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Original Article

Optimal management of pulmonary atresia with intact ventricular septum in a developing country: the art of pulmonary valve mechanical perforation in the era of CTO hardware

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Abstract: Background: Transcatheter valve mechanical perforation (TVMP) in pulmonary atresia with intact ventricular septum (PAIVS) is an acceptable yet challenging alternative to radiofrequency. Aims: To evaluate and compare safety, feasibility, and efficiency of two TVMP techniques. Methods: Clinical data of neonates with PAIVS who underwent an attempt for TVMP between 2009 and 2019 were retrospectively reviewed. Patients were divided into two groups according to perforation technique: using the stiff end of a percutaneous transluminal coronary angioplasty (PTCA) ordinary 0.014" wire (group A) and subsequently with the floppy tip of a chronic total occlusion (CTO) guidewire (group B). The technical aspects, procedural and discharge outcomes of both groups were compared. Results: A total of 19 antegrade TVMP procedures (Group A, n=10, and Group B, n=9) were attempted in 18 neonates with an overall success rate of 73.7% and no procedure-related mortality. Groups' analysis showed that the introduction of CTO hardware maximized procedure success rates (P=0.002) with zero failure and misperforations (P=0.022). The significant drop in perforation time (P < 0.001) and irradiation exposure (P=0.006) allowed additional ductal stenting during the same procedure, optimizing patients' clinical outcomes and shortening overall hospital stay. Discharged patients had room air mean oxygen saturation of 91.4% (± 5.5) with no evidence of heart failure. Conclusions: In selected cases of PAIVS, TVMP using CTO wires is a safer, highly efficient, and simplified alternative to other mechanical perforation techniques. It substantially revolutionized the management of PAIVS in our center optimizing short-term prognosis.

Keywords: Pulmonary atresia, cardiac catheterization, mechanical perforation, chronic total occlusion, guidewire

Introduction

The heterogeneous morphology and hemodynamic implications of pulmonary atresia with intact ventricular septum (PAIVS) keep on challenging pediatric cardiologists in clinical decision-making [1]. In selected patients with favorable anatomy for biventricular repair, establishing antegrade flow by right ventricle (RV) decompression is the fundamental step for optimal primary management [1, 2]. Among all described valvotomy options, radiofrequency-assisted perforation stood out as the most acceptable and established practical alternate in well-equipped catheterization laboratories [3-5]. However, experienced interventionists reported the use of coronary guidewires for transcatheter valve mechanical perforation (TVMP) with variable success rate and procedural outcomes [6-11]. The TVMP has been associated with significant risks including RV perforation and optimal catheter positioning is crucial for procedure success [12-14]. Over the past decade, continuous advances in chronic total occlusion (CTO) hardware technology have led to the development of a wide range of specialized guidewires with enhanced maneuverability, tip support, torque force, and penetrating power [15, 16]. We report our initial experience of TVMP using the stiff tip of ordinary per-

cutaneous transluminal coronary angioplasty (PTCA) 0.014" wires and the technical promising advantages of TVMP using CTO hardware.

Methods

Study design and patients selection

All neonates with PAIVS and in whom TVMP was attempted in our institution between January 2009 and December 2019 were retrospectively reviewed and included in this study. Included neonates had membranous total atresia, well-developed infundibulum with no RV coronary artery dependent circulation, and were considered likely candidates for biventricular repair [1]. All patients were severely cyanotic, and the diagnosis of PAIVS with ductal-dependent pulmonary circulation was confirmed by transthoracic echocardiography (TTE). Ductal patency was maintained by continuous prostaglandin infusion. This study protocol was reviewed and approved by the Saint Joseph University research ethics committee on human clinical research. Data was collected from admission day to hospital discharge and included patients' demographics, clinical and echocardiographic characteristics as well as detailed procedural data and short-term outcomes. All procedures contributing to this work comply with the ethical standards of the relevant national guidelines on human experimentation, and with the Helsinki Declaration of 1975, as revised in 2008.

Catheterization technique

All interventions were performed by the same experienced operator in a single plane catheterization laboratory under general anesthesia and fluoroscopic control with intensive care unit (ICU) backup for postoperative recovery. Informed consent was signed by patients' legal guardians to perform the procedure after they were provided with a comprehensive explanation about the procedural details, the advantages, and possible complications. Prostaglandin infusion was kept on standby if needed for prolonged interventions or deep cyanosis. One 5F femoral vein and one contralateral 4F femoral artery were accessed. Intravenous heparin (100 IU/kg) was administered and activated clotting time was regularly monitored and maintained longer than 200 seconds. An aortogram using a 4F pigtail catheter (Cordis Corp., Miami, FL, USA) was performed to rule out the presence of any significant coronary anomaly or sinusoid, and to delineate the patent ductus arteriosus (PDA) morphology and the degree of development of the pulmonary branches. A 5F diagnostic catheter N.I.H (Cordis Corp. Miami, FL, USA) was used to measure RV pressure and to perform a diagnostic RV angiogram in lateral projection confirming echocardiographic findings and ruling out RV-dependent coronary filling. After that, a 4F or 5F Judkins right (JR) coronary catheter (Cordis Corp., Miami, FL, USA) was transvenously maneuvered into the RV outflow tract (RVOT) to face the atretic pulmonary valve (PV). A minimal volume of contrast was intermittently hand-injected to localize the atretic PV plane and then to confirm the catheter tip central position against the PV. From the arterial side, another 4F JR coronary catheter was advanced across the PDA and positioned just distal to the plane of the PV accomplishing coaxial central alignment of catheters.

Early in our experience, the stiff end of the available PTCA ordinary 0.014" guidewire (Pilot 150 or Balance Middle Weight (BMW) wire (Abbott Vascular, Santa Clara, CA, USA)) was used for TVMP. The last 2 to 3 mm of the stiff tip were slightly curved to delineate the catheter tip when advanced to its edge. The wire was then gently pushed in a controlled fashion keeping the catheter tip close and perpendicular to the valve plane. Across a Y-connector, small contrast hand injections were used to control the location of the wire-catheter assembly to the PV (**Figure 1A**). A 5 mm loop 4F gooseneck snare (Ev3 Endovascular, Inc., Plymouth, MN, USA), was introduced through the arterial JR catheter and deployed in the pulmonary trunk, ready to receive the wire stiff tip immediately after perforation (**Figure 1B**). Once succeeded, the venous catheter was gently pushed into the pulmonary artery lumen over the established arteriovenous circuit (**Figure 1C**). At this point, the catheter was stabilized in place, the wire was retrieved and then reintroduced by advancing its soft tip distally in the descending aorta across the PDA where it was snared again to secure its position. The arteriovenous loop establishment enhanced the tractability of the assembly and allowed one-step snare-assisted

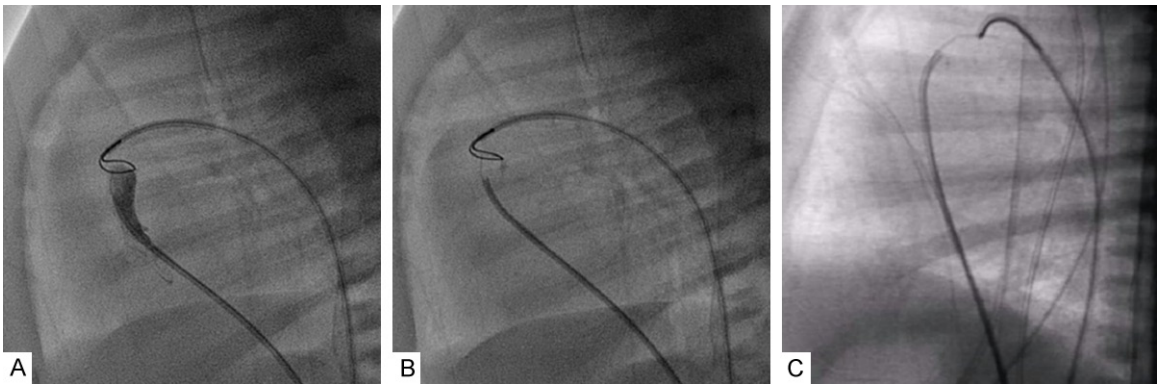

Figure 1. Perforation using the stiff end of a PTCA ordinary 0.014" wire. Wire advanced to the tip of the JR catheter with the snare ready to receive it for the arterial side (A). Gentle pushing of the wire against the atretic valve (B). Established arteriovenous circuit after successful perforation over which the venous catheter is gently pushed into the pulmonary artery lumen (C).

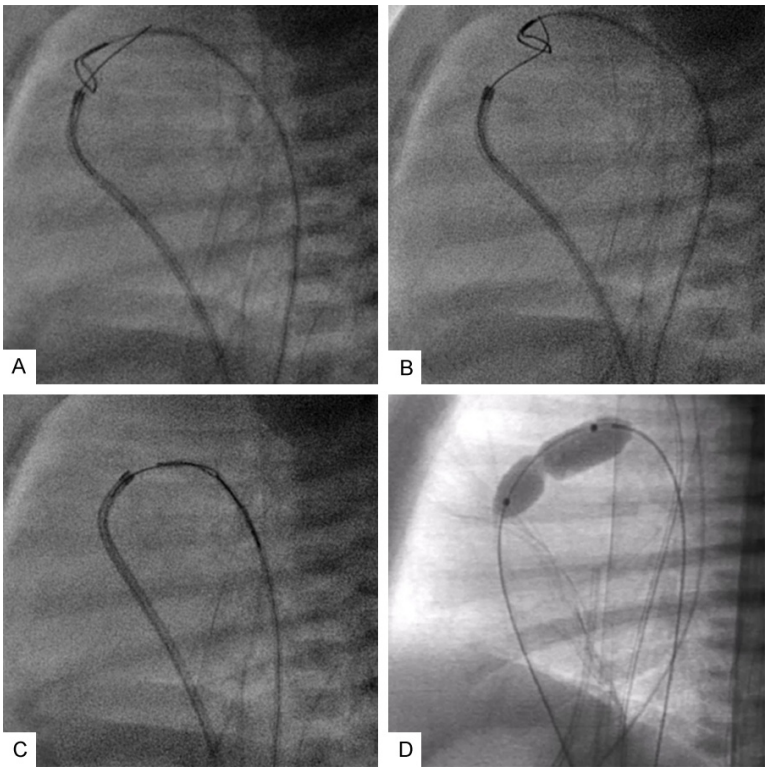

Figure 2. Perforation using the floppy tip of 0.014" CTO wire (Cross-it 200XT). Directly snared wire after successful perforation (A, B) and pulled to the descending aorta (C), providing a stable position for balloon pulmonary valvuloplasty (D).

balloon pulmonary valvuloplasty (BPV) using a 20 mm-long TyShak Mini PTV Balloon dilatation catheter (NuMED, Inc., Hopkinton, NY, USA) with a diameter ranging between 110% and 140% of the PV annulus diameter. At the end of the procedure, pull back gradient and right ventriculogram were performed routinely in all cases.

In January 2016, the perforation technique was substantially modified with a fortuitous introduction of the CTO hardware to our catheterization laboratory. Perforation was similarly performed anterogradely but using the floppy tip (instead of the stiff end) of a special coronary wire originally conceived for recanalization of CTOs in coronary interventions. The wire was advanced transvenously through the PV with rotational motion using a torquer. The snare was manipulated transarterially through the ductus and kept opened with some light pressure against the atretic PV plane (**Figure 2**). This maneuver provided a clear demarcation of the RVOT preventing misperforation. Following perforation, the same wire was directly snared and pulled to the descending aorta, providing a stable position for accurate BPV and subsequent ductal stenting when judged indicated.

Additional procedures and post-procedure care

Early in our experience, ductal stenting was anticipated during the same setting only in

Table 1. Patients clinical characteristics, n=18

Variable	M ± SD (range) or N (%)
Weight (Kg)	3 ± 0.35 (2.3-3.8)
BSA (m^2)	0.13 ± 0.15 (0.1-0.16)
Male	6 (33.3)
PR diameter (mm)	7.3 ± 1.6 (4-10)
TV annulus diameter (mm)	12.2 ± 3 (7-17)
MV annulus diameter (mm)	14.2 ± 2.4 (12-19)
Prenatal diagnosis	4 (21.2)

M ± SD = Mean ± Standard deviation; BSA = body surface area; PR = pulmonary ring; TV = tricuspid valve.

patients whose RV cavity was deemed diminished on initial TTE assessment and who likely required additional pulmonary blood flow even following BPV. In these cases, prostaglandin infusion was stopped in the few hours before the procedure according to PDA responsiveness as tested before in the ICU. An appropriate bare metal, balloon pre-mounted coronary stent was deployed in a prograde fashion to establish ductal patency. Prophylactic antibiotic therapy using intravenous cefazolin and anticoagulation using intravenous heparin were given for 24 hours. Aspirin therapy (5 mg/kg/day) was subsequently administered and continued as long as needed. In excessively prolonged TVMP procedures, ductal stenting was postponed to another setting. Neonates waived from immediate stenting returned to the ICU and were kept under prostaglandin infusion for a period of up to 3 weeks to support pulmonary circulation. During the first few days, we were able to determine whether ductal patency was still required by testing the tolerance at prostaglandin weaning. Ductal stenting was undertaken secondarily only in those who did not tolerate prostaglandin infusion or remained hypoxic (with persistent oxygen saturations below 70%), despite all therapeutic measures (oral propranolol and fluid therapy) to assist the RV diastolic function.

Statistical analysis

Statistical analyses were performed using the Statistical Package for the Social Sciences Statistics (SPSS), version 22 for Macintosh (IBM, Armonk, NY, United States). Categorical variables were reported as frequency and percentage. Continuous variables are represented as mean with standard deviation or median with the range depending on the normality of distribution. Statistical analysis for continuous variables was conducted using t-test and Mann-Whitney U as appropriate and by Fisher's exact test for categorical variables. A p-value < 0.05 was considered statistically significant. All reported p values are two-sided.

Results

Patients and procedure characteristics

A total of 18 neonates were identified with a mean bodyweight of 3.0 (± 0.35) Kg. Nineteen TVMP was attempted at a median of 3 days of life. Procedure success rate was 73.7% with an immediate fall in RV systolic pressures. The overall procedure lasted for a mean of 123.1 (± 51.1) minutes with a median perforation time of 17 minutes (range, 4 to 120 minutes) and a mean fluoroscopy time of 35.3 (± 18.7) minutes. Patients' clinical characteristics are summarized in **Table 1**. Early in our experience, perforation was performed using the stiff end of a PTCA ordinary 0.014" wire in 10 (52.6%) patients and then with the floppy tip of a 0.014" CTO wire in the last 9 (47.4%) consecutive patients. The procedure was abandoned in 5 out of 10 (group A) patients after it was complicated with RVOT perforation leading in four cases to life-threatening cardiac tamponade and emergent pericardiocentesis. These four patients were sent on the following day for surgical valvotomy with Blalock-Taussig shunt placement. The fifth failure that occurred in the last (group A) patient was the first (group B) patient in whom TVMP was successfully re-performed after three days using a CTO wire. The CTO wires used for TVMP in (group B) patients were the Cross-it 200XT (Abbott Vascular, Santa Clara, CA, USA) in 6 (66.7%) patients and the PROGRESS 200T (Abbott Vascular, Santa Clara, CA, USA) in 3 (33.3%) patients. In one (group B) patient, perforation attempt using the MiracleBros 12 (Asahi Intecc Co. Ltd., Aichi, Japan) failed but sequentially succeeded using the Cross-it 200XT. Comparison of procedure data between the 2 groups is summarized in **Table 2**. It turned out that TVMP using CTO hardware was associated with a significant increase in procedural success (P=0.022) with zero failure or misperforations (P=0.022). A major drop in perforation time (< 0.001) and fluoroscopy time (P=0.006) was noticed. The median hospital stay duration was remarkably

Table 2. Group comparison, n=19

		Total n=19	Group A, n=10	Group B, n=9	*p*-value
TVMP success	*N (%)*	14 (73.7)	5 (50.0)	9 (100.0)	**0.022**[a]
TVMP-related complications	*N (%)*	5 (26.3)	5 (50.0)	-	**0.022**[a]
Perforation time (min)	*Median (range)*	17 (4-120)	45 (15-120)	10 (4-18)	**< 0.001**[b]
Overall SI-SO (min)	*M ± SD (range)*	123.1 ± 51.1 (50-240)	129.4 ± 45.2 (80-240)	116.7 ± 58.4 (50-215)	0.611[c]
Overall fluoroscopy time (min)	*M ± SD (range)*	35.3 ± 18.7 (7.1-65)	46.5 ± 12.3 (23.2-59.5)	24.1 ± 17.7 (7.1-65)	**0.006**[c]
LOS from perforation attempt date (days), *n=16*	*Median (range)*	6 (3-17)	12 (3-17)	5 (3-9)	0.121[b]
Intrahospital mortality, *n=18*	*N (%)*	2 (11.1)	1	1	-

TVMP = Transcatheter valve mechanical perforation; SI-SO = sheath in-to-sheath out; LOS = length of stay. Group A: TVMP with the stiff end of a percutaneous transluminal coronary angioplasty (PTCA) ordinary 0.014" wire; Group B: TVMP with the floppy tip of a 0.014" chronic total occlusion (CTO) wire. [a]: Fisher's exact test; [b]: Mann-Whitney U test; [c]: T-test. Bold values are significant *p*-values.

decreased yet this finding was not statistically significant.

Additional procedures

Additional ductal stenting was undertaken in 11/14 cases (group A, n=2, and group B, n=9). It was performed immediately following BPV in 9 patients (group A, n=1 and group B, n=8) while it was differed to another setting in the 2 other patients, one week following BPV. All the patients received one single stent to establish ductal patency without any complication.

Discharge outcomes

Two early deaths occurred during the same hospital stay. The first one occurred in a (group B) patient on day 16 of life (8 days after ductal stenting, 14 days after TVMP) when the baby developed a severe septic choc. Stent patency was proven 2 hours before death. The other patient died 5 days after a complicated attempt of TVMP using the stiff tip of 0.014" coronary wire. The patient had successful surgery but died from severe ventilator-associated pneumonia. All 16 surviving cases were discharged from the hospital after a median of 6 days with a room air mean oxygen saturation of 91.4% (± 5.5) (range, 78% to 97%) and no evidence of heart failure.

Discussion

Decompression of the RV and the establishment of antegrade pulmonary blood flow are the recommended first-steps in the management of PAIVS with suitable anatomy for biventricular repair [1, 2]. At first, surgical valvotomy was the only option, but it was associated with high morbidity and mortality rates [5]. More recently, the most preferred percutaneous approach requires advanced expensive equipment, limiting its availability in developing countries with limited financial resources. Therefore, mechanical perforation stood out as the only available alternative after it was successfully reported by Latson in 1991 [17]. The complexity of the procedure in a neonatal heart and the lack of specialized catheter systems made the procedure even more challenging. Initially in our experience, TVMP was undertaken using the stiff tip of PTCA ordinary 0.014" wire and presented with several technical difficulties. The major procedural complication was misperforation outside the heart. The wire needed to remain coaxial with the catheter tip correctly positioned in front of the PV. Nevertheless, it turned out extremely difficult as the wire stiffness tended to frequently straighten the catheter, anteriorly disorienting its tip, thus leading to RVOT wall perforation [8] with life-threatening complications and procedure abandonment in 50% of our cases (**Figure 3**). As failure was not related to the incapacity of the wire to perforate the atretic membrane, wire preshaping, and the use of a heavier 5F JR catheter in the hope to overcome these technical challenges turned out uneasily reproducible. The immediate creation of an arteriovenous loop was mandatory to avoid advancing the stiff tip into the distal pulmonary arteries or descending aorta, fearing subintimal injury. After a successful perforation, the wire was pushed only very few mm and immediately snared in the pulmonary trunk. The venous catheter was then advanced over the circuit into the pulmonary artery lumen, enabling wire retrieval and its reintroduction from its floppy side. All of these aforementioned technical difficulties lengthened the procedure and increased radiation exposure.

In January 2016, a TVMP attempt using the stiff tip of a PTCA ordinary 0.014" wire had to be stopped after 120 minutes for uncomplicated

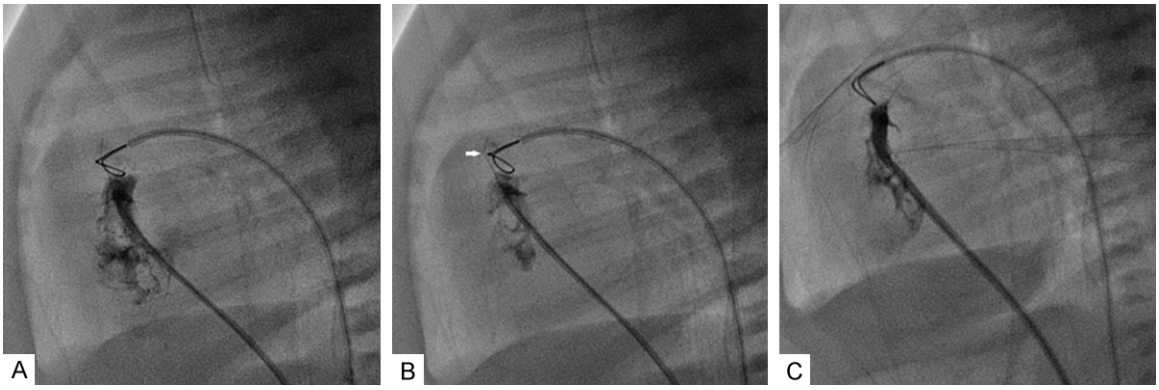

Figure 3. Misperforation using a stiff end of a PTCA ordinary 0.014" wire. Wire stiffness straightening the catheter and disorienting its tip leading to misperforation (A, B). Note the angled rigid tip (B). Another case of misperforation (C).

misperforation and access bleeding. Three days later, perforation was reattempted by the same operator and in the same facility but using the Cross-it 200XT wire. Surprisingly, the procedure succeeded in a record time of 4 minutes. The absence of the learning curve effect tempted us to adopt CTO wires for all subsequent TVMP. The immediate results came up spectacular, and the same setting ductal stenting was attractively undertaken whenever deemed appropriate after BPV. This further shortened hospital stay duration and contributed to a decrease in morbidity. All procedural limitations became easily avoidable with the CTO wires. Increased stability and excellent tactile feedback allowed proper orientation of the wire tip and the catheter right in front of the valve floor; as previously reported by Bakhru et al. [11]. Patil et al. highlighted the advantage of the tapered tip design that amplifies the capacity of the wire to lock and puncture while being submitted to a rotational movement with the support of a catheter next to the membrane [10]. Another important advantage of CTO wires previously reported by Alwi et al. [8] is controlled penetrability and straight-forward pushability that significantly reduced perforation time through precise perforation, particularly when the wire tip never displaced the JR catheter as it was being pushed across the PV plate. Due to advanced torquability and steerability, it also became possible to guide the catheter through the PDA and into the aorta even without an arteriovenous circuit. However, a snare was always deployed in place to certify the guide correct position into the lumen following perforation reducing the theoretic risk of dissection or perforation of the fragile neonatal vessels, and stabilizing the assembly, thus avoiding subsequent serial BPV with incremental balloon diameters.

The complexity and variability of CTO wires have expanded greatly over the past decade with competitive iteration and innovation. Manufacturers combined design elements in various ways to engineer guidewires with performance characteristics that can be used to advantage in different situations targeting specific technical challenges [16]. In parallel, coronary interventionists have discovered performance properties that were not intended by design, but that emerged as important in real-world use especially when targeting totally occluded vessels. With this in mind, the use of CTO wires for TVMP was thought of as a good alternative given its peculiar property described as the penetration power [8-11]. The wire penetrability depends on the tip load and stiffness as well as torque transmission. The comparison of different CTO wires was not reasonable given the limited number of recruited patients. Previous reports suggested that the predictability of CTO wire with high penetration power for successful perforations was strong [9, 11]. Nevertheless, after reviewing the case during which perforation succeeded with the Cross-it 200XT guidewire following the failure of a more powerful MiracleBros 12 wire, we could tentatively conclude that tip diameter should be taken individually into consideration in adjunction to penetration power. Wire tips, generally defined as the distal few centimeters, are the most complex assemblies in a coronary wire and play the biggest role in determining the

performance features discerned by interventionists [15]. For any given value of bending stiffness, reduced tip designs can generate higher tip penetrating pressure that can be exerted by the tip to penetrate soft tissue within an occlusion. When pushed against membranous pulmonary atresia, this property might improve the ability of the wire to pierce forward in a directed fashion and conferred the potential risk reduction of severe pericardial effusion in the event of unintended misperforation [8].

Study limitations

This is a retrospective study from a single tertiary congenital cardiology center of a series of selected patients with PAIVS anatomy suitable for TVMP. Hence, caution should be exercised in generalizing results in all the cases with pulmonary atresia or in comparing patient outcomes. Ideally, biplane fluoroscopy is essential as it reduces radiation dose and contrast load. It may also shorten procedural and perforation time by better outlining wire to PV plane position using simultaneous projections. The experience accumulated during the ten years of the study might have contributed to better results with the CTO wires. Operator experience is crucial in selecting the proper CTO hardware for a given case as CTO wires have variable penetrating power and intrinsic features. Long-term follow-up was not collected as patients had various managements following TVMP and this was not the primary objective of the study.

Conclusion

Introduction of CTO material for TVMP with subsequent technique modifications revolutionizes the entire procedure in our center. When compared to PTCA ordinary 0.014" wire, TVMP using CTO guidewires shorten perforation time, reduce irradiation and complications rate while optimizing short-term outcomes. This approach for the initial management of PAIVS is efficacious in centers where laser and radiofrequency techniques are unavailable. Appropriate patient and hardware selection remain the cornerstone of the procedure. More data from different centers are needed to compare the outcomes of different CTO wires.

Disclosure of conflict of interest

Z. Saliba is a proctor and consultant for Abbott Vascular since 2017. R. Haddad has no conflict of interest to declare.

Author contributions

RH designed the study, collected data, performed all statistical calculations, analyzed, and critically interpreted the results. RH took the lead in writing the entire manuscript. Both authors discussed the results, read and approved the final manuscript.

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