

Surgery for Congenital Heart Disease

Chronic and adjustable pulmonary artery banding

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Objective: Banding of the pulmonary artery might be required to prevent pulmonary vascular damage in patients with increased pulmonary artery flow and to retrain the left ventricle in preparation for an arterial switch operation in patients with congenitally corrected transposition of the great arteries. Readjustment of the pulmonary artery band might be required in the postoperative period. In this study we aimed to test the feasibility of a novel device for bidirectionally adjustable pulmonary artery constriction.

Methods: A hydraulic main pulmonary artery occluder was implanted in lambs and gradually inflated to create right ventricular pressure overload at a systemic (aortic) level. During the following period (up to 12 weeks), this pressure overload was monitored by measuring aortic and right ventricular pressures by means of implanted subcutaneous reservoirs. If required to maintain the right ventricular pressure overload at a systemic level in the growing animals, the occluder was deflated through a third subcutaneous reservoir.

Results: After the banding period (average of 64 ± 8 days), the main pulmonary artery cuff could still be adjusted, and the animals showed no clinical signs of heart failure. Histologic analysis of the pulmonary artery showed extensive fibrosis, a giant cell response around the device, and small areas of tissue necrosis; complete transmural necrosis was not detected.

Conclusions: This device allows adjustment of the pulmonary artery cuff in a precise manner over a prolonged period of time without surgical reintervention. Potentially, the device might have applications for clinical use in children with congenital heart disease.

Pulmonary artery banding (PAB) is used in patients with a variety of cardiac malformations to reduce pulmonary blood flow^{1,2} or to prepare the left ventricle for systemic afterload in cases of late referral for an arterial switch operation for transposition of the great arteries.³⁻⁵ Preparation of the left ventricle facing relatively low afterload for future systemic performance might also be required with the failing systemic right ventricle in atrial correction of transposition of the great arteries or in congenitally corrected transposition of the great arteries.⁶ During a PAB operation, the optimum degree of constriction can not always be achieved at once. This might require a further surgical intervention to readjust the band. Such surgical procedures

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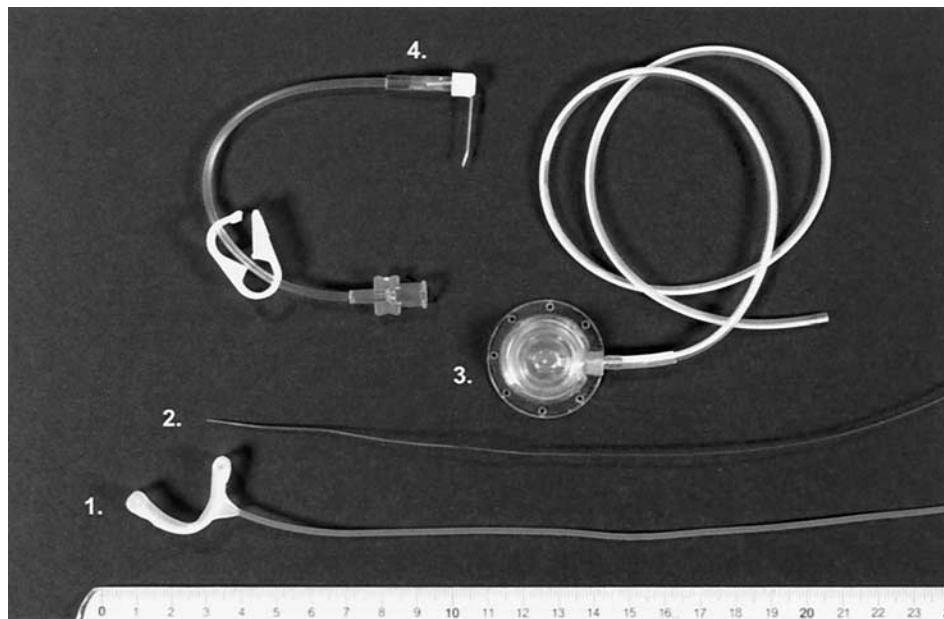


Figure 1. 1, Bidirectionally adjustable cuff. After placement of the cuff around the pulmonary artery, the 2 free ends of the cuff are tied together with a ligature. 2, Hollow guide wire used for filling of the cuff with hypertonic saline solution before placement. 3, PAC with attached pressure line. The little holes on the side of the reservoir are used for fixation of the reservoir on the underlying muscle layer. 4, Huberpoint needle with connector used for transdermal puncture of the PAC. The scale is shown in centimeters.

continue to be associated with significant postoperative morbidity and mortality.^{7,8} This has led to the development of several adjustable PAB devices.⁹⁻¹⁴ However, none of these devices have gained widespread clinical use. Furthermore, although rare, serious complications of PAB in patients have been reported. These include erosion of the pulmonary artery band in the vascular lumen,^{15,16} pseudoaneurysm formation,^{17,18} and rupture of the vessel wall.^{18,19} Possible negative local effects of adjustable devices on the pulmonary artery wall, which, if present, might limit their clinical use, are not well known. The aim of our study was to test the feasibility of a novel device of bidirectionally adjustable pulmonary artery constriction in lambs. We tested the device in an animal model that included simultaneous right ventricular (RV) and aortic pressure monitoring in a relatively noninvasive way to achieve optimal monitoring of percutaneous band adjustment without surgical reintervention.

Methods

Eight lambs were used in this study. At the time of the operation, the lambs were between 2 and 3 weeks of age and had an average body weight of 6.4 ± 1.7 kg. They were treated according to the "Guide for the Care and Use of Laboratory Animals" published by the US National Institutes of Health (National Institutes of Health publication no. 85-23, revised 1996). The protocol was approved by the animal research committee of the Leiden University Medical Center.

PAB Operation

All lambs were anesthetized with propofol (4-6 mg/kg) after preoxygenation with 100% oxygen. The animals were intubated and artificially ventilated with 0.5% to 1.5% isoflurane in a mixture of 80% to 100% oxygen supplemented with room air by using a volume-controlled respirator (Servo 900B, Siemens-Elema). General anesthesia was maintained with a mixture of 1% to 2.5% isoflurane in room air and continuous intravenous propofol infusion (6-18 mg/kg/h). Analgesia was provided with a combination of ramifenazone and phenylbutazone (Tomanol; 0.03 mL/kg administered intravenously).

Under sterile conditions, two 0.25-mL subcutaneous reservoirs (Port-a-Cath [PAC], UNO, Zevenaar, The Netherlands) with pressure lines attached (2.1 mm outer diameter \times 1.0 mm inner diameter, Figure 1) were placed subcutaneously and fixed to the neck muscles. The distal end of a pressure line of one PAC was surgically inserted into the right carotid artery and fixed. During the operation, arterial blood pressure was monitored through this PAC. After median sternotomy, the heart was exposed in a pericardial cradle. The distal end of the pressure line of the second PAC was tunneled subcutaneously from the neck toward the thorax, where it passed under the sternal notch. It was introduced directly into the right ventricle through a minor stab wound in the RV free wall and fixed with a purse-string suture. Through this second PAC in the neck, RV pressure was also monitored during the operation. Some extra tubing was left behind in the thorax and the neck to allow for the expected growth of the animals during the study.

The main pulmonary artery was mobilized carefully by means of blunt dissection, and an inflatable cuff with a noninflated lumen

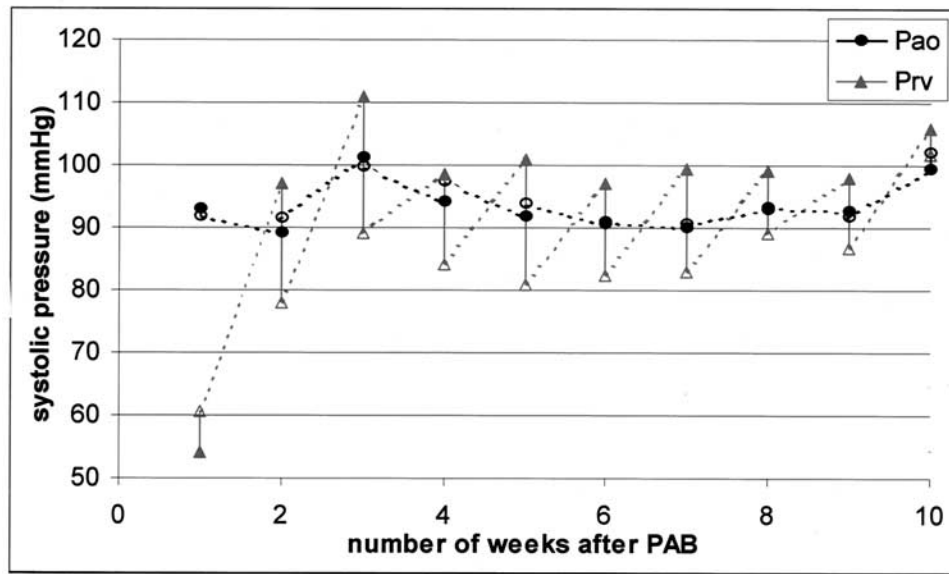


Figure 2. Schematic representation of the course of average RV (filled and open triangles) and aortic (filled and open circles) peak systolic pressures in time obtained during pressure monitoring in the lambs undergoing PAB. Filled symbols represent the pressure values before PAB adjustment, and open symbols represent the pressure values after PAB adjustment. Solid lines represent the change in systolic pressures as a result of the band adjustment during one monitoring session. Because pressure was not continuously monitored, the pressure course between 2 monitoring sessions is indicated by dotted lines. Note that aortic peak systolic pressure is relatively constant in time. This is in contrast to RV peak systolic pressure, which increases between 2 pressure-monitoring sessions (gray dotted lines) in the growing animals. Pao, Aortic pressure; Prv, right ventricular pressure.

diameter of 12 mm (UNO, Zevenaar, The Netherlands) was loosely placed around it. Great care was taken to prevent coronary artery compression or pulmonary valve obstruction by the cuff. A line attached to the cuff was exteriorized through the right lateral thoracic wall and connected to a third subcutaneous PAC (0.25 mL) fixed on the underlying muscles of the back. Through this PAC, the cuff diameter could be altered by means of injection or withdrawal of hypertonic saline solution. After testing proper functioning of the cuff (see below), the pericardium was approximated for two thirds, and the thorax was closed in layers.

Pressure Monitoring and Cuff Adjustment

After recovery from the operation during the first week, RV peak systolic pressure was gradually increased to peak aortic pressure over a 2-week period by means of subsequent injections of saline solution (Figure 2). During this procedure, the lambs were quietly resting in a canvas sling. Half an hour in advance, the skin over all 3 PACs was locally anesthetized with a 1% lidocaine cream, thereby minimizing any animal discomfort during needle puncture. Aortic and RV pressures were monitored by means of transdermal puncture of the PACs with special Huberpoint needles (Figure 1), which were connected to pressure transducers (model 56S, Hewlett Packard). A sample of blood was withdrawn from the PACs to remove the heparin lock from the previous monitoring session. Through hypertonic injections of saline solution into the third PAC on the back of the animals, the cuff was gradually inflated under continuous monitoring of aortic and RV pressures. An adjustable

valve in the external line prevented deflation of the cuff when no fluids were injected. After cuff adjustment and before disconnecting the Huberpoint needles, both PACs were flushed with sterile 0.9% saline solution, after which a 2-mL bolus of heparin solution (500 IE/mL) was injected to prevent thrombotic occlusion. After 2 weeks, when RV pressure had been increased to a systemic level, RV and aortic pressures were monitored biweekly during the following 8-week period. If necessary, the pulmonary artery cuff was adjusted to maintain RV peak systolic pressure at the level of aortic peak systolic pressure by means of injection or removal of saline solution from the cuff.

Postmortem Examination

After 8 weeks of RV pressure overload, hemodynamic testing was performed, which is described elsewhere.²⁰ After these tests, the lambs were killed by means of lethal injection with KCl, and a block resection of the hearts and pulmonary artery trunks, including the devices, was performed. The pulmonary trunk and cuffs were sliced carefully in transverse sections. After removal of the pulmonary artery cuff, which did not adhere to the surrounding tissue, the tissue was embedded in paraffin and cut at 5 μ m. Sections were stained with hematoxylin and eosin.

Results

In the initial phase of the experiments, 2 of the 8 animals died as a result of the PAB operation, which could have

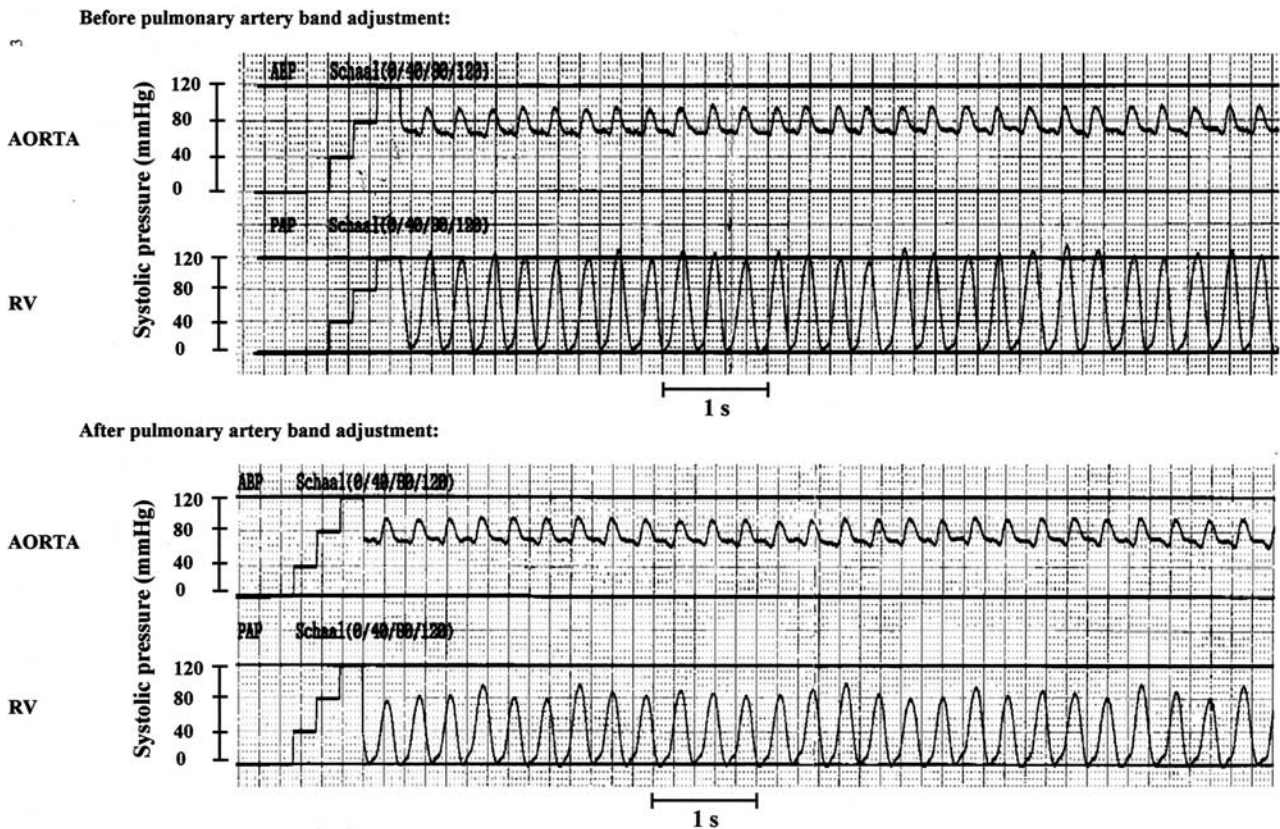


Figure 3. Example of pressure tracings obtained after connection of the 2 PACs in the neck to a pressure transducer. The *top panel* indicates aortic (*upper tracing*) and RV (*lower tracing*) pressures before cuff adjustment. The *lower panel* indicates aortic (*upper tracing*) and RV pressures (*lower tracing*) after cuff adjustment. Each block on the y-axis represents a pressure interval of 40 mm Hg, and paper speed on the x-axis averaged 25 mm/s^{-1} . Before cuff adjustment (*top panel*), aortic pressure was 97/67 mm Hg, and RV pressure was 128/2 mm Hg. After slight cuff deflation, aortic pressure was 96/67 mm Hg, and RV pressure was 86/−1 mm Hg (*lower panel*).

been the result of the learning curve of this delicate procedure. In a third animal technical problems prevented deflation of the PAB cuff after 33 days of banding, which led to heart failure and the death of the animal. No attempt was made to remove the cuff operatively. Extreme constriction of the pulmonary artery by the band, which resulted in RV dilatation and probably caused failure, was confirmed at the time of the autopsy. The constrictor was found to be deflated maximally. The outer diameter of the cuff proved to be too small for the pulmonary artery size. This was identified to be the cause of technical problems and not a malfunction of the cuff itself because it was still inflatable at the time of the autopsy. The remaining 5 lambs were successfully banded by using a larger cuff with a lumen diameter of 12 mm. After a banding period of at least 8 weeks (mean, 64 ± 8 days), these cuffs could still be deflated, and none of the animals showed clinical signs of heart failure during the period of banding.

In one animal pressure monitoring failed because of an

obstruction of the pressure line, which, as confirmed at the time of surgical intervention, was caused by a blood clot in the distal tip of the line. To remedy this, the heparin dose was doubled to 500 IE/mL for the remaining experiments. Since then, there were no further cases of occlusion of the right ventricular or arterial pressure line during the entire banding period. The average course of RV peak systolic pressure and aortic peak systolic pressure during the entire banding period is shown in Figure 2. Figure 3 is a typical example of a pressure tracing of both RV and aortic pressures before and after cuff adjustment during one of the pressure-monitoring sessions.

PAB resulted in a significantly increased RV/left ventricular wall-thickness ratio, as measured at the midventricular level postmortem (from 0.43 ± 0.04 to 0.94 ± 0.15 , $P < .01$). Histologic analysis of the pulmonary artery after 8 weeks of PAB (mean 64 ± 8 days) revealed the following abnormalities (Figure 4). The vessel wall tissue directly adjacent to the device showed the features of a fibrosing

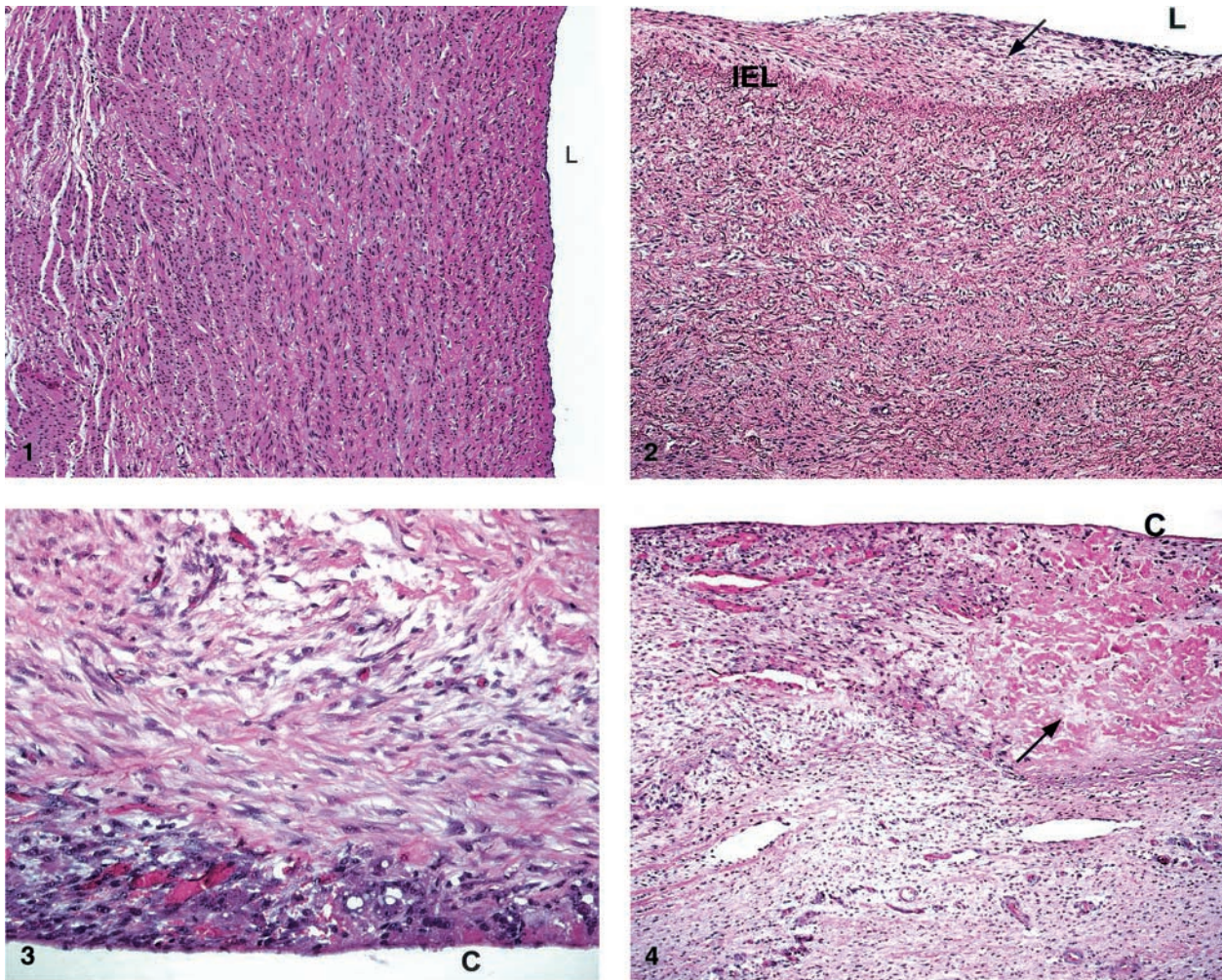


Figure 4. Histologic stainings (hematoxylin and eosin) of the pulmonary arterial wall after chronic constriction. *L*, Luminal side of the vessel wall; *C*, adventitial side of the vessel wall where the constrictor was placed; *IEL*, internal elastic lamina. 1, Normal pulmonary artery; 2, intimal thickening caused by fibrosis (*arrow*); 3, histiocytic (foreign-body type) reaction in the adventitia next to the constrictor; 4, small local area of necrosis (*arrow*). Note the absence of nuclei in this area.

chronic inflammatory response of the type that is elicited by the introduction of foreign material, with the presence of numerous histiocytes, including multinucleated histiocytes, directly facing the device. Directly underneath this surface, fibrous tissue with an increased number of blood vessels was found. Adjacent to and within this scar tissue, smooth muscle cells of the media could regularly be identified. Deposition of varying amounts of calcium and iron salts on matrix components was common. In 3 of the 5 cases, an irregular small area of necrosis was detected. These foci of necrosis were detected in the parts of the vessel wall that were underneath the device. The necrotic foci focally made contact with the device or were positioned immediately underneath the intima. In none of these 3 cases, however,

did we identify overt transmural necrosis reaching from the device to the intima.

Discussion

The results of our study indicate that the pulmonary artery can successfully be banded with the described hydraulic occluder. The occluder allows bidirectional adjustment of the degree of constriction. In our study in young growing animals, this adjustment was possible up to 12 weeks after implantation without further surgical intervention. Histologic analysis of the pulmonary artery revealed that the use of this occluder did not result in transmural wall necrosis, which, if present, would limit its clinical use.

PAB continues to be used in young children with in-

creased pulmonary flow. PAB has gained renewed interest in adults with congenitally corrected transposition of the great arteries to train the left ventricle for future systemic afterload, as part of the double-switch operation. Inadequate postoperative PAB, in most cases as a result of a loose band, adversely affects outcome in these patients and demands aggressive assessment and management.⁸ The banding procedure itself results in acute and important changes in ventricular loading conditions. Optimal band adjustment can not always be achieved in a single surgical procedure because the postoperative state changes with respect to respiratory patterns, postural state, and level of consciousness. Furthermore, especially in adult patients, acute ventricular failure might occur as a result of poor tolerability if the band is tightened too much.⁶ In addition, adjustment of the band diameter to match growth would ideally be required in children. Because of these reasons, several attempts have been made to develop a percutaneously adjustable pulmonary artery constrictor. Systems previously described used the following principles:

1. A metal snare is placed inside a plastic sling, which is connected to a metal screw adjuster. The screw adjuster is placed subcutaneously and a snare adjustment requires a small skin incision.^{9,10}
2. A metal snare coated with a synthetic cuff is connected to a screw contained in a cylindrical body. Attached to this body is a flexible guiding tube, which exits the chest. Adjustment of the cuff is performed with a flexible screwdriver through the guiding tube.^{13,14}
3. Two different-sized polytetrafluoroethylene grafts enclose each other as a sheath over a nylon ligature, which is fixed with hemoclips. Readjustment of the cuff requires a small skin incision to retrieve the distal clipped end of the nylon ligature.¹¹
4. The cuff is comprised of 2 Silastic sheets on a reinforced sheet and is connected through a tube to a reservoir with a steel bottom, which is placed subcutaneously on the anterior chest wall.¹² Our model resembles this last system.

Adjustment of the abovementioned cuffs (nos. 1-3) requires a small incision or implies potential risk of infection because part of the device is exteriorized through the chest wall and thus provides only a short-term solution. Adjustment of the cuff used in our study was easy and only required a small needle puncture. This reduces the risk of infection. Recently, Le Bret and colleagues²¹ showed the feasibility of adjustable cuff implantation by means of thoracoscopy. Although we did not test this approach, our device can most likely be implanted in a similar way.

In the postoperative period, an indwelling catheter is frequently present to monitor ventricular or pulmonary pressures, but this information is lost because of the necessity of

removing the lines relatively shortly after the operation. Furthermore, the presence of such a catheter is accompanied by the risk of infection. In our study we used 2 PAC systems to monitor RV and aortic pressures biweekly by means of transcutaneous needle puncture of the reservoirs. With this ambulatory approach, actual and simultaneous pressure gradients can be obtained in a relatively noninvasive way for months after the operation (up to 12 weeks in our study) without great difficulties, thus providing important hemodynamic information that guides the adjustment of the pulmonary artery band. Furthermore, all the materials used are magnetic resonance imaging (MRI) compatible. This is important because MRI is an attractive technique for monitoring changes in ventricular wall mass and for assessing RV function, including both global²² and regional function.²³

It is not known whether the use of an adjustable device might adversely affect the vessel wall in terms of wall degeneration resulting from local wall compression. One of the potential complications is rupture of the pulmonary artery because of pressure necrosis resulting from the constrictor, which might result in a life-threatening situation. A major issue requiring further study is the long-term significance of the vascular damage inflicted by the banding device. The interpretation of the severity of the histologic changes found in the present experiment is somewhat speculative. The fibrosis will not result in immediate danger or rupture but might lead to the formation of a pseudoaneurysmatic dilatation later on, as found in some studies.^{8,24} The iron-calcium incrustation is probably not very significant. The small and local areas of necrosis are more difficult to interpret in terms of risk. To what extent they weaken the vessel wall and whether the device masks weakening of the vessel wall cannot be inferred.

Study Limitations

Although this study has shown the feasibility and effectiveness of the bidirectionally adjustable cuff to produce a controlled chronic RV pressure overload in sheep, the technique involved must undergo further study before it can be used for clinical application in patients. Pressure monitoring with noninvasive aortic blood pressure measurements and echocardiography (pressure levels evaluated by means of transvalvular flow velocities) would be especially useful. Furthermore, the potential use of this device for longer than 12 weeks needs further study.

Conclusions

We tested an MRI-compatible device for PAB that can be adjusted bidirectionally without surgical reintervention for a prolonged period of time (in our study up to 12 weeks). Histologic analysis of the pulmonary artery after chronic constriction revealed a fibroinflammatory (foreign body-

type) reaction; transmural necrosis was not detected, which, if present, would limit its application. Potentially, this device might have implications for clinical use for palliation and left ventricular retraining in children and adults with congenital heart disease.

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