Use of Balloon-Expandable Stents to Treat Experimental Peripheral Pulmonary Artery and Superior Vena Caval Stenosis: Preliminary Experience

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SUMMARY. Current therapy of congenital or acquired stenoses of the peripheral pulmonary arteries and superior vena cava are frequently ineffective. This report describes our initial experience with the use of a balloon-expandable stainless steel stent to treat experimentally created branch pulmonary artery and superior vena cava stenosis. Fifteen adult mongrel dogs had surgically created stenoses of either a branch pulmonary artery and/or superior vena cava. A balloon-expandable stainless steel (0.076 mm), 3 cm long, intravascular stent was used in all animals. Stents were successfully placed in 13 of 15 dogs (nine with branch pulmonary stenosis and four with superior vena caval stenosis) with hemodynamic and angiographic relief of the stenoses in all. In three animals, successful stent placement was not accomplished because the distal right pulmonary artery was found to be totally obstructed in two and in one dog with combined vena cava and pulmonary stenosis the distal right pulmonary artery was so severely stenotic that the stenosis could not be crossed. Repeat catheterization performed 6 months following stent placement documented persistent gradient relief and angiographic evidence of unobstructed flow through the stent without thrombus formation and with patent side branch vessels. Our preliminary results suggests that balloon-expandable stents are a potential therapy for the treatment of branch pulmonary artery and superior vena cava stenoses.

KEY WORDS: Balloon angioplasty—Congenital heart disease

Peripheral pulmonary artery stenosis and superior vena caval stenosis are two lesions in which surgical reconstruction is difficult and sometimes impossible to perform. Although balloon dilation has also been used to successfully treat patients with peripheral pulmonary artery stenosis [2, 4, 9, 12, 13] or vena caval stenoses [5, 10, 14], there are many patients who have had less than satisfactory results. Balloon angioplasty has been reported to be successful in dilating approximately 50% of patients with branch pulmonary artery stenosis [2, 13] and in approximately 80% of patients with superior vena cava obstruction [5]. In both of these lesions, although angioplasty can acutely dilate the stenotic vessel to three or four times its original size, the stenoses frequently recur immediately following balloon deflation. The immediate recurrence of obstruction after dilation is thought to be due to the natural elastic recoil of the pulmonary artery and superior vena cava or, in the postoperative cases, due to resilience and resistance of scar tissue [2].

A stainless steel balloon-expandable graft (stent) has recently been developed by Palmaz and coworkers [7, 8]. Both Mullins and coworkers [6] and Benson and coworkers [1] have recently demonstrated the feasibility of placing such stents into the normal pulmonary arteries of dogs and pigs. There is only limited experience with the use of these stents to treat experimentally created stenoses. The purpose of this report is, therefore, to

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describe our experience with the development of a dog model of peripheral pulmonary artery and/or superior vena cava stenosis and to evaluate the efficacy of relieving the experimentally created stenosis with a balloon-expandable stainless steel stent.

Methods

Creation of Stenotic Lesion

Peripheral pulmonary artery stenosis and/or superior vena cava stenosis was created in 15 adult mongrel dogs [11], weighing 19.2 ± 2.3 kg. All dogs were anesthetized with halothane anesthesia. A thoracotomy was performed and the left or right pulmonary artery and/or superior vena cava isolated. Two pieces of 2-0 vicryl suture (three loops each) were placed around the pulmonary artery 1–2 cm from its origin and/or placed around the cava 1–2 cm from its junction with the right atrium. The sutures were tightened so that the pulmonary artery and/or vena cava was narrowed by 30–40%. All dogs received intramuscular antibiotics for 3 days after surgery to prevent infection and morphine sulfate as necessary for pain. Isolated right pulmonary artery stenosis was created in four dogs, isolated left pulmonary artery stenosis in seven, isolated superior vena cava stenosis in three, and combined right pulmonary artery stenosis and superior vena caval stenosis in one.

Stent Placement

Two to three months after creation of the stenosis all dogs underwent cardiac catheterization under suritalol anesthesia. The right heart catheterization was performed percutaneously from the right femoral area. After hemodynamic (superior vena cava, right atrial, right ventricular, main pulmonary artery, proximal left pulmonary artery, and distal left pulmonary artery pressures were measured) and angiographic (right or left pulmonary artery and/or superior vena cava angiograms) assessment of the stenosis, stent placement was attempted. A no. 7F end-hole catheter was passed into the distal pulmonary artery or vena cava. A 0.038-inch Teflon-coated 250-cm exchange guidewire was advanced into the distal vessel. The end-hole catheter was removed, leaving the wire fixed in the vessel, and a no. 12F (for the pulmonary arteries) or 16F (for the superior vena cava) long sheath and dilator were introduced over the guidewire into the vessel beyond the stenosis. Although the 8-mm angioplasty balloon with stent could fit through a 10F sheath, because of the canine anatomy a 12F sheath provided each movement of the balloon and stent across the tricuspid valve, pulmonary valve, and right pulmonary artery. Despite the discrepancy between sheath and catheter, bleeding from the sheath was minimal and a back-flow device was not necessary. A stainless steel stent, which was 0.076 mm in thickness, 3 cm in length, and 3.7 mm in diameter before expansion (provided by Johnson and Johnson Inc.), was placed on an 8-mm diameter (for pulmonary arteries) or 18-mm diameter (for the superior vena cava) balloon angioplasty catheter (Fig. 1). The size of the angioplasty catheter was chosen to be ~1 mm larger than the normal vessel diameter. The long dilator was removed from the sheath and the stent-mounted balloon angioplasty catheter was advanced through the long sheath into the distal pulmonary artery or vena cava. After the angioplasty catheter was positioned across the stenosis, the sheath was withdrawn off the proximal end of the angioplasty catheter into the main pulmonary artery or right ventricle (for pulmonary arteries) or into the right atrium (for the superior vena cava). The balloon was then expanded to 4–6 atm of pressure. The balloon was deflated and then exchanged for an end-hole catheter leaving the expanded stent across the area of stenosis. Repeat hemodynamics and angiography were performed. The catheter was removed and the groin held until hemostasis was obtained. To prevent thrombus formation in the long sheath, the dogs received 50 U/kg heparin during the catheterization. The dogs received 3 days of antibiotic after the catheterization and morphine sulfate as necessary for pain. The dogs received no anticoagulation or antiplatelet agents. The dogs were recatheterized at 3 and 6 months following placement of the stent. At these catheterizations hemodynamic and angiographic assessment of the stent was made. After the stent had been in place for 6 months, the dogs were killed for pathological assessment of the stent and vessel.

Statistical Analysis

All data are presented at the mean ± standard error (SE). To assess changes in the gradient across stenoses over time, a repeated measures analysis of variance was used.

Results

Dilatable peripheral pulmonary artery stenosis or superior vena caval stenosis was produced in 13 of 15 dogs (peripheral pulmonary artery stenosis in nine and superior vena caval stenosis in four). In