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[Original article]

Radiofrequency perforation of the pulmonary valve: an efficient low cost solution

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Objective The aim of the study was to assess the feasibility of using commonly available catheterization laboratory equipment for radiofrequency perforation of the pulmonary valve in patients with pulmonary atresia and intact ventricular septum.

Methods The system (off-label use for all items) is made up of a co-axial telescopic arrangement consisting of a 0.014" PT[2] ™ coronary guidewire, for insulation inside a 2.7-F microcatheter which has an inner lumen of 0.021". The microcatheter was passed via a standard 4-F right coronary catheter to just below the atretic pulmonary valve. Radiofrequency (RF) energy was delivered using a standard electrosurgical system. In vitro testing had been performed and indicated that 5-10 W for 2-5 s would be sufficient for valve perforation.

Results Radiofrequency perforation was successfully performed in all (n = 5, 100%) patients at a median age of 3 days (range: 1-36) and weight 2.7 kg (range 2.3-3.0). In one patient the pericardium was entered during the initial attempt; the generator was put on coagulation mode during retrieval of the guidewire and no haemopericardium occurred. The pulmonary valve was dilated in all; in three patients (n = 3) the ductus arteriosus was stented during the same session.

Conclusion Results of the study show that it is feasible to perforate the pulmonary valve safely using this system. Availability, simplicity and cost are noteworthy benefits.

Keywords *Pulmonary atresia-intact septum – radiofrequency – perforation – angioplasty – guidewire.*

INTRODUCTION

Percutaneous interventions for right-sided obstructive lesions have come a long way and represent excellent alternatives to traditional surgery. For example, in the case of pulmonary atresia with intact septum with suitable anatomy, perforation of the valve followed by balloon angioplasty is accepted as standard treatment especially in the case of pulmonary atresia with intact septum[1-7]. Due to efficacy and ease of use, radiofrequency perforation and balloon angioplasty have become the preferred method[4,8,9].

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Radiofrequency technology comes in two modes – cutting and coagulation[5,10,11]. Cutting currents (pure sine wave) produce acute rapid heat increases (over 100°C) in the tissues which cause the water inside the cells to boil resulting in cellular rupture with vaporization; this leads to cleavage of the tissues in contact with the electrode (surgical knife). In contrast, coagulation currents (pulsed sine wave) induce a slower rise in temperature causing cellular dehydration and shrinking without rupturing; the coagulation of cells is typically used for haemostasis in the region of the electrode.

The aim of the study was to assess the feasibility of using commonly available catheterization laboratory equipment for radiofrequency perforation of the pulmonary valve.

PATIENTS AND METHODS

The system (off-label use for all items) is made up of a co-axial telescopic arrangement[12]. A 0.014" PT[2™]

coronary guidewire (Boston Scientific, Marlborough, US) was selected because the radio-opaque tip is straight and has proven electrical conductance; for insulation the wire was put into a microcatheter (Progreat™, Terumo Europe N.V. Belgium). We selected the 2.7-F system which has an inner lumen of 0.021" (outer diameter comparable to 0.035" guidewire). To add stability the microcatheter was passed inside a standard 4-F right Judkins coronary catheter (Cordis Corp., NJ, USA) (figure 1). Radiofrequency (RF) energy was delivered using a standard electrosurgical system (Erbe ICC 80, GA, USA).

As a first step, in vitro testing was performed on a sheep heart submerged in saline solution at room temperature. Energy was applied to the semilunar valves at a frequency of 350 kHz with continuous power output. Voltage and power are automatically adjusted by the generator to deliver the required energy output. Cutting energy was applied to the tissues for 2-5 seconds at 1, 3, 5 and 10 watts. Valvar tissue demonstrated perforation at 5 watts for all attempts (figure 2).

Only patients with suitable anatomy meeting the criteria for percutaneous intervention were included. The study was performed between July 2008 and February 2016. After discussion with the parents, written informed consent was obtained. Five patients with pulmonary atresia and intact septum (PA-IVS) and demonstrated stable position of the end-hole catheter pointing to the pulmonary trunk in the right ventricular outflow tract, were included. Patients were not considered if this angiogram showed pulmonary valvar stenosis. All procedures were performed under general anaesthesia with access via the femoral vessels. Standard regimens for anticoagulation and antibiotics were followed. A co-axial system as described was used to position the 0.014" guidewire microcatheter assembly in a stable location in the right ventricular outflow tract. In patients with difficult anatomy, a small gooseneck snare was positioned in the main pulmonary artery to act as a target for electrosurgical perforation of the pulmonary valve plate. The guidewire was advanced forward with 2 mm protrusion from the distal end of the microcatheter. Gentle forward "pushing" was maintained on the guidewire microcatheter complex while burning; radiofrequency RF energy was delivered at 5-10 W for 3 s in cutting mode (figure 3). The guidewire was pushed in such a way that immediately upon perforation of the valve and progression into the pulmonary trunk, the longer tip was no more insulated with broader dissipation of the energy, preventing further unnecessary tissue damage. Once the valve was perforated, the guidewire was advanced and the microcatheter was slid over the guidewire allowing it to be gently advanced through the ductus arteriosus down the descending aorta in order to obtain a stable guidewire position (figure 4). Balloon angioplasty was subsequently carried out in routine fashion, often requiring a small coronary balloon as the first step to allow passage for larger balloon diameters. Control angiography was routinely carried out throughout the

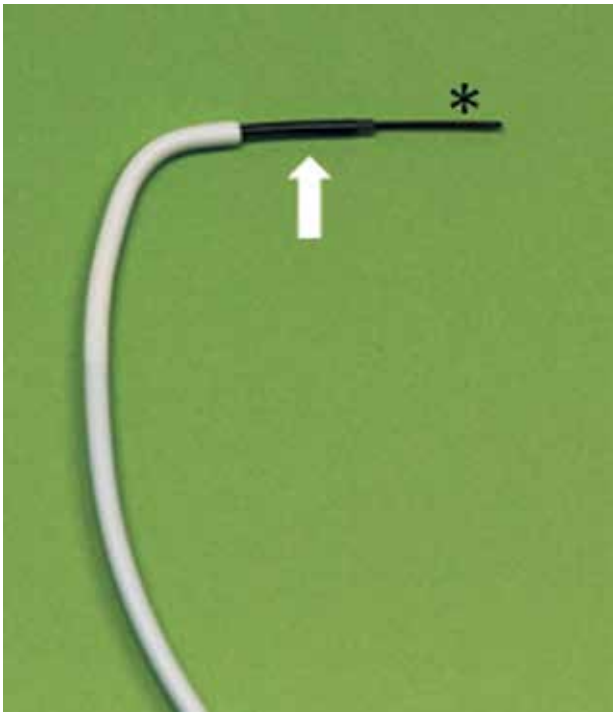

Fig. 1 Co-axial delivery system
The 0.014" guidewire (asterisk) can be seen protruding from the tip of the 2.7-F microcatheter (arrow). The perforation system is passed through a 4-F Judkins right coronary catheter, inner lumen 0.035" (blue).

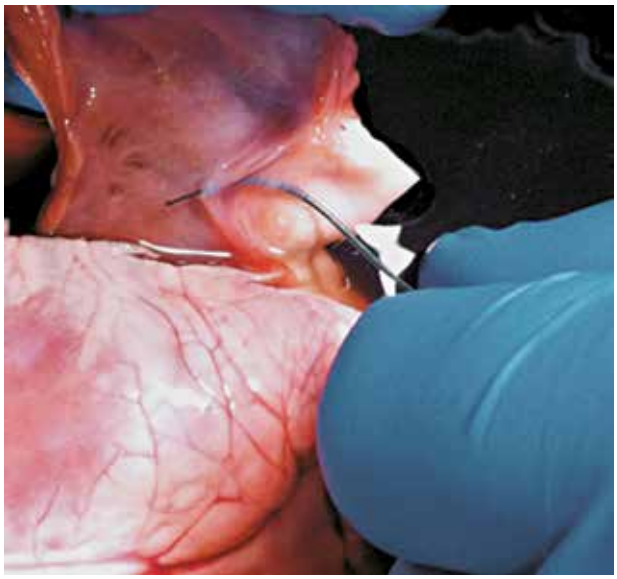

Fig. 2 In vitro testing.
Perforation of semi-lunar valve cusp of sheep heart in saline at 5 watts demonstrated.

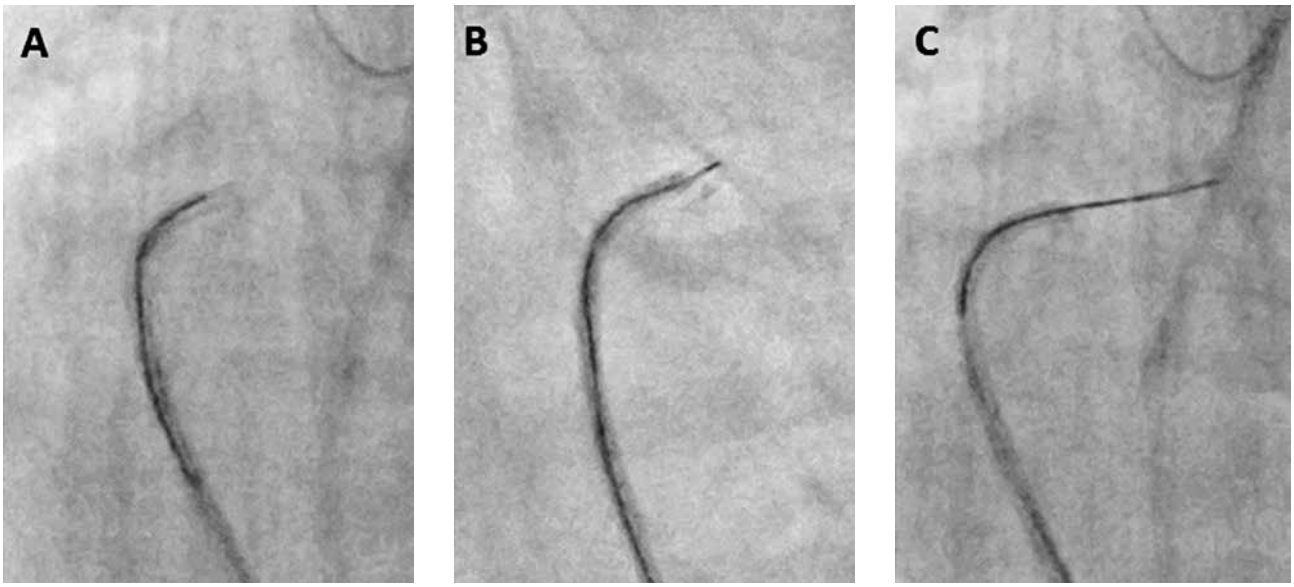

Fig. 3 Perforation of right ventricular outflow tract using co-axial system
Sequential perforation of right ventriclular outflow tract using system demonstrated. (**A**) System still in 4-F catheter. (**B**) 2-mm protrusion of guidewire and application of energy. (**C**) Guidewire advanced immediately upon perforation.

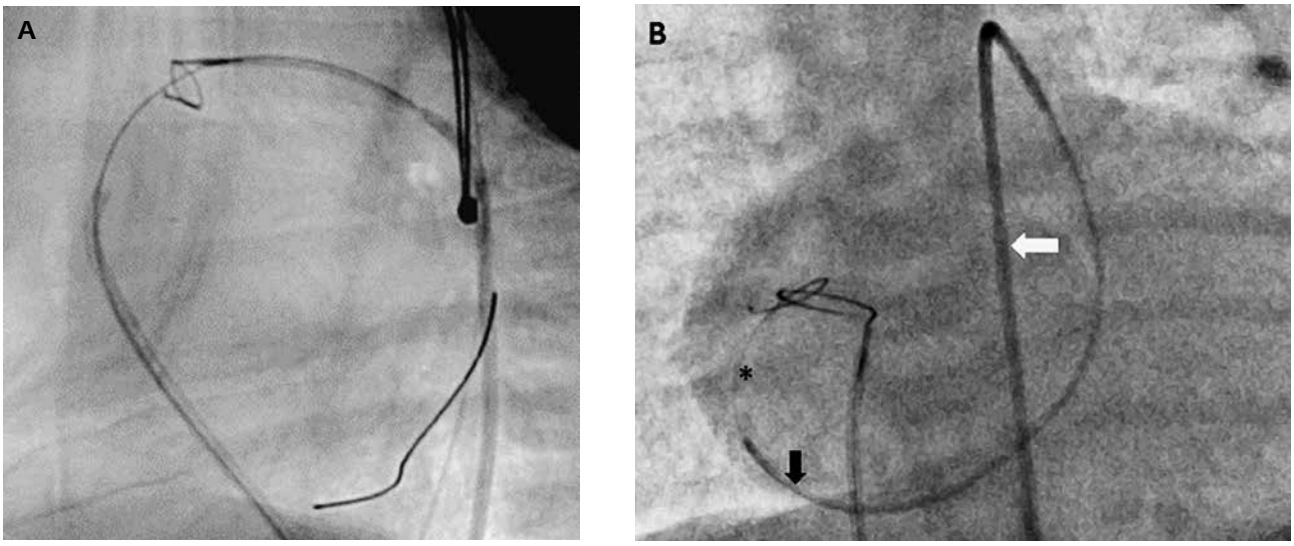

Fig. 4 Positioning of guidewire
Guidewire can be observed in descending aorta (asterisk). A small gooseneck snare (arrow) was positioned in the pulmonary artery via the ductus arteriosus to guide radiofrequency perforation. (B) Snaring of 0.014" guidewire following retrograde perforation of the pulmonary valve plate. Note the components – guidewire (asterisk), microcatheter (black arrow) and 4-F delivery catheter (white arrow).

procedure through a 4-F 45-cm long Flexor® Ansel sheath (COOK Medical Inc., Bloomington, USA).

RESULTS

The procedure was successfully performed in all 5 (100%) patients at a median age of 3 days (range: 1-36) and weight 2.7 kg (range 2.3-3.0). There were three boys and two girls. Patient details are shown in table 1. None of the children had major sinusoids or right ventricle-dependent coronary circulation.

After perforation of the valve, the microcatheter was easily pushed across the valve to obtain a stable position for the 0.014" coronary guidewire in all but one patient; in the latter case predilation with a 1.5-mm low-profile coronary balloon was required. Angiography demonstrated good results with antegrade flow after balloon angioplasty. In two patients (n = 2) the perforation was carried out retrogradely via the ductus arteriosus and

Table 1 Patient details

Patient	Diagnosis	Age (d)	Weight (kg)	Method	MPA (mm)	Balloon diam (mm)	Ductal stent	Outcome
1	PA-IVS	1	2.45	retrograde	8.2	8	no	biventricular repair
2	PA-IVS	3	2.70	antegrade	6.8	6	yes	biventricular repair
3	PA-IVS	36	2.30	antegrade	5.9	5	yes	univentricular repair
4	PA-IVS	3	3.00	retrograde	9.1	8	no	biventricular repair
5	PA-IVS	3	2.97	antegrade	7.1	6	yes	follow-up – biventr.

MPA: main pulmonary artery diameter, diam: diameter, biventr: biventricular repair.

the guidewire snared in the right atrium. The microcatheter could be pushed over the guidewire into the pulmonary artery or right atrium to attain a good wire position in all patients. The ductus was stented during the procedure in three patients. Patient 4 was not considered for primary stenting; he required a systemic to pulmonary artery shunt 10 days later.

Complications

There were no peri-procedural deaths. In patient 3 stable positioning was difficult to maintain in the right ventricular outflow tract. The guidewire entered the pericardial space twice. During retraction of the guidewire, the system was switched to the coagulation mode. No pericardial effusion was observed during follow-up echocardiography. However, out of precaution, the procedure was stopped at that stage and the valve plate was successfully perforated 48 hours later with an adapted curved catheter.

Patient 1 was desaturated and became shocked hours after a successful procedure; echocardiography showed significant circular flow via the duct (which remained wide open despite stopping prostin administration), the pulmonary artery and right ventricle with severe pre-existent tricuspid regurgitation. Minimal antegrade flow over the pulmonary artery was detected. The ductus was urgently ligated and the child made a full recovery.

Follow-up

Patients have been followed up a mean of 4.2 ± 2.6 years. Biventricular repair was effective in three, univentricular repair in one and one child is still in progress.

DISCUSSION

With high surgical mortality, treatment of PA-IVS remains challenging. Percutaneous pulmonary valve perforation in suitable candidates is regarded as the preferred treatment in many institutions[1-9,13]. Available options for the interventionalist include laser, stiff end of a guidewire or radiofrequency perforation.

Laser is effective, but very expensive and requires certain preventive measures to protect staff. It is rarely used nowadays. Mechanical perforation by means of special guidewires or using the stiff end is technically challenging. The rigidity of the wire often displaces the delivery catheter making alignment difficult and increasing the risk of complications. Cost and availability are the advantages of mechanical systems[14]. Radiofrequency perforation is probably nowadays the preferred method because of ease of use and the fact that minimal collateral damage occurs in the surrounding tissues. Commercially available systems consisting of generators with dedicated wires and catheters have been developed specifically for this purpose but are expensive and not available in all institutions. Re-imbursement by health insurers for use of the dedicated electro-generators is also problematic.

Results of our study show that using a standard "off-the-rack" system consisting of catheters, guidewires and a standard electrosurgical unit for radiofrequency perforation of the pulmonary valve, is feasible. We could safely and successfully perforate the pulmonary valve in 100% of our patients. This compares favourably to other studies where success rates of between 66% - 100% have been reported[4,7,8,14]. The pericardial space was entered in one (20%) of our patients twice, but no tamponade ensued. The authors speculate that using coagulation mode whilst retrieving the guidewire was helpful in this case and probably sealed off the puncture hole and therefore no haemopericardium occurred. Complications during the procedure have been reported to range from 16% - 50%. However, only one study reported inadvertent perforation of the right ventricular outflow tract which led to haemopericardium only in one patient of the series[15]. Even though we preferred balloons no larger than 100% of the pulmonary valve annulus, during follow-up two of the three children who proceeded to

biventricular repair, required treatment for significant pulmonary regurgitation.

In our unit we prefer to cross the ductus arteriosus with a co-axial system using a Progreat™ microcatheter. This setup also allowed to perform valve perforation retrogradely in two patients. It was also beneficial to stent the ductus during the procedure and this was usually performed from the pulmonary arterial side.

Series of these patients consist of small numbers. We have observed in our unit a declining incidence of "real atresia" since we systematically perform a hand injection below the pulmonary valve showing that it is frequently a critical pulmonary valvar stenosis in contrast to what is seen on echocardiography. In that situation the valve can invariably be crossed by a coronary guidewire. This will further limit the number of children requiring true valve perforation and need for expensive equipment rarely used.

Of note, we found it helpful to accentuate the curves of the 4-F right coronary Judkins catheter before use. This allows easier crossing of the tricuspid valve, and better positioning and more stability below the pulmonary valve during the procedure.

The advantage of this radiofrequency system is that it is effective for valve perforation and not inferior to other systems. The components are readily available in most catheterization laboratories and staff are familiar with the use. Using a thin 0.014" guidewire potentially should cause less serious complications and switching to coagulation power during inadvertent perforation could seal the hole and limit haemopericardium to some extent. The same guidewire is also used to deliver the balloons for subsequent valvar angioplasty. The available commercial systems (Osypka MicroHAT, Baylis RFP-100) use a 0.020 - 0.024" wire, each dedicated for its own system only. However, the major benefit of this "off-the-rack" system is availability and cost: an electrosurgical systems can be found in any operation theatre and in Belgium the cost for the PT^2 guidewire is €160 and €250 for a Progreat™ microcatheter.

STUDY LIMITATIONS

The numbers are small, but this condition is quite rare. There is no control group due to the low numbers but the aim of the study was to determine feasibility of commonly available material. It must be emphasized that using the components for this purpose is off-label.

CONCLUSION

Using readily available materials in a co-axial system, an effective radiofrequency system can be constructed. Results of our study show that it is feasible to perforate the pulmonary valve safely using this system. Availability, simplicity and cost are noteworthy benefits.

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CONFLICT OF INTEREST: none declared.

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