Radiofrequency Thermal Angioplasty Maintains Arterial Duct Patency
An Experimental Study

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Background Long-term maintenance of arterial duct patency by a catheter technique would be a valuable nonsurgical method of palliation for duct-dependent circulations. We used a new method: percutaneous radiofrequency thermal balloon angioplasty of neonatal lamb arterial ducts.

Methods and Results Radiofrequency balloons 5 or 6 mm in diameter were introduced via the femoral vein of 32 neonatal lambs and inflated to 4 atm. In 28, a radiofrequency generator was used to heat the saline/contrast mixture in the balloon to 65°C (n=2), 75°C (n=2), 85°C (n=10), 100°C (n=8), and 120°C (n=6). In 4 lambs, angioplasty alone was performed. Lambs were recatheterized to assess patency at intervals up to 78 weeks. Immediate results showed the arterial duct to be patent in all cases, with a mean rise in systolic pulmonary artery pressure of 13±8 mm Hg and a mean rise in pulmonary artery oxygen saturation of 12±15%. With a mean follow-up of 45.7±28 weeks, 3 of the 4 (75%) angioplasty alone ducts closed, but only 5 of the 28 (18%) radiofrequency-treated ducts (P<.05). The mean rise in oxygen saturation between the superior vena cava and the pulmonary artery was 7.6±7% at last follow-up. Follow-up angiography of the arterial ducts showed the development of stenoses in all patent ducts.

Conclusions Radiofrequency thermal balloon angioplasty leads to long-term arterial duct patency in lambs in >80% of the treated group and is significantly more effective than balloon angioplasty alone. (Circulation. 1994;90:442-448.)

Key Words • heart defects, congenital • heart diseases • radiofrequency

Congenital heart lesions with severe underdevelopment of the pulmonary or systemic circulations, such as pulmonary atresia or hypoplastic left heart syndrome, are usually duct dependent in neonatal life. Current management is aimed at temporarily maintaining arterial duct patency with prostaglandins until either a surgical shunt or reconstructive surgery can be performed. A catheter technique that maintains long-term ductal patency offers a central shunt without surgery and its potential complications of pulmonary artery distortion and disconnection.1

Most previous attempts at producing long-term patency have met with limited success. Formalin infiltration2 and cryosurgery3 of the duct have been used but require a thoracotomy, limiting potential benefits. We have shown that simple balloon angioplasty maintains patency in human neonates with duct-dependent circulations for up to a few weeks4,5 but is unreliable in the long term. Catheter-mounted metallic endovascular stents have been used in lambs6-8 and piglets9 and neonates with pulmonary atresia10 and hypoplastic left heart syndrome.11 Little long-term follow-up is yet available.

Normally, the arterial duct closes within the first few hours or days after birth. The closure mechanism is a combination of smooth muscle contraction within the duct wall and postnatal intimal proliferation obstructing the lumen.12 We hypothesized that thermal inactivation of the smooth muscle in the duct wall in neonatal life would prolong patency.

Spears,13 using a laser balloon, showed that thermal energy causes necrosis and hence inactivation of smooth muscle cells in vascular tissues. Direct application of heat would require a thoracotomy. Laser balloon angioplasty is a recognized technique in coronary artery stenoses, and Radtke et al14 used small-diameter (three-mm) laser balloons in the arterial duct of lambs and showed patency at 60 minutes in 9 of 9 treated ducts. No long-term follow-up has been reported. Radiofrequency is a well-established method of heating tissues and is used extensively in catheter ablation of intracardiac pathways of aberrant conduction.15,16 Radiofrequency balloon angioplasty of animal peripheral17 and human coronary arteries18 has been reported recently. We report our results using radiofrequency thermal balloon angioplasty to establish and maintain arterial duct patency in neonatal lambs.

Methods

Balloon and Generator

The radiofrequency thermal balloon angioplasty system (Boston Scientific/Mansfield) consists of 4-cm-long angioplasty balloons of either 5- or 6-mm diameter, mounted on a 5.8F shaft. On the catheter shaft, within the balloon, are two radiopaque platinum markers that double as radiofrequency electrodes (Fig 1). These are connected via wires running in the shaft to a plug into the radiofrequency generator. The generator delivers a radiofrequency signal of 640 kHz at a voltage of 0 to 100 V and a power output of 0 to 100 W. Sited between the two electrodes is a thermistor connected to a
feedback mechanism in the radiofrequency generator. Temperatures up to 120°C can be preselected and maintained within approximately 1°C by a feedback loop between the generator and the thermistor. A timer allows the temperature to be maintained for a preset period. There is an integrated pressure monitor that prevents radiofrequency from being applied unless the balloon is inflated.

In Vitro Study of Balloon Temperatures

The balloon was heated to preset temperatures measured by the thermistor at the core of the balloon. We assessed the gradient between this core temperature and the balloon surface in a 37°C water bath. A second thermistor was placed on the balloon surface and, while both core and surface temperatures were recorded concurrently, the following conditions were varied: (1) inflation medium (saline versus saline/contrast in a proportion of 3:1) in the range of core temperatures of 65°C, 75°C, 85°C, 100°C, and 120°C; (2) external thermistor on top versus beside the horizontal balloon in the range of core temperatures of 65°C to 120°C; and (3) external thermistor on the proximal, middle, and distal parts of the balloon, with the balloon vertical and horizontal, at a core temperature of 85°C (Fig 2).

In Vivo Study

The care and treatment of animals in this study conform to the Animals (Scientific Procedures) Act 1986.

Experimental Animals

Thirty-four neonatal Cambridge cross and Friesland lambs were entered into the study. Ages ranged from 12 to 120 hours (mean, 38 hours); weight ranged from 2 to 5 kg (mean, 3.8 kg). In one lamb, passage of the exchange guide wire across the arterial duct resulted in a small dissection of the duct and aorta. The procedure was abandoned, and the lamb was returned to the ewe in a healthy state. In a second lamb, an 8-mm-diameter balloon was used and resulted in ductal rupture, tamponade, and death. The 32 remaining lambs constitute the study population. Radiofrequency thermal balloon angioplasty was used in 28, and 4 controls had simple angioplasty without heat application. The number of lambs treated at each temperature and balloon size is set out in Table 1.

<table>
<thead>
<tr>
<th>Balloon Temperature</th>
<th>Balloon Size, mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control (simple angioplasty)</td>
<td>6</td>
</tr>
<tr>
<td>65°C</td>
<td>5</td>
</tr>
<tr>
<td>75°C</td>
<td>5</td>
</tr>
<tr>
<td>85°C</td>
<td>5</td>
</tr>
<tr>
<td>100°C</td>
<td>5</td>
</tr>
<tr>
<td>120°C</td>
<td>1</td>
</tr>
</tbody>
</table>

Treatment Protocol

All lambs received an intramuscular dose of penicillin and streptomycin before treatment or follow-up study, and further doses were given on the following 2 days. For the neonatal lambs, general anesthesia was induced and maintained with halothane in oxygen. A 5F vascular sheath was introduced into the femoral vein. The duct was crossed with a 0.035-in exchange guide wire through a 4F Gensini catheter (Balt). Pressures and oxygen saturations were recorded in the pulmonary artery and aorta. An angiogram was taken with the catheter through the duct in the adjacent descending aorta. With the exchange guide wire across the duct, the diagnostic catheter and sheath were removed, and the radiofrequency thermal balloon was passed percutaneously over the wire and positioned across the arterial duct using the platinum radiopaque markers for accurate placement. The balloon was inflated to 4 atm with a 3:1 saline/contrast mixture (Omnipaque, Nycomed Ltd), and the generator was switched on. Radiofrequency was applied to heat the balloon to the preset temperature.

We considered that the period of inflation should be long enough for a thermal effect to occur but short enough not to be of excessive hemodynamic consequence were it in a duct-dependent circulation. Becker et al\(^1\) showed that maximal thermal weld effects occurred around 300 to 500 J in an experimental model of radiofrequency angioplasty on postmortem aortic tissue. We have shown that a steady 20-W output from the generator in a 37°C water bath produced a temperature of around 90°C to 100°C (unpublished observations). We therefore decided to maintain temperatures for 15 seconds, giving a power output of around 400 J at the higher temperatures.

The balloon was then deflated without delay and repositioned. The total period of inflation was calculated by adding the time taken to reach the preset temperature to the 15-second treatment time. The treatment procedure was performed three consecutive times. Slight repositioning ensured that the entire duct received treatment from the hottest section of the balloon. The radiofrequency balloon catheter was then removed and the diagnostic study repeated. All catheters were removed, hemostasis was obtained, and anesthesia was reversed. The lambs were observed for 1 hour, by which time they were usually walking around satisfactorily, and then were returned to the ewes.

Follow-up Study Protocol

Clinical review of the lambs was performed frequently, and if heart failure developed, furosemide at 1 to 2 mg/kg was given.
All lambs were restudied at 2 weeks, 6 weeks, 3 months, and one or two intervals thereafter, up to 78 weeks, to assess patency. For follow-up studies, anesthesia was induced either with halothane/oxygen or, with larger lambs, ketamine 5 mg/kg and diazepam 0.5 mg/kg. Follow-up catheterizations of the right and left heart via venous and arterial routes were performed. Pressures were recorded in the aorta and pulmonary artery and oxygen saturations in the aorta, pulmonary artery, and superior vena cava. Angiography of the duct was performed with either a pigtail catheter in the descending aorta or a Gensini catheter across the arterial duct from the venous side. The arterial duct lumen diameter was measured from the angiograms by reference to the known size of the catheters.

**Histological Methods**

Postmortem specimens were placed in 10% formalin for at least 48 hours before processing. Sections were cut at 7 μm and stained with alternate hematoxylin and eosin and Miller's elastic stain.

**Statistical Methods**

Comparison of groups was performed with parametric paired and unpaired t tests where appropriate. Confidence intervals of 95% were deemed significant. Means are quoted plus or minus 1 SD unless otherwise stated.

**Results**

**Balloon Data**

The gradient between the core and surface temperatures was less at all temperatures except 120°C when saline alone was used to inflate the balloon as opposed to saline/contrast mixture. The gradient between the core and the surface was greater when the surface thermistor was on the side of the balloon versus on top of the balloon. With the balloon held vertically, the distal part had a considerable gradient between the core and the surface. Details of the core/surface gradients are shown in Fig 3A through 3C.

**Immediate Results**

At the time of the initial diagnostic study, the duct was physiologically closed in all lambs. Gentle pressure on the guide wire was required to pass from the pulmonary artery to the aorta, and angiograms showed that little or no contrast medium crossed the duct (Fig 4). After both radiofrequency angioplasty and simple angioplasty, the duct was widely patent in all lambs. Ducts appeared as uniform tubes on angiography (Fig 5). The 6-mm balloon produced patent ducts with slightly wider lumens than the 5-mm balloon, 4.2±0.8 mm versus 3.7±0.7 mm, respectively (P=.05). The mean diameter for all ducts after angioplasty was 3.9±0.8 mm. The mean ratio of balloon size to duct size was 1.4:1. There was no correlation between immediate duct diameter and the temperature used in the balloon.

The rise in pulmonary artery systolic pressure from before angioplasty to after was 13±8 mm Hg (P<.0001), and the mean rise in pulmonary artery oxygen saturation was 12±15% (P<.004).

The heat-up time varied from 5 to 36 seconds; adding the 15 seconds of maintained temperature and the short inflation and deflation cycles gave a mean total cycle of 27±7 seconds.

The procedure was well tolerated in all cases. Increases and decreases in heart rate of up to 15 beats per minute were recorded. Minor conformational changes occurred in the ECG as a result of interference from the radiofrequency generator. No significant arrhythmias nor any other hemodynamic disturbances occurred.

**Long-term Follow-up**

Median length of follow-up for all lambs was 41 weeks (mean, 45.7±28 weeks); 7 lambs were followed for more than 70 weeks. The hemodynamic measurements, duct lumen diameters, and mean weights are set out in Table 2. The duct was patent at last follow-up in 23 of the 28 (82%) radiofrequency-treated lambs, whereas in the simple angioplasty group, only 1 of 4 (25%) remained patent (P<.05). Control ducts were found to be closed at the 2-week restudy in 1 and the 6-week restudy in the other 2. The five radiofrequency-treated ducts that closed were found at the 6-week restudy in 1 and at the 3-month restudy in the other 4. No ducts had closed after 3 months. The one patent duct from the simple
The angiographic appearance of the radiofrequency-treated ducts (Fig 7) was notably different at follow-up studies compared with immediately after treatment. Lumen diameters had decreased, and one or more stenoses were present (Fig 8). Serial angiograms showed the changes to have occurred in the first 2 weeks with further diminution in the lumen diameter over the following 4 weeks to the 6-week restudy.

Complications

Four of the radiofrequency-treated lambs (numbers 5, 8, 21, and 31) developed clinical signs of heart failure within 24 hours of treatment. Lambs 5 and 8 required diuretic therapy for 3 days and had no further problems. Lambs 21 and 31 died despite diuretic therapy. Details of these lambs are set out in Table 4. Lambs 11 and 12 died from causes related to separate procedures (unsuccessful attempts to treat a systemic artery with the radiofrequency balloon performed in those two lambs only), number 11 at 29 days and number 12, 24 hours after treatment. In both cases, the duct was patent at the time of death. Lamb 15, treated at 85°C with a 6-mm balloon, developed a ductal aneurysm and pulmonary hypertension (pulmonary artery pressure, 65/36 mm Hg). Lamb 27, which had a widely patent duct and poor weight gain, was noted to be breathless at age 5 months. Its condition improved after a short course of frusemide.

On no occasion did it appear that the balloon was stuck to the duct wall, and on withdrawal there was no evidence of adherent clot or ductal tissue on the balloon and no embolization. Follow-up angiography and examination of the postmortem specimens of those lambs

Table 2. Follow-up Details of Lambs With Patent Ducts Having Radiofrequency Thermal Balloon Angioplasty

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean pulmonary artery systolic pressure, mm Hg</td>
<td>30±8</td>
</tr>
<tr>
<td>Mean aortic systolic pressure, mm Hg</td>
<td>97±16</td>
</tr>
<tr>
<td>Mean step-up in oxygen saturation from superior vena cava to pulmonary artery, %</td>
<td>7.6±7, P&lt;.005</td>
</tr>
<tr>
<td>Mean narrowest duct diameter, mm</td>
<td>2.9±1.8</td>
</tr>
<tr>
<td>Mean widest duct diameter, mm</td>
<td>5.2±2.3</td>
</tr>
<tr>
<td>Mean weight, kg (mean±SEM)</td>
<td>32.9±3.6</td>
</tr>
</tbody>
</table>

Values are mean±SD except mean weight.

angioplasty group was 1.4 mm at its narrowest part at 71-week follow-up. A Kaplan-Meier actuarial analysis of patency is shown in Fig 6. For the lambs whose ducts closed, the temperatures and balloon sizes used and the time when patency was last noted are shown in Table 3. The number of ducts closing treated with the 5-mm balloon (4 of 13) compared with the 6-mm balloon (1 of 15) does not reach the 95% confidence interval for significance, nor did the numbers closing at the different temperatures. There is no correlation between balloon size and narrowest ductal dimension or between balloon temperature and narrowest ductal dimension at last follow-up.

Angiographic Appearance

The angiographic appearance of the radiofrequency-treated ducts (Fig 7) was notably different at follow-up
that died have not demonstrated any damage to the pulmonary valve.

**Morphology and Histology of Treated Ducts**

Postmortem specimens have been examined in 4 lambs: 2 that died at 24 hours, 1 that died from an unrelated procedure at 29 days, and 1 that was electively killed at 61 days for examination.

Histology showed that in the early postprocedural phase, tissue changes are restricted to acute physical trauma damage seen as intimal stripping, slight laminar fragmentation, localized recent clots, some luminal debris, and some neovascularization. Also seen in this phase are some "natural phenomena" such as delamination, some cell death, and minor loss of wall integrity.

In the medium postprocedural phase, increased fragmentation and delamination, probably due to interlamellar cell death, result in loss of dying tissue into the lumen of the duct. Neovascularization, as a repairing reaction, creates friable blood capillaries that are traumatized during the fragmentation of the tissue, resulting in hemorrhage and more clotting. At this stage, the beginnings of intimal and medial hyperplasia are seen, sometimes as tissue "flaps" at the junctional edges with the aorta and sometimes as thickening of the surviving viable duct wall.

In the late postprocedural phase, there is considerable medial hyperplasia, which in general overlies trapped necrotic and calcifying tissue defining the original luminal border of the duct. This is accompanied by the shedding of fragmented tissue into the lumen of the duct and by large amounts of neovascularization. Where the hyperplasia has completely covered and trapped the necrotic tissue, a new intima is formed (Fig 9).

In all phases, aortic tissue contiguous with treated duct shows normal structure, with no histopathological evidence of treatment-associated changes. In all of the sections studied, the duct appears patent.

**Discussion**

Our results show that radiofrequency thermal balloon angioplasty maintains long-term arterial duct patency in >80% of the treated lambs for >70 weeks (7 lambs). All closures occurred within the first 3 months after treatment. While remaining patent, the ductal lumen changes from a uniform tube immediately after treatment to one with variable stenoses.

We did not attempt to measure the degree of shunting using the Fick method. In the first 5 lambs, oxygen saturations were found to be variable in the distal left and right pulmonary arteries, suggesting streaming, and in such situations the method is highly inaccurate.\textsuperscript{19} Angiograms clearly showed left to right flow, and filling of the pulmonary circulation via the duct was extensive. Since the ducts are not uniform tubes, the narrowest ductal dimensions recorded are only moderately accurate indications of the minimum width of the ducts. There was no way of measuring the eccentricity of the lumens. It is clear, however, from combining all the measured indexes, including step-up in oxygen saturation, high mean systolic pulmonary artery pressure, mean narrowest ductal dimension, and failure to grow normally, that flow through the ducts was substantial. Although this remains a poor measurement of actual flow, the calculation becomes irrelevant when one looks for comparisons with duct-dependent circulations, in which flow dynamics are completely different. A central shunt with a lumen of 3 mm is often adequate for a duct-dependent pulmonary circulation but would be inadequate for a duct-dependent systemic circulation.
We were not able to demonstrate that the 6-mm balloon produced a wider duct in the long term than the 5-mm balloon. To show a significant difference with such a small number of animals and a small difference in balloon sizes would have required a substantial effect. It is the angioplasty effect that determines the initial lumen diameter, as demonstrated by the significant difference in lumen diameters between the two balloon sizes immediately after treatment. Temperature appears to play no role in immediate duct diameter. This would fit our hypothesis that the heat inactivates smooth muscle constriction. It would be expected, therefore, that balloon size would play a significant role in lumen diameter. The arterial duct in a human neonate with a duct-dependent circulation has a variable diameter dependent not only on the degree of constriction but also on whether the pulmonary or systemic circulation is dependent. In systemic dependency, the duct has formed the aortic arch in utero and is a large vessel approximately 7 to 10 mm in diameter, whereas in pulmonary dependency, it is a branch vessel only 3 to 5 mm in diameter. Use of a radiofrequency balloon of appropriate size would be essential in such circumstances.

We were initially concerned that the higher temperatures would not be tolerated by either the lambs or the balloons and that fatal damage might occur. It was therefore only after we gained experience with 85°C that we progressed to the 100°C and 120°C treatments. Data from radiofrequency endocardial catheter ablation studies have shown that myocardium must reach a temperature of approximately 48°C for irreversible damage to occur.23 The in vitro experiments suggested that lower core balloon temperatures might not result in tissue temperatures above 48°C. The in vivo results do not demonstrate significantly different effects between the higher and lower temperatures, although this may have been because of the small numbers treated at 65°C to 75°C (4 lambs).

The total inflation/deflation cycle of 27 seconds would be too long for a completely duct-dependent circulation to safely tolerate. We used 4-cm-long balloons designed for peripheral angioplasty work in human adults without any modifications. Both human and lamb arterial ducts are approximately 1 to 2 cm long, and a more appropriate balloon length would be 2.5 to 3 cm. For work on human neonates with duct-dependent pulmonary circulations, passage of a high-profile balloon on a 5.8French shaft through the arterial system is likely to have a significant morbidity. Although newer techniques of radiofrequency perforation of atretic pulmonary valves may enable venous passage of the balloon,24 we consider that the profile of the balloon and shaft must be reduced before preliminary clinical application can be considered.

Other workers have looked at the histological effects of radiofrequency thermal angioplasty on vessel walls. Fram et al22 showed no significant difference between peripheral vessels treated with radiofrequency balloon angioplasty or angioplasty alone in pigs killed immediately after treatment with respect to amount of intimal damage, internal elastic lamina damage, delamination, medial dissection, elastic fiber straightening, or degree of thrombus. However, the degree of medial necrosis and wall thinning increased with the temperature used.

Kaplan et al23 reported histological comparisons at intervals up to 8 weeks after radiofrequency thermal angioplasty and simple angioplasty to canine arteries. They noted reduced medial cellularity; the internal elastic lamina was intact except at the transition zone between the site of thermal injury and the normal artery, where disruption was found. Sites treated with balloon angioplasty without thermal energy showed disruption of the internal elastic lamina and normal medial cellularity. Myointimal hyperplasia was seen at 2 weeks at sites at which disruption of the internal elastic lamina had occurred. Thus, in the group treated with balloon alone, it was seen along the entire treated length, but in the thermal angioplasty group, it was seen only at the transition zones. Repopulation by spindle-shaped cells with the appearance of smooth muscle cells began at 4 weeks in the media, and by 8 weeks, diffuse repopulation had occurred.

Our findings contrast with those of Kaplan, with myointimal hyperplasia throughout the treated area and fragmentation of the inner layers. However, the arterial duct is a very different vessel from a normal artery. In particular, the internal elastic lamina of the normal arterial duct is usually already fragmenting at the time of birth.24

Our histological results suggest that the stenoses that appear in the ducts from 2 weeks to 3 months after

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**Table 4. Treatment Details of Lambs Developing Heart Failure**

<table>
<thead>
<tr>
<th>Lamb</th>
<th>Weight, kg</th>
<th>Balloon Size, mm</th>
<th>Temperature, °C</th>
<th>Duct Diameter, mm</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>5.5</td>
<td>5</td>
<td>85°C</td>
<td>3.4</td>
<td>Recovered</td>
</tr>
<tr>
<td>8</td>
<td>5.0</td>
<td>5</td>
<td>75°C</td>
<td>3.9</td>
<td>Recovered</td>
</tr>
<tr>
<td>21</td>
<td>2.0</td>
<td>5</td>
<td>100°C</td>
<td>3.0</td>
<td>Died</td>
</tr>
<tr>
<td>31</td>
<td>2.1</td>
<td>5</td>
<td>120°C</td>
<td>3.2</td>
<td>Died</td>
</tr>
</tbody>
</table>

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*Fig 9. Histological section stained with hematoxylin and eosin from a lamb treated at 85°C with a 6-mm balloon and killed 61 days after treatment showing that the hyperplasia has completely covered and trapped the necrotic tissue and a new intima is formed.*
treatment are due to fibrocellular intimal hyperplasia. If closure has not already occurred by 3 months after treatment, then it will not occur thereafter. This “risk of closure” period fits with the known duration of fibrocellular intimal hyperplasia in response to injury noted in other animal models of angioplasty damage. Our in vitro work suggests that parts of the balloon are more than 20°C cooler than the balloon center, and therefore the thermal effect is reduced. It was not apparent from the limited number of histological specimens that there were significant areas of undertreatment. The three consecutive treatments with repositioning of the balloon to ensure highest temperature treatment at all parts of the duct may have prevented regional undertreatment.

The occurrence of a ductal dissection was of concern but is a recognized complication of all forms of angioplasty. The balloon ends lie in the aorta and pulmonary artery, partially obstructing them. One might expect coagulum to form on the balloon surface and subsequently embolize, but there was no evidence that this happened. There was no clinical evidence of any thromboembolism; however, the histological appearance of the ducts suggests that thrombus formation occurs and tissue debris from the vessel wall passes into the lumen after thermal angioplasty. Short-term anticoagulation would therefore be required for human neonates.

The incentive for seeking an alternative to metallic stenting of the arterial duct arose because of its tortuous nature in duct-dependent pulmonary circulations and the problems associated with stenting the entire length, as noted by Gibbs et al. Whether it will be easier to pass an angioplasty balloon down such ducts remains to be seen.

Radiofrequency thermal angioplasty of the arterial duct results in long-term patency in a large proportion of treated lambs. It is of concern that the duct closed in nearly 20%. If closure occurred slowly, then, in a clinical setting, it would be possible to deal with it, for example by placement of a surgical shunt or a percutaneous metallic stent. If closure were abrupt, as reported for formalin infiltration, then the results could be catastrophic. We have no data to further elucidate this point. If closure as well as stenoses occurred as a result of fibrocellular intimal hyperplasia, the methods to prevent restenosis after coronary angioplasty might be applicable. Metallic stenting could be used subsequently to treat these stenoses. Thermal angioplasty would inactivate the closure mechanism, and metallic stenting would define the lumen diameter.

Acknowledgments

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