Intraluminal Ultrasound Imaging Through a Balloon Dilation Catheter in an Animal Model of Coarctation of the Aorta

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Background. Controversy still exists over the optimal balloon size, extent of vascular disruption, and long-term results of balloon dilation therapy for coarctation of the aorta. Intravascular ultrasound imaging has been used in patients with coronary artery disease to provide further insight into the anatomy of atherosclerotic lesions and the results of angioplasty and atherectomy. Initial observations of the results of balloon dilation of coarctations with intravascular ultrasound imaging have shown prominent dissections of the inner vascular layers that are often not detected by angiography. The purpose of this study was to test a new transballoon catheter ultrasonic imaging system capable of on-line direct visualization of lumen diameter and vessel wall structure for imaging before, during, and after dilation in an acute animal model of aortic coarctation.

Methods and Results. Abdominal aortic coarctations were created surgically in three 14-19-kg mongrel dogs by using Teflon gauze ties. The 6.8F ultrasound balloon catheter was placed percutaneously in the right femoral artery through a 9F sheath. Ultrasound imaging allowed measurement of the coarctation diameter, characterization of the vessel wall structure, localization of the stenosis, and placement of the midpoint of the balloon at the narrowest area. Imaging through the balloon was performed through several dilations (five to eight per animal), and after balloon deflation, it provided information on postdilation diameter, intimal tears, long-segment dissections, and intramural thrombi, findings that were confirmed at postmortem examination.

Conclusions. The results of this study demonstrate that imaging with a new intraballoon ultrasound device is feasible during inflation to therapeutic dilation pressures; it allows visualization of the changes in diameter and vascular wall structure after serial dilations without having to recross the obstructed area. Adaptation to larger balloon sizes and lower frequencies should make this system applicable to interventional catheterizations in patients with congenital cardiac and vascular lesions. (Circulation 1992;85:2291-2295)

KEY WORDS • intravascular ultrasound • balloon dilation • coarctation, aortic

After the first balloon dilation of an aortic coarctation in a postmortem aortic specimen from a neonate by Sos et al,1 Lock et al2,3 and Constaneda-Zuniga et al4 showed that balloon angioplasty was feasible in surgically excised coarcted aortic segments and in experimentally created coarctations in animals. Since then, balloon dilation in infants and children with native and recurrent coarctations of the aorta has become widespread.5-8 There is considerable controversy, however, about optimal balloon size in relation to the stenosis, whether there is an “ideal” disruption of the inner layers of the aortic wall, and what the risk factors are for restenosis and aneurysm formation, especially after dilation of native coarctations.5,6,8-11 In adult coronary artery disease, recently developed intravascular ultrasound catheters have generated substantial interest because of their ability to image the anatomy of atherosclerotic lesions and the effects of balloon angioplasty and atherectomy with more detail than angiography.12-16 Our own experience and the work of others using intravascular ultrasound to examine the effects of coarctation balloon angioplasty suggests that intimal tears are more common and often more severe than detected by postdilation angiography on the same patients.17,18 In fact, disruption of the intima and part of or all of the media appears to be required for a successful coarctation dilation;2,19 however, the relation of the extent of vascular damage to success and complications of the procedure is unclear. Recently, a transballoon ultrasonic scanning system capable of imaging the vessel wall and lumen during
dilation has been used. Preliminary human trials for peripheral artery disease suggest accurate wall and luminal imaging with the advantage of avoiding catheter changes after each dilation or frequent recrossing of the dilated area, a maneuver that could result in extension of the intimal tear or transmural rupture. The purpose of the present study was to test this ultrasonic system for imaging the vessel wall and lumen during and after balloon dilation in an acute experimental dog model of coarctation of the aorta.

Methods

Three 14–19-kg mongrel dogs were anesthetized with intravenous pentobarbital and ventilated in the supine position. Through a retroperitoneal incision, the abdominal aorta was dissected free, and acute obstructions were created with 4–5-mm strips of Teflon gauze wrapped around the aorta to the diameter of the deflated balloon catheter, clamped with a needle holder, and then sewn together with 6-0 Tevdek sutures. Several obstructions were created in each dog, followed by five to eight balloon dilation procedures in each animal. To exaggerate the mechanical damage to the arteries, we deliberately recrossed dilated areas with the balloon catheter and a curved stiff end of a 0.035-in. guide wire. At the end of the experiment, an overdose of pentobarbital was administered to the animal, and the appropriate segments of the aorta were removed for gross examination.

The balloon ultrasound imaging catheters (Boston Scientific, Watertown, Mass.) are on a 6.8F shaft, terminate in 7-mm-diameter, 4-cm-long polyethylene balloons, and allow passage of a 0.019-in. guide wire under the balloon. The inner lumen used for inflation and deflation of the balloons also houses a rotary drive shaft for the single-element, side-looking ultrasound transducer, which scans through a window directly in the center of the balloon (Figure 1). The catheters were inserted percutaneously through a 9F sheath in the dogs. Use of these catheters has previously been reported in a limited clinical series for dilation of peripheral vascular lesions. For our studies, the 20-mHz crystal in the catheter scanner was used with the receivers of the ultrasound instrument tuned to 12.5 mHz to improve sensitivity for imaging larger vessels. The intravascular images were obtained in real time at 10 rotations per second with a specially modified Diasonics intravascular ultrasound scanner (Diasonics Corporation, Milpitas, Calif.). Balloons were inflated to 1–6 atm with saline (drawn, flushed, and filled carefully to remove air and avoid bubbles). Images were acquired on half-inch super VHS videotape for later review.

Results

Eighteen separate aortic obstructions were produced in the abdominal aortas of the three dogs, and each was dilated. Echo images demonstrated that all the vessel obstructions reduced the cross-sectional area at least by 70%, and dilation back to baseline followed rupture of
away from the balloon to its baseline diameter, which was larger than the 7-mm balloons. However, in two animals, recoil of the aortic wall toward the balloon was observed, presumably secondary to arterial spasm. Ultrasound visualization of the vessel wall was achieved through full balloon inflation; however, it was only during the deflation sequence, as the balloon separated from the aortic wall, that anatomic details of intimal dissections and other mural changes were seen. The imaging balloon catheters could be moved freely across the obstructions; they were inflated and deflated at least five times with no deterioration of imaging unless air bubbles had entered the balloon. In this case, repeated flushing and evacuation of the balloon with fresh saline was effective for debubbling.

Intimal tears (Figures 2 and 3) were observed by ultrasound imaging and later confirmed by direct post-mortem examination. Most initial dilations were not associated with intimal tears, this being secondary to the acute model in which there is no intrinsic anatomic stenosis or fibrosis of the inner vascular layers. However, balloon dilation of vessels in spasm often resulted in intimal dissections similar to those seen with intravascular imaging after balloon angioplasty of aortic coarctations in patients. The vessel wall changes could only be seen during balloon deflation, when the balloon came away from the wall and allowed separation of the vascular layers.

We deliberately exaggerated the mechanical damage produced by the balloons by crossing the dilated area multiple times with the balloon catheter and the stiff end of a guide wire. Lesions that were produced included a frank dissecting aneurysm (Figure 3) into which the catheter could be passed, giving a characteristic echocardiographic appearance, longitudinal intimal dissections, intimal flaps and tears (Figures 2 and 3), and thrombus formation in the dissection as well as the femoral artery and the distal end of the introducing sheath (Figure 3). The accuracy of the intravascular ultrasonic visualization of these procedure-related complications was grossly examined on the aortic specimens postmortem, verifying the one dissecting aneurysm, the four intimal disruptions, and the positions of two mural aortic thrombi and the one thrombus at the end of the sheath. Superficial abrasions and localized intimal tears that did not extend more than 1 mm into the aortic wall and did not protrude as flaps into the lumen were not defined by ultrasound.

**Discussion**

Our studies indicate that it is possible to construct balloon catheters suitable for coarctation dilation in infants and children while simultaneously providing detailed ultrasonic imaging of stenosis severity, vessel wall characteristics, and the effects of balloon dilation. In these animal experiments, we did not investigate angiographic and ultrasonic imaging correlates, because those have already been obtained with nonballoon intravascular ultrasound systems in clinical studies. The method described here provides on-line real-time visualization of the balloon as it is inflated and engages the vessel wall. Intramural damage, however, can only be seen after partial or complete balloon deflation, because at full inflation the dissection spaces are com-

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**Figure 2.** Image through the deflated balloon in the narrowest portion of the coarctation (top panel). Middle panel: Dilation viewed through the partially inflated balloon. Bottom panel: Magnified view of an intimal dissection after balloon deflation.
transultrasound imaging can be performed simultaneously and do not interfere with each other. Aside from visualization of vascular tears, another complication of arterial balloon dilation that can also be imaged with this system is thrombosis, which may occur during prolonged and difficult procedures.

It has been our experience that a lower transmission frequency on the transducer itself has improved the detail of wall structures and boundaries in intravascular studies. This was also the case when nonballoon ultrasound catheters were passed into these same dogs to compare the images with the transballoon scans. The images from the nonballoon 20-mHz catheters were only mildly improved compared with those obtained through the trans-balloon catheters, but vascular detail was maximized when 12.5-mHz nonballoon scanning catheters were used.

A potential problem, because the lumen for balloon inflation is shared with the scanner drive shaft, is that the inflation and deflation times are longer for these balloon catheters compared with those usually used for dilation. The mean inflation and deflation times for the 6.8F catheters using a 50/50 mixture of saline and Renografin are 4.7 seconds and 12.8 seconds, respectively. However, these can be minimized by using more dilute contrast for filling the balloon without compromising fluoroscopic visualization, especially in high-resolution catheterization laboratories equipped with digital enhancement capability. In our experiments using saline only, mean balloon inflation and deflation times were 3.5 seconds and 5.3 seconds, respectively.

Among the controversial issues surrounding balloon dilation of coarctations in infants and children are the size of the balloon and the "optimal" degree of vascular wall injury. Some authors advocate a balloon 2.5 to three times the narrowest area; others use balloons with a diameter approximating the caliber of the aorta proximal to the obstruction, the aorta at the level of the diaphragm, or the largest aortic diameter distal to the obstruction. The mechanism of obstruction relief has been shown by some investigators to involve tearing of part or all of the vascular intima and media; others have demonstrated an increase in aortic coarctation diameter without vascular disruption in a postmortem specimen. As such, the degree of dilation to obtain adequate gradient relief but at the same time minimize the risk of recurrence of the coarctation or the development of aneurysms is unclear. The problem is complicated by the variety of anatomic substrates in coarctations with different proportions of fibrous, elastic, and ductus arteriosus tissue as well as cystic medial changes in the spectrum, ranging from a discrete area of narrowing to long-segment hypoplasia of the aortic arch. Furthermore, there is special concern regarding aneurysm formation after native coarctation dilation because there is absence of fibrotic tissue surrounding the aorta, such as is observed in patients who have already undergone surgery for the coarctation in the past.

The balloon ultrasound imaging catheter offers potential advantages in attempts to clarify some of these issues. By delineating changes in vessel diameter and the associated mural changes immediately after coarctation balloon angioplasty and correlating them with the results at follow-up, the "ideal" degree of vessel injury

FIGURE 3. Image of thrombus on the end of the sheath (top panel). Middle panel: Aortic dissection imaged with the scanning catheter in the false lumen. Bottom panel: Small intimal tear protruding into the aortic lumen after balloon dilation.

pressed by the balloon. Therefore, in the clinical situation, repeated inflation, recoil, and examination steps would be indicated but with the advantage of not requiring a catheter exchange or an intervening angiogram, because repeated inflations are often performed or required during clinical angioplasties until the waist on the balloon disappears or satisfactory angiographic or hemodynamic results are obtained. Fluoroscopic and angiographic observations of the balloon are still possible if the balloon is filled with diluted and debubbled contrast material. Furthermore, fluoroscopic and ul-
may emerge. Because imaging is a part of the dilating catheter, the number of catheter and wire exchanges is minimized, lowering the time of the procedure and the risk of transmural rupture at the site of an intimal tear. The use of this technology does not have to be confined to coarctation dilation; similar issues exist for balloon angioplasty of other arteries such as peripheral pulmonary artery stenoses. Reports of ultrasound investigation of coronary arteries before and after interventions such as angioplasty and atherectomy for atherosclerotic lesions have already generated interest. It is hoped that such studies will provide information about plaque content and morphology, calcium deposits, thrombus formation, the differing effects of the various therapeutic interventions to aid in predicting initial success, and the risks for and mechanism of recurrence of coronary artery obstruction. For coronary studies, this will require very small catheters and very high-frequency ultrasound technology. Aortic coarctations are generally easier to access, and of course, require larger dilating balloons. Encouraged by the quality of balloon ultrasound visualization in this animal study, we are preparing 12-mm and 15-mm balloon catheters with 12.5-MHz ultrasonic crystals to begin a limited clinical trial of coarctation balloon angioplasty in infants and children with simultaneous transballoon intravascular ultrasound imaging.

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