CLINICAL RESEARCH

Transcatheter patent arterial duct closure in premature infants: A new technique to ease access to the patent arterial duct, with particular benefit for the tricuspid valve

Fermeture percutanée du canal artériel persistant chez les prématurés : une nouvelle technique pour faciliter l'accès au canal avec un intérêt particulier pour la valve tricuspide

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Summary
Background. — Transcatheter patent arterial duct (PAD) closure in premature infants has been shown to be feasible. Since our early transcatheter PAD closure procedures in premature infants at Hôpital Necker Enfants Malades, we have changed our technique several times to advance the guidewire through the right heart to avoid tricuspid valve damage.
Aim. — To describe the technique we have been using since May 2019, to report our results with a particular focus on tricuspid leaks and to analyse the potential mechanisms of tricuspid lesion development with previous methods.
Methods. — All premature infants weighing < 2 kg who underwent transcatheter PAD closure with this new technique were included. Demographic data, procedural data, outcome and procedural complications were reviewed, with particular attention to the occurrence of tricuspid regurgitation.

Results. — Between May 2019 and May 2020, 33 patients were included. Median gestational age was 25 weeks. Median birth weight and procedural weight were 690 g (range 490—1065 g; interquartile range [IQR] 620—785 g) and 1160 g (range 900—1900 g; IQR 1030—1300 g), respectively. Median age at procedure was 35 (IQR 30—46) days. PAD anatomy was evaluated on transthoracic echocardiography only. The median duct diameter was 3 (IQR 2.5—3.2) mm at the pulmonary end. Success rate was 100% (defined as successful closure without residual shunt). One patient had a renal vein thrombosis, which fully resolved with low-molecular-weight heparin anticoagulation. No tricuspid regurgitation or stenosis of the left pulmonary artery or the aorta was seen. One patient died of a superior caval vein obstruction with bilateral chylothorax related to a central catheter thrombosis 56 days after the procedure, unrelated to the catheter procedure.

Conclusion. — In this prospective study, we describe a new technique to avoid tricuspid valve damage and facilitate delivery of the PAD device.

MOTS CLÉS
Fermeture
percutanée ;
Persistance du canal
artériel ;
Prématurité ;
Extrême prématuré

Résumé

Contexte. — La fermeture par voie percutanée est devenue une option incontournable pour traiter les canaux artériels persistants (PCA) et hémodynamiquement significatifs des nouveau-nés prématurés. L'efficacité de la procédure n'est plus à démontrer et les évènements indésirables semblent moins fréquents qu'avec l'alternative chirurgicale. Au cours de notre expérience de fermeture des PCA des nouveau-nés prématurés à l'hôpital Necker-Enfants-Malades, nous avons néanmoins observé plusieurs fuites tricuspides consécutives à la procédure, et avons modifié à deux reprises notre technique pour éviter les récidives.

Objectif. — L'objectif de cet article est de décrire la technique que nous utilisons depuis mai 2019, de rapporter nos résultats en s'intéressant particulièrement aux fuites tricuspides, et d'analyser les potentiels mécanismes des lésions tricuspides avec les méthodes antérieures.

Méthodes. — Tous les prématurés de moins de 2 kg adressés pour fermeture de PCA par voie percutanée avec cette nouvelle technique ont été inclus. Les données démographiques et procédurales, les résultats et les complications de la procédure ont été passés en revue, avec une attention particulière sur la survenue de fuites tricuspides.

Résultats. — Nous avons inclus 33 patients de moins de 2 kg adressés pour fermeture du PCA entre mai 2019 et mai 2020. L'âge gestationnel médian était 25 semaines, et le poids médian au moment de la procédure 1160 g (étendue 900—1900 g ; IQR 1030—1300 g). Le taux de succès de la procédure (défini comme la fermeture du PCA sans shunt résiduel) était de 100 %. Nous n'avons constaté aucune coarctation de l'aorte ou de l'artère pulmonaire gauche, ni aucune fuite tricuspide dans les suites immédiates de l'intervention ou au cours du suivi. Nous avons recensé deux évènements indésirables graves: une thrombose de la veine rénale gauche d'évolution favorable après 6 semaines d'anticoagulation, et un décès secondaire à un syndrome cave supérieur compliqué d'un chylothorax bilatéral réfractaire au traitement médical, sans rapport avec la procédure.

Conclusion. — Nous espérons que cette nouvelle technique permettra d'améliorer la prise en charge du canal artériel persistant chez cette population particulièrement fragile.

Background

Patent arterial duct (PAD) is the most common cardiac anomaly in premature infants, and its prevalence is inversely correlated to gestational age and birth weight [1]. Over the last few years, multiple reports have shown feasibility, success and acceptable complication rates for transcatheter PDA closure [2—9]. The AMPLATZER Piccolo™ Occluder device (St. Jude Medical, St. Paul, MN, USA) has now been approved by the US Food and Drug Administration (FDA) and has a CE mark for PAD closure in preterm infants aged > 3 days and weighing > 700 g [10,11].

Complications have been described [3—5,9]; some are related to the method of advancing the device through the heart, and others are related to the technique used to accurately position the device within the duct. In the first group,

inferior caval vein, tricuspid valve and infundibular damage have been described [3,6]. In the second group, device embolization, left pulmonary artery (LPA) stenosis and aortic coarctation have been reported [3,4,9]. The second type of lesion can be avoided by familiarity with device performance, adequate and precise echocardiography guidance and use of angiography before device release, if necessary [5,6]. The first group of complications may be avoided by procedural technique.

We previously described a multicentre series of 102 preterm infants with transcatheter PAD closure [3], in which we reported the occurrence of three cases of traumatic tricuspid regurgitation. We have changed our technique several times to avoid tricuspid valve damage. We describe here our most recent technical modification, attempting to reduce tricuspid valve damage, and the results of this technical change, in a cohort of 33 patients.

Methods

Study population

We reviewed demographic data before transcatheter PAD closure in premature babies, procedural data and procedural complications, with particular emphasis on the occurrence of tricuspid regurgitation, for each of the three successive techniques that we used over time. The first two techniques described briefly below have already been reported [3]. The third technique was used between May 2019 and May 2020. Informed consent was obtained for all patients from legal guardians.

Precatheterization care

Preprocedural care is now standardized in our centre. The patient is transferred to our neonatal intensive care unit the day before the procedure. Once the patient has been stabilized, we perform echocardiography to assess the morphology, length and diameter at the pulmonary end of the ductus, and its anatomical relationship to adjacent structures [12]. Antibiotic prophylaxis with vancomycin infusion is started before transfer to the catheterization laboratory.

Procedural technique

Procedures are performed under general anaesthesia, with the patients connected to their own ventilator (Leoni Plus, Lowenstein Medical, Bracknell, UK). To minimize the length of the procedure, only non-invasive haemodynamic data are collected during the catheterization. A per procedure echocardiogram is performed in the catheterization laboratory to measure again the diameters and length of the PAD, and to select the size of the AMPLATZER Piccolo™ Occluder device. The best echocardiographic window to guide the procedure is noted. The length of the device selected is always the shortest to avoid the LPA or aortic obstruction. The diameter of the device is chosen according to the smallest diameter of the PAD. As a rule of thumb, 1 mm is added to the narrowest diameter of the PAD [11]; this is similar to the instructions for use (Fig. 1).

D mm (in)	E mm (in)	
	3.12 (0.118-0.472)	≥ 12.1 (≥ 0.476)
≤ 1.7 (≤ 0.067)	9-PDAP-03-02-L	9-PDAP-03-04-L
1.8-3.2 (0.071-0.126)	9-PDAP-04-02-L	9-PDAP-04-04-L
3.3-4.0 (0.130-0.157)	9-PDAP-05-02-L	9-PDAP-05-04-L

Figure 1. Instructions for use of the AMPLATZER Piccolo™ Occluder (ADO II AS; St. Jude Medical, St. Paul, MN, USA). D: duct diameter; E: duct length.

For all transcatheter PAD closure procedures, a femoral vein is cannulated using a 22 gauge needle, and a 3 Fr sheath (IVA3F; Balt Extrusion, Montmorency, France) is positioned in the femoral vein, later exchanged for a 4 Fr sheath (Radiofocus; Terumo, Tokyo, Japan). Saline heparinized with 100 IU of heparin is used to flush the catheters before insertion. The AMPLATZER Piccolo™ Occluder was the only device used for transcatheter PAD closure in our institution.

Former right heart catheterization techniques

In our early experience of transcatheter PAD closure in preterm infants, we used a 0.014 inch PILOT™ guidewire (length 180 cm; St. Jude Medical, St. Paul's MN, USA) to cross the tricuspid valve. A 4 Fr Judkins right coronary catheter 2.0 (length 80 cm and inner size 0.89 mm; Cordis, Miami Lakes, FL, USA) was then advanced on the PILOT™ guidewire and placed in the descending aorta, followed by the 4 Fr TorqVue™ LP Delivery System (St. Jude Medical, St. Paul's, MN, USA).

We observed three tricuspid regurgitations as a result of tricuspid valve trauma using this method. We hypothesized that damage to the tricuspid valve was a consequence of the mismatch between the 0.014 inch guidewire and the 0.048 inch lumen of the TorqVue™ LP Delivery System. We therefore modified our technique as follows: the tricuspid valve was crossed the same way using a 0.014 inch PILOT™ guidewire, and the right coronary catheter was positioned in the descending aorta on the PILOT™ guidewire. A stiff 0.014 inch wire (Spartacore™; Abbott Vascular, Santa Clara, CA, USA) was advanced beside the PILOT™ wire through the right coronary catheter in the descending aorta. Then, the TorqVue™ LP Delivery System was advanced to the adequate position. However, we also observed tricuspid valve regurgitations with this second technique.

New right heart catheterization technique

A 2.7 Fr Progreat® microcatheter (length 130 cm, inner size 0.65 mm; Terumo, Tokyo, Japan) is modified, before starting the venous puncture, by cutting the extremity to get rid of the proximal hub (Fig. 2A). A 0.014 inch HI-TORQUE PILOT™ 50 guidewire (St. Jude Medical, St. Paul's MN, USA) is introduced into the microcatheter. The soft extremity of the wire is manually curved in order to be oriented when in the right
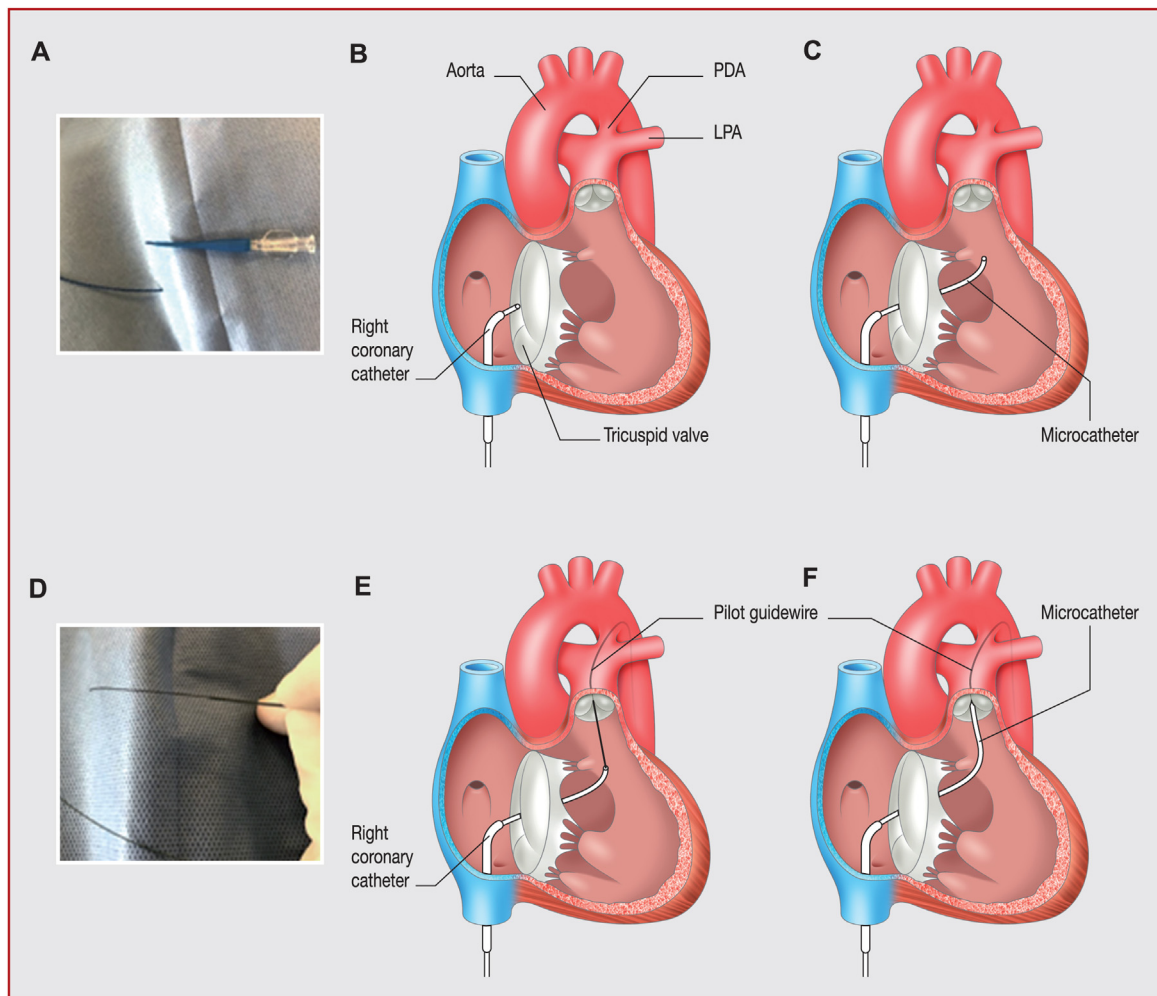
Figure 2. A. The Progreat® microcatheter (Terumo, Tokyo, Japan) is prepared for the procedure: the extremity is cut to get rid of the proximal hub. B. 0.014 inch HI-TORQUE PILOT™ guidewire (St. Jude Medical, St. Paul, MN, USA) is introduced into the microcatheter, and the soft extremity manually curved in order to ease manipulations in the right ventricle.

ventricle (Fig. 2D). The microcatheter is inserted in a 4 Fr Judkins right coronary catheter 2.0 (Fig. 2). All three are advanced into the right atrium.

The microcatheter is used to cross the tricuspid valve, and is placed in the right ventricle under biplane fluoroscopic guidance (Fig. 2). Once the microcatheter is well positioned in the right ventricle, the PILOT™ is advanced to cross the pulmonary artery and the PAD (Fig. 2), and is placed in the descending aorta. The microcatheter is then advanced to the descending aorta (Fig. 2). The right coronary catheter, which always remained in the right atrium, is finally removed, and the TorqVue™ LP Delivery System is advanced on the microcatheter. Positioning and deployment of the device are done using echocardiography and fluoroscopy (Fig. 3). We do not perform angiography.

Statistical analysis

Categorical variables are given as number and percentage. Continuous variables are summarized by median, interquartile range (IQR) and minimum—maximum range.

All statistical analyses were performed using R statistical software (R foundation for Statistical Computing, Vienna, Austria).

Results

Between May 2019 and May 2020, 33 patients benefited from this new technique. Demographic details are shown in Table 1. In 27 patients, pharmacological treatment (acetaminophen and/or cyclooxygenase inhibitor) had failed to close the PDA. The other patients were contraindicated for medical treatment.

Median (IQR) age at procedure and procedural weight were 35 (30—46) days and 1160 (1030—1300 g), respectively. Eleven patients (33.3%) were on high frequency oscillation at the time of the procedure.

Echocardiographic data, with haemodynamic and PDA assessment before and after the procedure, are shown in Table 2. The median (IQR) PDA diameter was 3 (2.5—3.2) mm at the pulmonary end and 3.5 (IQR 3—4) mm at the aortic end.
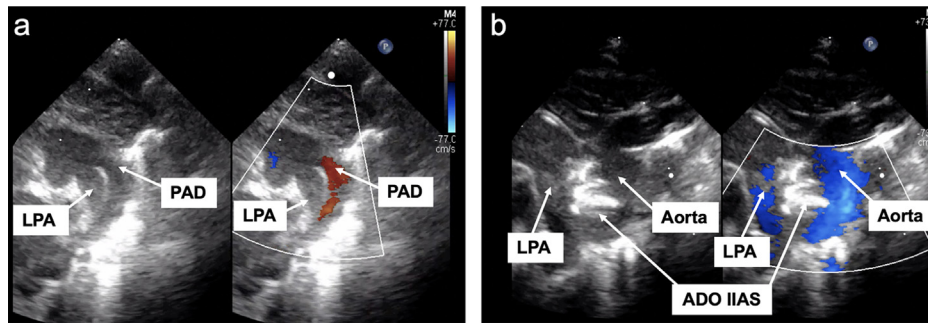
Figure 3. A. Transthoracic echocardiogram (high left parasternal view) before device implantation. B. Transthoracic echocardiogram (high right parasternal view) at the time of device implantation. The AMPLATZER Piccolo™ Occluder (ADO II AS; St. Jude Medical, St. Paul, MN, USA) is still attached to the delivery system, and the team ensures that it does not obstruct the left pulmonary artery (LPA) or aorta in two-dimensional and colour Doppler. PDA: patent arterial duct.

Table 1 Demographic data.

Gestational age at birth (weeks)	
Median (IQR)	25 (24—26)
Minimum—maximum	24—30
Birth weight (g)	
Median (IQR)	690 (620—785)
Minimum—maximum	490—1065
Procedural age (days)	
Median (IQR)	35 (30—46)
Minimum—maximum	18—57
Procedural weight (g)	
Median (IQR)	1160 (1030—1300)
Minimum—maximum	900—1900

IQR: interquartile range.

Table 2 Haemodynamic and patent arterial duct assessment.

	Median (IQR)	n
Before procedure		
PDA size, pulmonary end (mm)	3 (2.5—3.2)	33
PDA size, aortic end (mm)	3.5 (3—4)	22
PDA length (mm)	7 (6—9)	23
LA/aorta ratio	1.8 (1.675—2)	32
LPA velocity (m/s)	1.3 (1.2—1.4)	30
Mean LPA velocity (m/s)	0.6 (0.57—0.71)	27
After procedure		
LPA velocity (m/s)	1.4 (1.0—1.7)	30
Aortic velocity (m/s)	1.0 (0.8—1.3)	30
Tricuspid leak	None	33
Residual shunt	None	33

IQR: interquartile range; LA: left atrium; LPA: left pulmonary artery; PDA: patent arterial duct.

Table 3 Procedural data.

High frequency oscillation	11/33 patients (33.3%)
Procedural length (minutes)	
Median (IQR)	30 (20—30)
Range	15—60
Median (IQR) duration of fluoroscopy (minutes)	4.9 (4.1—5.8)
Cineangiography yes/no	1/33 patients (3%) (1 mL)
Median (IQR) radiation exposure	
mGy	3.8 (2.8—5)
μGy.m^2	6.4 (5—7.6)
Type of device	ADO II AS 3*2: 3 patients ADO II AS 4*2: 20 patients ADO II AS 5*2: 10 patients
Repositioning of the device	11 patients (33.3%)
Device changed	2 patients (6%)

ADO II AS: AMPLATZER Piccolo™ Occluder (St. Jude Medical, St. Paul, MN, USA); IQR: interquartile range.

Procedural data

Procedural data are shown in Table 3. Rate of success, defined as delivery of a device without residual shunt, was 100%. Median (IQR) procedural time was 30 (20—30) minutes (range 15—60 minutes). AMPLATZER Piccolo™ Occluder devices were used in all patients: 3×2 ($n = 3$); 4×2 ($n = 20$); and 5×2 ($n = 10$).

The device had to be repositioned in 11 patients. In some patients the device protruded into the aorta, and in other cases the device protruded into the LPA. Obstruction was defined as significant decrease of arterial flow downstream of the device, presence of an accelerated flow with diastolic component next to the device or a maximal flow velocity > 2 m/s in spectral Doppler. In one patient, paraprosthetic shunt associated with protrusion in the LPA was noted, and was resolved after device repositioning. The positioning of the device was a matter of consensus between the sonographer and the interventionist. In three patients, the device position seemed unusual (too vertical or too close to the
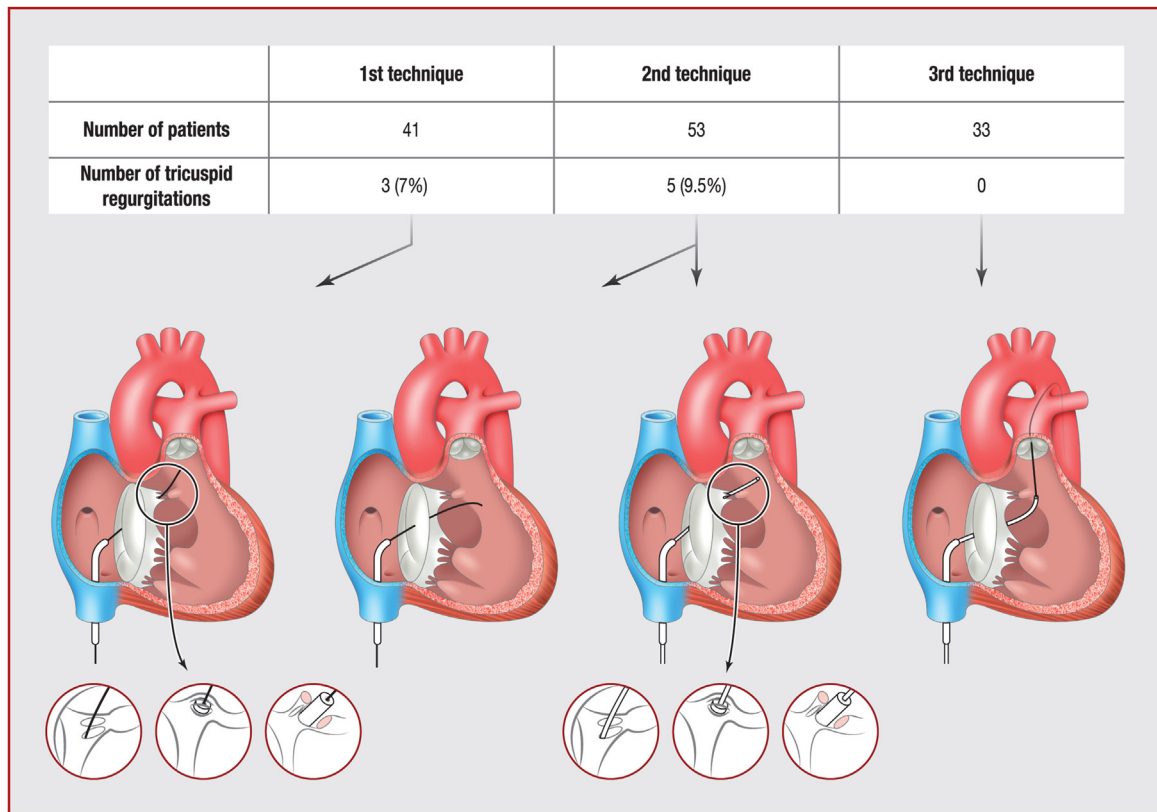
	1st technique	2nd technique	3rd technique
Number of patients	41	53	33
Number of tricuspid regurgitations	3 (7%)	5 (9.5%)	0

Figure 4. A—D. The microcatheter is used as a tutor for the 4 Fr right coronary sheath and then the TorqVue™ Delivery System (St. Jude Medical, St. Paul, MN, USA). LPA: left pulmonary artery; PDA: patent arterial duct.

aorta) on fluoroscopy, although there were no significant obstructions on transthoracic echocardiography; this is to be expected when the ductus is superimposed on the aorta in transthoracic echocardiography or its path is more vertical than usual. Moreover, the conformation of the ductus may be greatly altered by the presence in it of the rigid delivery system.

In two patients, the device initially chosen was changed for a smaller one; in both cases the device caused simultaneous obstruction of the LPA and aorta. The decision was made to try a smaller device, and to leave it only if a stable position was obtained and no residual shunt was seen on transthoracic echocardiography. No embolization occurred in this series, and no residual shunt was reported on discharge. AMPLATZER Piccolo™ Occluder devices were deployed completely intraductally, without any disc in the pulmonary artery or in the aorta. At last follow-up, the median LPA maximum velocity was 1.4 (IQR 1.0—1.7) m/s and the median aortic maximum velocity was 1 (IQR 0.8—1.3) m/s. No tricuspid regurgitation was noted with the latest technique.

Complications

One patient had renal vein thrombosis, diagnosed because of macroscopic haematuria, with good evolution after 5 weeks of low-molecular-weight heparin treatment (enoxaparin 75—150 IU/kg/12 h). No LPA or aortic stenosis was noted during follow-up.

Deaths

One patient died 56 days after the procedure, of a superior caval vein occlusion with bilateral chylothorax, which was refractory to medical treatment and was not related to transcatheter PAD closure.

Tricuspid regurgitation

The proportions of tricuspid valve regurgitations noted after the transcatheter PAD closure according to the three right heart catheterization techniques are shown in Fig. 4. With the first technique, all three tricuspid traumatic lesions were chordae rupture. With the second technique, we observed four chordae ruptures and one perforation of the anterior leaflet (Fig. 4).

After the procedure, three of eight patients had moderate-to-severe regurgitation, which was clinically well tolerated, without the need for inotropic support. Some of these regurgitations might have been amplified with the postoperative circulatory changes (abrupt elevation in left ventricular afterload, transient pulmonary hypertension). The evolution was favourable in all patients, with improvement in tricuspid regurgitation that is now mild to moderate and clinically silent, with little impact on right ventricular volume or right heart filling pressure at last follow-up. None of the patients required surgery. As we adopted the technique using the Progreat® microcatheter, we have not seen tricuspid valve damage. Fig. 4 illustrates the

hypothetical mechanisms for tricuspid valve trauma with the three techniques that we used.

Discussion

The feasibility of transcatheter PDA closure is now well established [5,6,9]. As with any technique, complications occur. The most reported complication of transcatheter PAD closure is LPA stenosis [7,9]; aortic isthmus stenosis is also a concern [3,9]. Tricuspid valve damage has been described in one series reporting 102 preterm infants who had transcatheter PDA closure [3]. When analysing the causes of tricuspid valve trauma in our series, it was difficult to say whether rupture occurred at the time of right coronary catheter mobilization or at TorqVue™ mobilization. Although it was noted that TorqVue™ positioning was sometimes not smooth, it remains uncertain whether the guidewire itself could cause chordal damage or if the guidewire was wrapped (in a spiral) around the chordae, causing rupture when tension had to be applied to TorqVue™ to access the PAD. In retrospect, adding a second guidewire may have increased tension on the tricuspid valve chordae and amplified the mechanisms, causing tricuspid regurgitation. The technique modification to access the PAD from the right atrium using the microcatheter streamlined the procedure in two ways. First, the microcatheter was flow guided, and this made it less likely that the guidewire would damage the tricuspid valve leaflet. Second, the microcatheter served as a ''tutor'' for the TorqVue™ LP Delivery System. Manipulation of the relatively stiff TorqVue™ catheter through the heart was thus simplified.

Other techniques have been demonstrated to be safe to cross the tricuspid valve. One such example is the use of a balloon catheter to enter the right ventricle, followed by a 0.014 inch guidewire. Alternatively a soft 4 Fr catheter (GLIDECATH®; Terumo, Tokyo, Japan) with a 0.035 inch Wholey™ guidewire (Medtronic, Minneapolis, MN, USA) may be used [5,6,9]. However, a balloon catheter can be difficult to manipulate in small babies. Additionally, a 0.035 inch guidewire might cause haemodynamic instability during manipulation through the right atrium and right ventricle, by maintaining right heart valves open. Some operators have avoided an intracardiac catheter course by adopting a retrograde femoral artery approach to the PAD [2,13]. However, the risk of femoral artery occlusion in extremely small patients precludes its regular use.

We currently exclusively use the AMPLATZER Piccolo™ Occluder because it has been designed to address the unique ductal morphology of very premature infants, which is commonly described as long and tubular, without significant stenosis [10,14]. The delivery system is also more suitable for these very-low-weight babies (short length, low-profile delivery system) [10,14]. Series with the AMPLATZER™ Vascular Plug II and Microvascular Plug [3,7,9,15] have reported good results, with acceptable rates of complications, but these devices do not have FDA approval or a CE mark in this indication. Although no comparative studies have been conducted to compare the different devices, most clinicians are now using the AMPLATZER Piccolo™ Occluder [14].

Surgical ligation, which used to be the gold standard for ductus closure in premature and low-weight infants, has been viewed with caution by neonatologists [15]. Postligation cardiac syndrome can be severe, with a difficult postoperative period. Morbimortality exists after surgery, with wound infection and phrenic palsy. Some controversial studies have raised concern about neurodevelopmental outcome after surgery. Some arterial ducts will not close, and surgery remains an option in many centres—even in centres with transcatheter closure programmes—if the ducts are too large or too short or are associated with hypoplastic aorta.

We suggest that the use of this technique for transcatheter PAD closure in premature babies is a safer method that could limit tricuspid valve lesions. It is also noteworthy that transthoracic echocardiography is a mainstay of the procedure, and that the microcatheter is easily seen on transthoracic echocardiography, which may ultimately ease cot-side closure of the PAD in the neonatal intensive care unit [9,13].

Study limitations

This was a single-centre study with a small number of patients. It is possible that the increasing experience of the operators reduced the risk of tricuspid valve damage, as the three techniques were not concurrent. The length of follow-up was 2 years at most, so we cannot draw conclusions about mid- and long-term follow-up; however, in our experience, if the tricuspid valve has been damaged, a tricuspid leak is seen immediately at the end of the procedure, just after removal of the material.

Conclusion

Today, transcatheter closure of a PDA is a safe alternative to surgical ligation in premature babies. We describe here a technical adaptation, using a microcatheter to avoid tricuspid valve damage during right heart catheterization to reach the arterial duct, which also eases atraumatic placement of the TorqVue™ LP Delivery System.

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