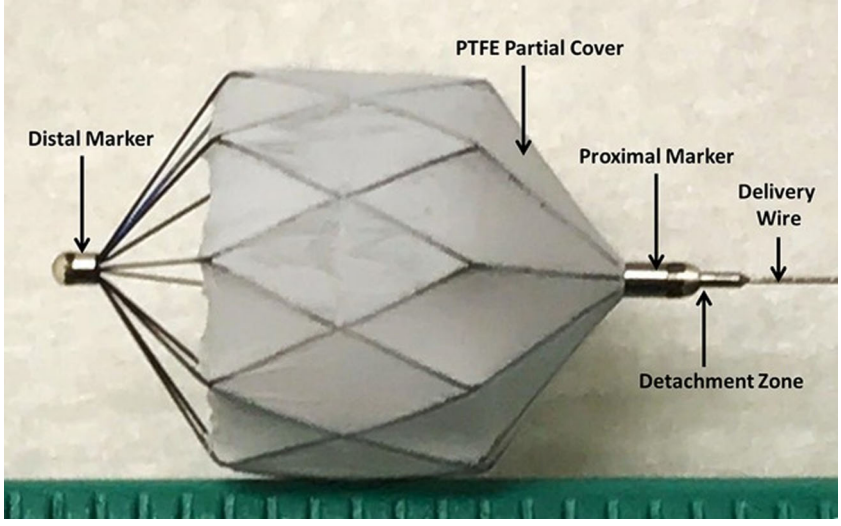

FIGURE 1 MVP device. MVP, microvascular; PTFE, polytetrafluoroethylene [Color figure can be viewed at wileyonlinelibrary.com]

indicated for occlusion of vessels up to 7 mm in diameter. The unconstrained length of the MVP-7Q is 16 mm. The MVP-7Q can be deployed through a 4-Fr catheter.

2.3 | Procedural details

All procedures were performed in a digital biplane cardiac catheterization laboratory under general anesthesia with mechanical ventilation. Preprocedural echocardiograms were reviewed with measurements of the PDA diameters and length. The MVP-7Q device was selected for PDA size above 4 mm, but less than 7 mm (Figure 1). The procedural technique utilized in CHI and LeBonheur Children's Hospital were similar. A 4-Fr introducer sheath is placed in the femoral vein using ultrasound guidance. Prophylactic antibiotics were administered. A 4-Fr angled nontapered Glide catheter (Terumo) is used to access the PDA over a Wholey™ guidewire (Medtronic) and is advanced to the aorta through the PDA. Following this, a small volume, hand injection of angiographic dye is administered in the PDA via a Tuohy-Borst (Cook Medical). The MVP is then introduced through the Tuohy-Borst and deployed in the body of the PDA as the catheter is withdrawn from the descending aorta. A hand injection angiogram is repeated to confirm the position and performed through the delivery catheter, to confirm that there is an appropriate waist with no obstruction of the left pulmonary artery (LPA) or the aorta. Transthoracic echocardiography (TTE) assessment of the LPA and descending aorta is performed before and just after device release. The device is released with counterclockwise rotation of the delivery cable using a torque mechanism. (Figure 2, Videos S1–S3). TTE is repeated 24 h postprocedure, unless otherwise indicated.

3 | RESULTS

PDA occlusion using the MVP-7Q was attempted on 22 patients (12 male). Thirteen patients in our cohort were reported in other series.[1–6,13] The median gestational age at birth was 26 weeks (IQR = 24.5–28 weeks) and the median birthweight was 800 g (IQR = 572–1075 g). Seven patients had weight ≤1 kg. Sixteen patients were done in Le Bonheur Children's Hospital, while the remaining were performed in Children Health Ireland at Crumlin. Table 1 summarizes the demographic and procedural details. The median age at the time of PDA closure was 32 days (IQR = 26–57 days). The median weight of the patients at the time of the procedure was 1100 g (IQR = 960–1700 g). Table 1 summarizes the demographic and procedural details.

Five patients (23%) had a history of sepsis, while three patients (15%) had a previous history of necrotizing enterocolitis. Other associated comorbidities included Pierre Robin Sequence, Galactosemia, and interventricular hemorrhage as outlined in Table 1. Two (9%) patients had pulmonary valve stenosis requiring pulmonary valvuloplasty during the same procedure.

All PDAs were considered hemodynamically significant as evidenced by a median left atrial size to aortic root size ratio (LA/AO) of

TABLE 1 Patient demographics and procedural details

Factor	Median (IQR)
Patient demographics	
Gender	Male = 13
Age at procedure (days)	32 (24–28)
Birthweight (g)	800 (572–1075)
Weight at procedure grams	1100 (960–1700)
Procedural details	
Procedure time (min)	30 (23–44)
PDA diameter aortic end (mm)	5.1 (4.9–5.5)
PDA diameter pulmonary end (mm)	4.8 (4.6–5.3)
PDA length (mm)	12 (11–12.65)
Contrast volume (ml/kg)	3 (2.8–4)
Fluroscopy time (min)	7.35 (4–9.25)
Radiation dose (mGy)	7 (4.5–11.8)

Abbreviations: IQR, interquartile range; PDA, patent ductus arteriosus.

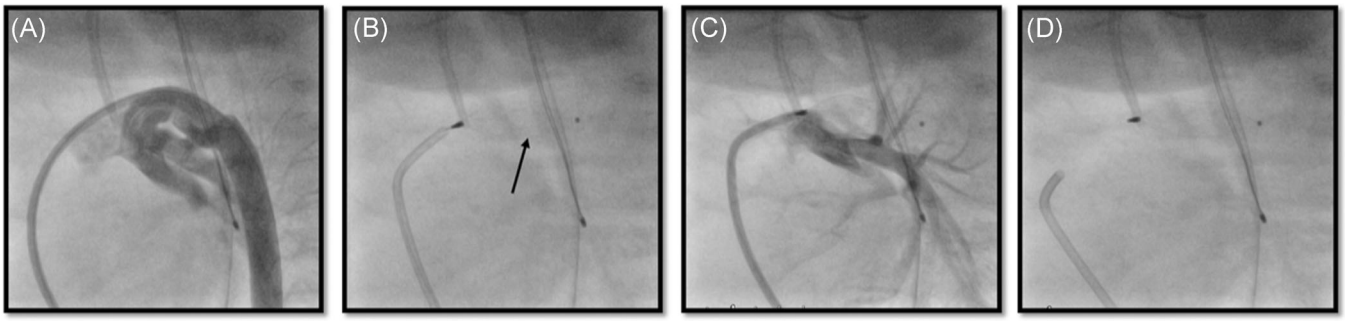

FIGURE 2 Series of lateral plane fluoroscopy images in 1 kg infant outlining: (A) Initial angiography demonstrating a large tubular PDA. (B) Deployed MVP-7Q. Note the aortic end of the device just distal to the temperature probe in the esophagus. The waist on the device is outlined by the black arrow. (C) Prerelease pulmonary artery angiogram demonstrates good device position with good filling of branch pulmonary arteries. (D) Final postrelease device position. MVP-7Q, Microvascular Plug 7Q; PDA, patent ductus arteriosus

1.5 (IQR = 1.4–2). All except one patient were ventilator and oxygen-dependent at the time of the procedure. Femoral arterial access was not obtained in any patient. All patients had femoral vein access using a 4-Fr sheath except in one patient in whom a 5-Fr sheath was inserted. One patient underwent right internal jugular venous access due to pre-existing lines in the femoral vein. The mean PDA length was 12 mm (SD: 1.5). The mean PDA diameters at the aortic and pulmonary ends were 5.2 (SD: 0.5) and 4.9 mm (SD: 0.5), respectively.

A 4-Fr Glide catheter (Terumo) was used to deliver the device in all patients. Fifteen patients (75%) required only one attempt to deliver the device, while in the remaining patients 2–3 attempts were made to achieve device deployment in the appropriate location. The median procedure and fluoroscopy times were 30 (IQR = 23–44 min) and 7.35 min (IQR = 4–9.25 min), respectively. The mean contrast volume utilized for angiograms was 3.6 ml/kg (SD: 1.7). The median procedural radiation dose was 7 cGy/m^2 (IQR = 4.5–11.8 cGy/m^2). The mean number of angiograms used per procedure was 3.4 (SD: 1.2).

Successful PDA occlusion was achieved in 20/22 patients. The procedural success rate was 91% (95% confidence interval of 70%–99%). All except one patient had immediate, complete occlusion of the PDA as demonstrated by TTE during the procedure. One patient, who was 26 days and 1.7 kg at the time of procedure, had a failed attempt to implant the MVP-7Q through a jugular venous access. The patient was eventually sent for surgical PDA ligation after multiple attempts to implant the device. Another patient, who was 42 days and weighing 970 g at time of procedure, had a significant LPA compression on the intraprocedural TTE and angiography following device release. The device was snared and retrieved during the same procedure and an Amplatzer Piccolo Occluder was used to close the PDA (although we do not recommend implanting Picclo devices for PDA's > 4 mm, it was successfully implanted in this unique case). No other procedural complications including vascular access complications, tricuspid valve injury, or LPA or aortic arch stenosis were encountered. The gradient across the LPA postprocedure was a median of 6.6 mmHg (IQR = 4.8–7.4 mmHg).

Patients were extubated at a median age of 9 days post-procedure (IQR = 3.5–14.25 days). Postprocedural TTE demonstrated complete occlusion of the PDA in all except one patient where there was a small residual shunt through the device. This was a 900 g infant who also underwent pulmonary valvuloplasty at the time of the PDA closure. The residual shunt was not visualized on color Doppler interrogation at 7 days follow-up. The median follow-up time was 2.5 years, (IQR = 12 months–4.3 years). At the latest follow-up, all patients were alive. No LPA stenosis, aortic arch obstruction, or residual shunting were observed.

4 | DISCUSSION

Almost 50% of premature infants have persistence of the ductus arteriosus, resulting in significant morbidities such as congestive heart failure, chronic lung disease, and necrotizing enterocolitis.[14] However, surgical closure of the PDA retains many risks including scoliosis, pneumothorax, chylothorax, and recurrent laryngeal nerve injury.[15] Recently, the transcatheter management of PDA has undergone significant development with recovery time after transcatheter closure usually shorter than surgical ligation of PDA.

This study demonstrates that large PDAs in very-low-birth-weight infants can be closed safely and effectively with the MVP-7Q. This follows on from previously published experience with this family of devices in premature infants.[6] Each device has its own unique advantages and limitations. As the PDA morphology is highly variable, no single device is universally applicable. The use of coil embolization using of a 4-Fr catheter, although helpful, has some limitations including the lack of controlled deployment, coil migration, incomplete occlusion, and recanalization which remained of a substantiated concern.[16] The Amplatzer ADO I and II (Abbott) improved the ability to close large PDAs, however, it was associated with aortic arch obstruction and LPA stenosis secondary to the large retention disc.[17,18] More recently, vascular plugs have proved to be a viable alternative. Advances in technology have led to the widespread availability of plugs in a variety of lengths and sizes and have helped overcome the access limitation. Although it is an effective embolic device, its primary shortcoming is that it still requires a 4- or 5-Fr catheter (0.038-in. inner-diameter lumen) for delivery and may not result in immediate occlusion. This precludes its utilization in a significant number of embolization procedures in which smaller-caliber PDAs necessitate a microcatheter or if a more rapid occlusion is desired. It also holds the potential risk of interference with aortic or LPA blood flow in this cohort of patients by its disks.[19] Based on our experience, the MVP holds several advantages. It is a diskless device and thus the chance of aortic arch or LPA stenosis due to the device is minimal even if parts of the device are not completely intraductal. The aortic end of the device is not covered with a PTFE membrane, thus causing less chance for arch obstruction. The delivery system of the AVP II is also somewhat stiff making the ultimate device position following release somewhat unpredictable in the extremely low-birth-weight infant.[20] By contrast, the MVP has a very soft delivery system, (0.027" cable for the MVP-7Q), which enables delivery through a 4-Fr catheter, and can be easily navigated through torturous vessels, without "stretching" of the heart, and thus avoids hemodynamic compromise.[21] Furthermore, the MVP can be delivered through the delivery catheter itself (Glide Catheter) without the need to exchange to a delivery system or guide catheter needed for the AVP II devices. The MVP also holds the advantage of having a partial PTFE membrane coverage at its pulmonary end, unlike the AVPII, and thus decreasing the risk of any residual shunt. The AVP II device sizes come in a 2 mm increasing order. This may preclude its use in some instances, as it may be either too large or too small. We have faced several situations in our experience, in which the 6 mm AVP-II is too small and the 8 mm AVP-II is too large to use, especially when we now know the fact that the AVP devices tend to lengthen significantly if oversized, in an inverse relation to the diameter of the vessel.[22] Since, a 7 mm AVP-II is not available; the MVP-7Q presents a good alternative.

The MVP-7Q also compares favorably to the Piccolo device where tricuspid regurgitation, albeit not clinically significant, was the most common complication in preterm infants.[1] Furthermore, in the series reported by Sathanandam et al.,[20] two sub-1 kg patients developed aortic arch stenosis after the Piccolo device implantation, eventually developing coarctation and requiring transcarotid stenting, while no patients developed significant LPA stenosis. In our cohort, no patients experienced aortic arch narrowing and only one patient showed significant LPA stenosis post-MVP implantation. This patient required snaring of MVP after implantation which was performed easily through the same 4-Fr glide catheter that was used to deliver the device, and no catheter or sheath exchange was necessary. It is important to note that these "neonatal type" PDAs are tubular in nature, and thus the aortic and pulmonary end measurements are crucial for optimal size selection, rather than the minimal PDA diameter.

Further advantages of the MVP include easy recapture and repositioning of the device and the absence of retention discs, which may precipitate obstruction of the LPA and/or the aortic arch. Although MVP-7Q is a relatively long device (unconstrained length of 16 mm, measured between the two radio-opaque markers on the device), mild protrusion of the device into the aorta is unlikely to cause aortic arch obstruction, since the distal 4 mm of the device toward the aorta is not covered with Gore-Tex. The actual portion of the device that is in contact with the PDA vessel lumen is 8 mm; while the covered portion of the device is 10 mm. Also, the MVP has relatively less Nitinol in its framework compared to the Amplatzer devices. This makes the device less stiff making it easier and safer to navigate through the blood vessels and heart of the smallest of patients.[23] Despite the lack of retention discs, we had no cases of device embolization with excellent occlusion rates. It is likely that the relative size of the device to patient size and the elongated tubular morphology of the PDA facilitate stable device position following deployment.

5 | LIMITATIONS

The major limitation of the study is the retrospective nature with its inherited referral and selection biases. The advantages listed in the discussion section is mainly based on the performers' experience rather than large clinical trials. Another limitation is the small number of patients, which may be considered acceptable for this newly introduced device for this particular procedure. Of particular interest, this retrospective study reported unique techniques and work-up in a selective cohort.

6 | CONCLUSIONS

There is currently an unmet need for a device to close large (>4 mm) PDA in small (<2.5 kg) infants. This report demonstrates the feasibility and safety of using the MVP-7Q for transcatheter closure of such large PDAs even in infants smaller than 1000 g. The MVP-7Q is a useful, alternative option while selecting the appropriate device for transcatheter PDA closure in very small infants with large PDAs.

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CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

DATA AVAILABILITY STATEMENT

Data are available on request from the authors.

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SUPPORTING INFORMATION

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