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Case Report

Successful transcatheter pulmonary valve implantation in a dog: first clinical report☆

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KEYWORDS
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Abstract Transcatheter pulmonary valve (TPV) implantation is a therapeutic approach approved by the United States Food and Drug Administration for human patients with failing pulmonary conduits in 2010 and for failing bioprosthetic surgical pulmonary valves in 2017. We report here the first successful transcatheter implantation of a stented valve in a pulmonary position in a dog with congenital pulmonary valve disease. A 3-year-old, 10.9 kg, client-owned Beagle dog was referred for a follow-up visit after a percutaneous balloon valvuloplasty performed 22 months before for treatment of a severe type A valvular pulmonary stenosis. The Doppler-derived peak pressure gradient was 348 mmHg before the procedure and 66 mmHg 24 h after. The dog was lethargic. Echocardiography revealed a mild pulmonary stenosis (pressure gradient—43 mmHg), severe pulmonary regurgitation, and secondary severe right ventricular and right atrial dilation. Worsening of right heart dilation was observed 2 months later despite medical therapy. A TPV implantation was performed using a prestented Melody bovine jugular bioprosthetic valve. The dog recovered uneventfully and was discharged 10 days after the procedure. Right heart dilation resolved within 15 days. The dog was doing well 7 months after valve implantation. This case demonstrates that TPV implantation with a stented valve is technically feasible in dogs with severe pulmonary valve disease. Stringent postoperative care, with particular attention to thrombosis and infectious endocarditis, and appropriate sizing and positioning of the valve stent are keys to the success of this procedure.

Abbreviations

BPV	balloon pulmonary valvuloplasty
PG	pressure gradient
PS	pulmonary stenosis
PT	pulmonary trunk
RA:LA	right atrium to left atrium ratio
RV	right ventricular
RVID:LVID	right ventricular internal diameter to left ventricular internal diameter ratio
RVOT	right ventricular outflow tract
TPV	transcatheter pulmonary valve

A 3-year-old, 10.9 kg, intact female client-owned Beagle was referred to the Alfort Cardiology Unit (National Veterinary School of Alfort, France) for a follow-up visit after percutaneous balloon pulmonary valvuloplasty (BPV) performed 22 months before. Pulmonary balloon valvuloplasty was performed for severe congenital type A pulmonary stenosis (PS). Indications for intervention included a Doppler-derived peak pressure gradient (PG) of 348 mmHg [1]; marked right ventricular (RV) hypertrophy (end-systolic RV free wall to left ventricular free wall thickness ratio of 1.7, normal maximal value = 0.5 [2]; right atrial dilation (end-diastolic right atrium to left atrium ratio (RA:LA) of 1.6, normal maximal value = 1.0 [3]); and dilatation of the caudal vena cava. Mild RV dilation was also observed before BPV (RV to left ventricular internal diameter ratio [RVID:LVID] at end-diastole of 0.46, normal maximal value of 0.37 [2]). Additionally, moderate pulmonary regurgitation was detected by color-flow Doppler that persisted throughout diastole, extended into the right ventricular outflow tract (RVOT) above the most rightward level of the aortic valve on the right parasternal transaortic short axis view and had a proximal width ratio of only 12% [4,5]. Twenty-four hours after BPV echocardiographic examination revealed a marked PG decrease from 348 mmHg to 66 mmHg with concomitant worsening pulmonary regurgitation (proximal width ratio of 52% vs. 12%). The dog recovered well, without any clinical signs reported by the owners, and an oral combination of spironolactone and altizide was prescribed (1.7 mg/kg and 1.0 mg/kg q24 h, respectively).

Physical examination 22 months after the first BPV procedure revealed a left cranial systolic and diastolic grade V/VI basal heart murmur. The remainder of the physical examination was normal, except that the dog was lethargic. Transthoracic echocardiography[f] showed mild PS (PG = 43 mmHg), severe pulmonary regurgitation (proximal width ratio assessed by color-flow

[f] Vivid E9, General Electric medical system, Waukesha, WI, USA.

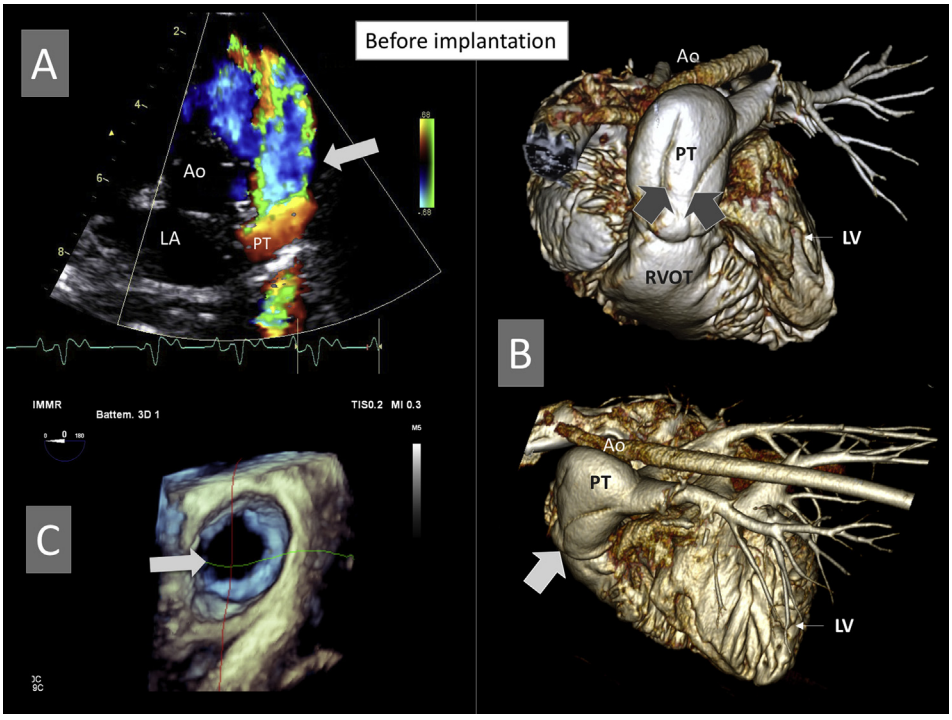

Fig. 1 Echocardiographic images of the pulmonary trunk and the pulmonary valve (A, C), as well as three-dimensional ECG-gated computed tomography (CT) reconstruction of the heart and great vessels (B) before transcatheter pulmonary valve implantation. The color-flow jet of pulmonary regurgitation (arrow) fills up the right ventricular outflow tract and its length extends to the right ventricular cavity up the tricuspid valve (right parasternal transaortic view at the level of the aortic valve). These Doppler features are consistent with severe pulmonary insufficiency. (B) Three-dimensional ECG-gated CT reconstruction of the heart and great vessels. Both CT images show aneurysmal dilation of the pulmonary trunk (PT) with arterial wall plications (arrows). By comparison, note the small aortic diameter (Ao) and the small size of the left ventricle (LV). (C) Transesophageal three-dimensional transverse view of the pulmonary trunk taken at end-diastolic and showing the large regurgitant orifice (19—20 mm m, arrow). Ao, aorta; LA: left atrium; RVOT: right ventricular outflow tract.

Doppler mode of 100%; Fig. 1A), and severe secondary RV and right atrial dilation. Effusion was not present, but vena cava and hepatic veins appeared dilated. The end-systolic RV free wall to left ventricular posterior wall thickness ratio had decreased from 1.7 to 1.0 owing to the successful PG decrease [4,6]. However, the severe pulmonary regurgitation was responsible for marked increases in the end-diastolic RVID:LVID ratio from 1.08 to 0.46 and RA:LA ratio from 1.6 to 1.9. Moderate secondary tricuspid regurgitation because of dilation of the valve annulus was detected on color-flow Doppler during systole. Elevated RV pressure caused premature closure of the tricuspid leaflets with mild tricuspid regurgitation during late diastole. The pulmonary trunk (PT) was markedly dilated. Lastly, isolated ventricular premature beats were detected on electrocardiography. Furosemide (0.45 mg/kg q24 h PO), L-carnitine (500 mg/day q24 h PO), and taurine (1.4 g/day q24 h PO) were added to the initial medical treatment. Although the dog was improved clinically, worsening of right heart dilation was observed 2 months later (Fig. 2A and B), end-diastolic RVID:LVID ratio of 1.26 and RA:LA ratio of 2.3. Transcatheter pulmonary valve (TPV) implantation was scheduled. A three-dimensional contrast-enhanced cardiac-gated computed tomography scan was performed 1 week before surgery (Fig. 1B) to accurately assess the pulmonary and coronary artery morphology and perform measurements of the pulmonary annulus and the RVOT maximal diameters (19 mm and 20 mm respectively). Aneurysm of the PT with plications of the arterial wall was confirmed. Pulmonary and coronary artery morphology were normal. Additionally, aspirin (3.1 mg/kg once PO), clopidogrel (3.4 mg/kg q24 h PO), and amoxicillin-clavulanic acid (22.9 mg/kg q8h PO) were administered 3 days before valve implantation.

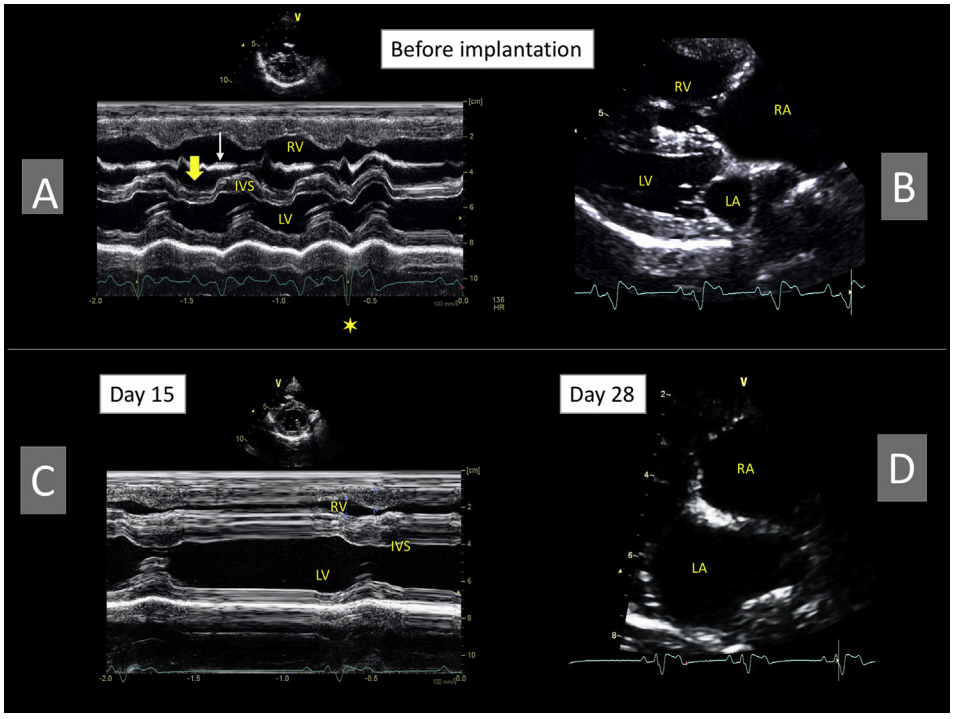

Fig. 2 M-mode echocardiographic views and two-dimensional (2D) right parasternal four-chamber views before (A and B) and after (C and D) transcatheter pulmonary valve implantation. (A) The M-mode image (left) shows severe right ventricular dilation, with a ratio between the end-diastolic RV diameter (29.3 mm) and end-diastolic left ventricular internal diameter (23.2 mm) of 1.26, and paradoxical motion of the interventricular septum (large arrow). This view also reveals a hyperechoic right papillary muscle (small arrow) and right ventricular myocardial hypertrophy, with an increased end-systolic right ventricular free wall (13.1 mm) to left ventricular free wall (11.7 mm) thickness ratio (1.12). Note also the presence of a ventricular premature beat (star). (B) The 2D right parasternal four-chamber view taken at end-diastole (right) shows dilation of both right cardiac cavities. A cranio-caudal right atrial dilation is observed associated with an increased latero-medial diameter: ratio between the right atrial (33.0 mm) and left atrial (14.6 mm) diameters (measured at the level of respective annulus) of 2.3. (C) The M-mode image (left) confirms disappearance of the septal paradoxical motion and the right ventricular dilation 15 days after valve implantation, with a ratio between the end-diastolic RV diameter (8.4 mm) and the end-diastolic left ventricular internal diameter (31.7 mm) of 0.27 (vs. 1.26). (D) Note also (right), 28 days after surgery, the right atrial diameter decrease, with a ratio between the right atrial (21.2 mm) and left atrial (20.5 mm) diameters of 1.0 (vs. 2.3). IVS: interventricular septum. LA: left atrium. LV: left ventricle. RA: right atrium. RV: right ventricle.

Transcatheter pulmonary valve implantation

The dog was sedated with butorphanol (0.3 mg/kg IM). After preoxygenation for 6 min, anesthesia was induced with propofol (4.0 mg/kg IV), lidocaine (2.0 mg/kg IV), and midazolam (0.3 mg/kg IV). Anesthesia was maintained by an IV infusion of 0.1—0.4 mg/kg/minute of propofol in combination with lidocaine (50—100 mcg/kg/minute IV) and butorphanol (0.2 mg/kg/h IV). Lactated Ringer's solution (2—5 mL/kg/h) was administered IV to maintain normovolemia. Cefazolin (20 mg/kg IV) was administered at anesthesia induction and every 120 min throughout the procedure.

The dog was placed in right lateral recumbency. The left jugular vein area was prepped for cardiac catheterization and was accessed via cut down technique. Two Rummel tourniquets were placed around the vessel, and a 5-Fr introducer sheath was introduced in the vessel in between the two tourniquets. An angiogram was performed by injecting 1 mL/kg of a non-ionic contrast agent[g] by hand, through a 5-Fr JR4 guide catheter advanced to the right ventricle and pulmonary artery over a 140 cm 0.035" hydrophilic J-tipped guidewire. The angiography confirmed preoperative echocardiographic and CT findings. Intraoperative transesophageal echocardiography demonstrated massive pulmonary regurgitation with a large regurgitant orifice area (Fig. 1C; Videos 1 and 2).

[g] Telebrix35, Guerbet, Roissy CDG, France.

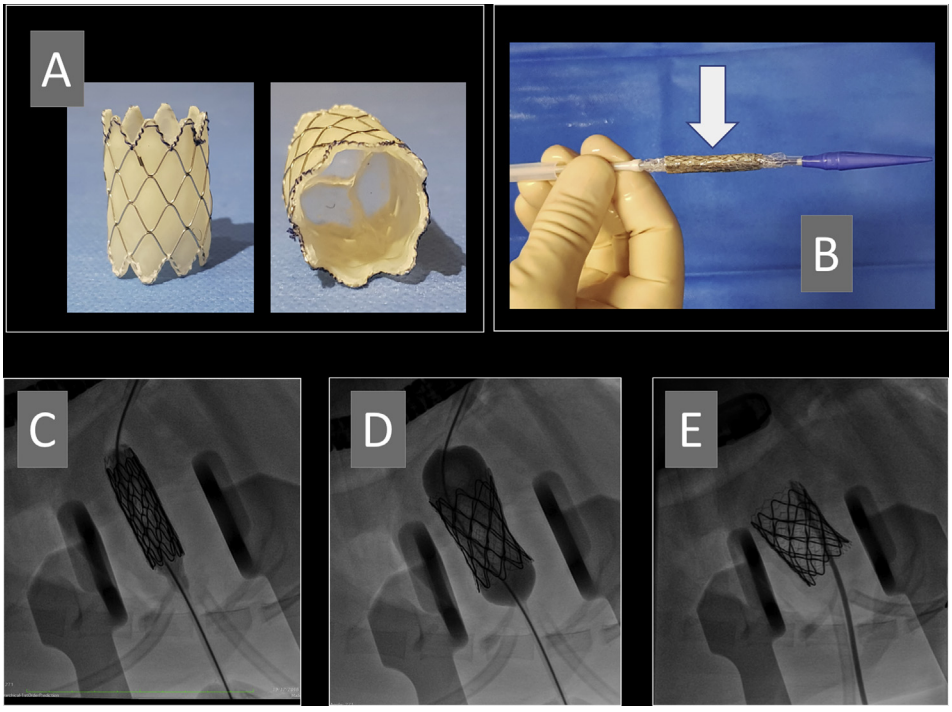

Fig. 3 (A—E): Transcatheter pulmonary valve implantation. (A) The Melody transcatheter pulmonary valve system: this valve system used in the present report has been specifically developed for transcatheter implantation to treat right ventricular outflow tract and pulmonary valve dysfunctions. It is comprised of a thin bovine jugular vein valve sutured within a radiopaque platinum iridium frame (or stent). The thin leaflets can open and close under minimal pressure, which is hemodynamically optimal for the low pressures registered within the right ventricular outflow tract. (B) This photo shows the entire Melody valve delivery system used here including a second stent (arrow) crimped over the stented valve (prestenting procedure). (C—E) Fluoroscopic images showing the transcatheter pulmonary valve implantation, with balloons' inflation allowing the Melody valve to expand into place. The valve is appropriately positioned on Fig. 3E, which was confirmed by transesophageal echocardiography (see Fig. 4).

A 16 mm Melody TPV[h] with an acceptable deployment up to 20 mm was chosen for the procedure. The valve was prepared on a second operating table (Fig. 3A and B). Preparation consisted of unpacking of the delivery system and the stented valve, thoroughly rinsing with 2 bowls of saline for 2 min, progressively and manually crimping the stent over a 5 mL syringe and then a 2 mL syringe, and positioning it over the balloon of the delivery system. A second stent[i] (biliary bare stent) was crimped over the stented valve to reinforce the stent (termed prestenting) per manufacturer recommendation. The full system was flushed with heparinized saline, and the sheath of the delivery system was advanced to cover the stents.

The original standard wire was exchanged with a 240-cm Amplatz Super stiff J-tipped 0.035" guidewire. The 5-Fr sheath was removed, and the tourniquets snugged tight. Unfractionated heparin was administered (50 UI/kg IV). The stented valve and its delivery system were advanced over the long wire and into the jugular vein. The preoperative measurement of the jugular vein was 6—7 mm, and the outer diameter of the delivery system is 22 F, thus slightly more than theoretically possible. The distention of the jugular vein was such that, despite numerous attempts with different angles and the use of propofol to lubricate the passage of the delivery system, it was deemed impossible to advance the delivery system without jeopardizing the animal. The jugular vein was ligated and the cut-down repaired. The minimally invasive approach was converted to a hybrid approach via left 3rd intercostal thoracotomy and transventricular delivery (prepped at the same time as the neck area in case of conversion).

The infusion of butorphanol was stopped, and an infusion of sufentanil[j] (1—2 mcg/kg/hour IV,

[h] Melody valve, PB 1016, Medtronic, Minneapolis, MN, USA.
[i] IntraStent Max LD Biliary Stent, S18-36, Medtronic, Minneapolis, MN, USA.
[j] Sufentanil Mylan, Mylan SAS, Saint-priest, France.

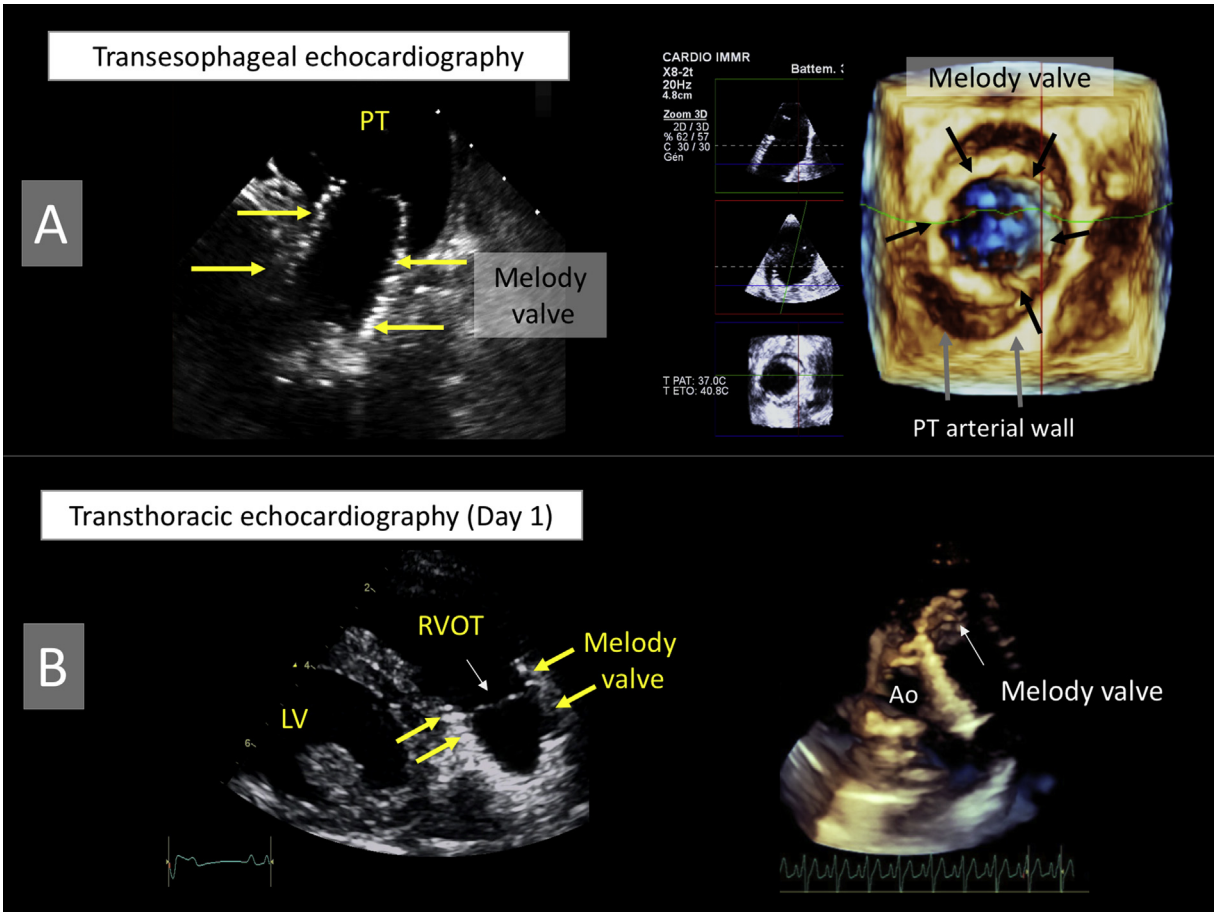

Fig. 4 Melody transcatheter pulmonary valve images after implantation, during the procedure (A) and 24 h after (B), using transesophageal and transthoracic echocardiography, respectively. (A) These 2D (left) and 3D (right) transesophageal echocardiographic views both show the Melody transcatheter pulmonary valve (arrows) in appropriate position despite marked dilation of the pulmonary trunk (PT). (B) These 2D (left) and 3D (right) transthoracic right parasternal echocardiographic views taken at end-diastole also show the appropriate position of the device, with the thin leaflets perfectly closed (thin white arrows). Ao, aorta; RVOT: right ventricular outflow tract; LV, left ventricle; 2D: two-dimensional; 3D: three-dimensional.

50 μg/mL) was started 30 min before thoracic incision. After an intercostal block with bupivacaine, the thoracotomy was performed, and the pericardium was opened widely. Two pledget-reinforced purse-string sutures of 4-0 polypropylene were placed in the RVOT approximately 15 mm ventral to the pulmonary valve.

A 5-Fr introducer sheath was introduced in the RVOT and pulmonary artery to perform an angiogram. A 240-cm long Amplatz Super stiff J-tipped 0.035″ guidewire was advanced to the distal pulmonary artery. The introducer sheath was removed. The Melody TPV delivery system was advanced over the guidewire and introduced in the RVOT, while the purse-string sutures were used to control hemostasis. The TPV with the prestent was positioned over the pulmonary valve under fluoroscopic guidance. The polytetrafluoroethylene sheath of the delivery system was retracted to uncover the stent. The two nylon balloons of the 'balloon in balloon' system were sequentially inflated (inner, then outer, inner balloon being half the diameter of the outer balloon; 10 mm and 20 mm, respectively, in this case: Fig. 3C to E; Video 3). Inflations were performed with 10 mL and 20 mL syringes filled with a mixture of 2/3 saline and 1/3 contrast media. During TPV deployment phase (approximately 15—20 s), there was a marked decrease in ejection and heart rate. After deployment and deflation, the delivery system was removed quickly, and cardiac ejection and rhythm were restored. The purse-string sutures were tightened, and hemorrhage was not visualized through the puncture site.

Angiography and transesophageal echocardiography confirmed the adequate TPV placement with

excellent leaflet coaptation and no regurgitation (Fig. 4A; Videos 3 to 5). The thoracotomy was closed in a routine fashion with placement of thoracostomy tube (removed 4 days postop).

The animal recovered uneventfully with the appropriate pain control (methadone 0.1—0.2 mg/kg q4h over 3 days) and the same preoperative treatment (spironolactone, altizide, clopidogrel, and aspirin every 3 days). A constant rate infusion of furosemide (0.4 mg/kg/h the first 24 h) was added to decrease RV overload and limit the risk of TPV fracture and displacement. Lidocaine (10—40 mcg/kg/minute for 3 days), ampicillin-sulbactam (30 mg/kg q8h IV), enoxaparin (120 UI/kg q8h SC), and atenolol (0.4 mg/kg q12 h PO) were also added to the treatment protocol. One day after TPV implantation (Day 1), cardiac auscultation revealed an intermittent grade I to II/VI systolic cranial heart murmur and no diastolic heart murmur. The echocardiographic examination confirmed that the TPV was well positioned with excellent leaflet coaptation (Fig. 4B). The right heart was markedly decreased in size (end-diastolic RVID:LVID ratio of 0.53 form 1.26 before TPV implantation and end-diastolic RA:LA ratio of 1.6 from 2.5 before implantation). Two trivial paravalvular leaks were noted in the RV on color-flow Doppler mode.

On Day 2, the dog was clinically well, and a further decrease in right cavities was observed on echocardiographic examination (end-diastolic RVID:LVID ratio of 0.46 and end-diastolic RA:LA ratio of 1.4). However, an increase in plasma protein C reactive of 146 mg/L was observed (normal value $<$ 10 mg/L) on Day 3, as well as leukocytosis of 38,610/mm^3 (reference range = 5050—16,760) and neutrophilia of 32,500/mm^3 (reference range = 2950—11,640). A focal hyperechoic thickening on one of the TPV leaflets was visualized via echocardiography on Day 6. Endocarditis, a known complication of TPV implantation in human patients [7—9], was therefore suspected and marbofloxacin was added to the ongoing treatment (4 mg/kg IV q12 h). The dog was discharged on Day 10, with continuation of oral drugs (i.e. spironolactone, altizide, clopidogrel, aspirin every 3 days, atenolol) together with oral amoxicillin-clavulanic acid (25 mg/kg q12 h), marbofloxacin, and enoxaparin at 120 UI/kg q12 h instead of q8h. According to the owners, the dog was more alert. The RV and right atrial diameters normalized on Day 14 (end-diastolic RVID:LVID ratio of 0.27) and on Day 27 (end-diastolic RA:LA ratio of 1.0), respectively. On Day 14, a small thrombus (1.8/3.5 mm) was attached to the focal hyperechoic valvular lesion previously observed on Day 6, the enoxaparin dosage was increased to120 UI/kg q8h, and aspirin was increased to daily administration from every 3 days. The thrombus disappeared within 2 weeks without impacting the TPV function. The hyperechoic lesion detected on one of the TPV leaflets was less visible, appearing as a small hyperechoic 'dot'.

At the time of writing, 7 months after the valve implantation, the dog was still doing well without clinical signs and no heart murmur. A trivial leak around the stent was still present. Leaflet coaptation of the TPV was excellent. Right cardiac chambers had normalized (end-diastolic RVID:LVID ratio of 0.13 and end-diastolic RA:LA ratio of 0.9). Trans-TPV velocity and PG were 1.94 m/s and 15 mmHg, respectively.

Discussion

Congenital PS, defined by a dynamic and/or fixed anatomic congenital obstruction to flow from the RV to the PT, is one of the most common congenital heart diseases in dogs, accounting for up to one third of all congenital heart diseases in this species [10—12]. The Beagle breed has been reported as predisposed to congenital PS, and pathologic features of the hereditary form of pulmonary valve dysplasia have also been described in a colony of Beagles [10,13]. The client-owned Beagle dog of the present report was initially suffering from a type A congenital PS. Balloon pulmonary valvuloplasty is considered as the gold standard treatment for such defect in both dogs and children [6,14], with high prevalvuloplasty Doppler gradient being one of the most important independent predictors of suboptimal immediate and long-term results of the BPV (as was the case here) [4]. In both children and dogs, short-term and long-term complications of BPV are rare and included valvular restenosis and severe pulmonary regurgitation [6,14,15]. In one study, pulmonary regurgitation developed in all dogs with congenital PS after BPV (n = 126) but was classified as severe for only one of them [6]. Pulmonary valve replacement is the procedure of choice for human patients with severe pulmonary regurgitation [14]. The transcatheter implantation of pulmonary valves was first demonstrated by Bonhoeffer et al. in 2000 in the lamb [16]. This technique, also called TPV implantation, was approved by the United States Food and Drug Administration in 2010 for patients with failing pulmonary conduits and for failing bioprosthetic surgical pulmonary

valves in 2017 [14]. The Melody TPV used in the present report was the first transcatheter valve commercially approved, with proven benefits including restoration of valve function (as demonstrated in the dog presented here), relief of conduit and surgical valve obstruction, and delay of the patient's next surgical intervention [7—9]. Prestenting, as performed in the present report, has been shown to improve long-term outcomes in patients with TPV implantation [7].

In human patients, valve stent fractures and endocarditis are the two main common complications of TPV implantation occurring in 8.6% and 10.2% of cases, respectively [7—9]. Coronary artery compression has also been described [7—9]. In the case of infective valvular endocarditis, early echocardiographic changes typically include slight thickening and/or increased echogenicity of the affected valve. In the case presented here, a focal hyperechoic thickening was observed on one of the TPV leaflets with concomitant increase in C-reactive protein, leukocytosis, and neutrophilia. A small thrombus attached to this focal hyperechoic thickened valvular lesion then was detected. Valvular endocarditis was thus suspected despite the absence of confirmatory blood culture. This can be considered a potential limitation of the present case report.

The first technical aspect paramount to success is achieving a perfect fit between the stent and the native anatomy. Preoperative measurement and planning are therefore particularly important. The computed tomography provided a clear evaluation of the aneurysmal PT landing zone for stent deployment without compromise the downstream pulmonary arteries. This three-dimensional approach was instrumental during the delivery under two-dimensional fluoroscopy. A second consideration was the capability to achieve delivery through the venous system. Considering the 22-Fr outer diameter of the delivery sheath, the jugular vein was the only option to avoid a direct open-chest delivery. It was anticipated that the sheath size might limit the possibility of a transvenous delivery. However, an attempt at a minimally invasive approach was still considered warranted. Unfortunately, it was not possible to advance the delivery system through the jugular vein of this small dog, despite progressive predilation and the use of lipid emulsion as a lubricant (propofol). Conversion to an intercostal thoracotomy was therefore performed and provided appropriate access and orientation of the system with regards to anatomy.

The transcatheter approach is appealing because it can diminish tissue trauma and the inherent risks associated with cardiac surgery under cardiopulmonary bypass. The biggest limitation we foresee before this approach becomes routine in veterinary interventional cardiology is the availability of devices. The cost of such devices in human medicine is very high, and the sizes are meant for infants or adults, which are still too large for small veterinary patients.

The computed tomography also gave a clear anatomic picture of the potential interactions between the pulmonary artery and the right coronary artery, which in the present case was normal. This could have been supported even better by a right coronary angiogram performed as a balloon was inflated to assess any future compression of the stent on the right coronary artery. In retrospect, this would have been a relevant adjunct to the procedure.

In conclusion, TPV implantation is an alternative to surgery that has been a tremendous advancement in human medicine. It can be foreseen that veterinary cardiology will, in some way, benefit from this revolution.

Conflicts of interest statement

The authors do not have any conflict of interest to disclose.

Acknowledgments

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Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jvc.2019.10.001.

Video table

Video number	Description
Video 1	Two-dimensional transesophageal echocardiographic view obtained before transcatheter pulmonary valve implantation with a cranial probe position. Note the enlarged pulmonary trunk and the abnormal pulmonic valve.
Video 2	Transesophageal color-flow Doppler view obtained before transcatheter pulmonary valve implantation with a cranial probe position. Note the mild pulmonic stenosis and the severe pulmonary regurgitation.
Video 3	The different steps of the transcatheter pulmonary valve implantation.
Video 4	Two-dimensional transesophageal echocardiographic biplane orthogonal views showing the Melody transcatheter pulmonary valve in an appropriate position and the markedly dilated pulmonary trunk.
Video 5	Transesophageal 3D reconstruction view obtained just after the transcatheter pulmonary valve implantation with a cranial probe position.

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