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CLINICAL EXPERIENCE WITH ULTRASONIC ANGIOPLASTY OF TOTALLY OCCLUDED PERIPHERAL ARTERIES

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We report further experience of ultrasonic angioplasty in patients with totally occluded peripheral arteries. The ultrasonic angioplasty device consisted of a 1.6mm diameter flexible wire attached to a piezoelectric crystal generating ultrasound at 20Khz. Patients (n=6) were selected previously for surgical arterial reconstruction. Prior to surgical repair, ultrasonic angioplasty was performed on the totally occluded arteries (n=7). None of the occlusions could be crossed with a guidewire. Following ultrasonic angioplasty, successful recanalization without perforation was achieved in all vessels. Energy levels of 12±2 watts were used. Length of recanalized segments was 4.3±1.4 cm. Mean procedure time was 80±39 sec. Histologic examination of the pressure-fixed sonified arteries revealed diffuse involvement of the intima with complicated plaque through which recanalization occurred. There was mild damage to the media in only one of the arterial segments. There was no damage to the adventitia and no histologic evidence of perforation in any of the arterial segments. Morphometric analysis revealed a recanalized luminal area of 5.9±1.8 mm^2 (33±10% of the original arterial lumen). The flow rate through the recanalized lumen was 50±22 ml/min at a pressure of 100 mmHg. Serial filtration revealed all debris from the recanalized lumen to be <100 μ in diameter. Of total debris obtained, 9±2% were in the 30-100 μ range, 53±8% were in the 8-30 μ range, and 36±5% were in the <8 μ range.
Conclusion: Ultrasonic angioplasty is a promising catheter-based technique for safe and effective recanalization of totally occluded arteries.

ARTERY COMPLIANCE IMPROVES AFTER ULTRASONIC ABLATION OF ATHEROSCLEROTIC LESIONS

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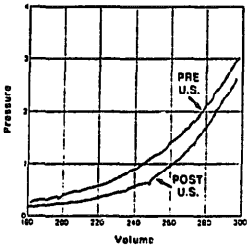
To assess the effect of ultrasonic ablation on atherosclerotic lesions, the pressure-volume (P-V) relations of stenoses in 5 calcified, atherosclerotic human cadaver arteries were measured before and after intraarterial application of ultrasound (US) energy. The P-V relation was measured by inflating a 3 mm angioplasty balloon at 0.025 cc/sec within each stenosis using a syringe instrumented with pressure and volume transducers. To minimize potential effects of balloon inflations on compliance, balloon inflation pressure was ≤ 3 atm prior to US application. Ultrasonic ablation was performed using a 2 mm diameter probe at a frequency of 20 kHz for 120 seconds. After US ablation, the P-V relations showed increased compliance: larger volumes at each level of pressure and decreased slope. Mean balloon volume at 1 atm of pressure increased 19.2 + 6.2% after US application. Mean balloon volume at 2 atm of pressure increased 5.8 + 1.5%. These data suggest that interruption of calcified plaque by US energy increases the pliability of such lesions, which may enhance vasodilation and render severely calcified lesions more amenable to balloon angioplasty.



FEASIBILITY OF HIGH-INTENSITY ULTRASOUND RECANALIZATION OF HUMAN CORONARY ARTERIES.

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In order to investigate the feasibility of ultrasonic recanalization of obstructed human coronary arteries *in vitro*, we applied high intensity ultrasound to 13 coronary arteries obtained at autopsy using a prototype instrument enabling insonification through a catheter tip. It was a 119 cm long, 0.95 mm thick wire in an 8 F catheter, connected to an external ultrasonic transformer and power generator (Sonic Needle, Co., Farmingdale, NY). The arteries were excised and perfused with saline at systemic pressure in a water tank. Flow rate and pressure gradient across the vessel were continuously monitored before, during and after recanalization. A 5 MHz phased array 2D echocardiography instrument was used to determine minimal luminal diameter and % diameter narrowing before and after ultrasonic irradiation. The wire was introduced through a catheter into the coronary lumen and advanced until obstruction was met.To relieve luminal obstruction ultrasonic energy was delivered at 22 KHz and average intensity at the tip of the wire of 45±22 Watts/cm^2, with a 61±12 μ amplitude of tip displacement. After completion of ultrasound exposure, all specimens were cut serially and histologically examined, and the size of debris in the perfusing fluid was measured. The mean % luminal diameter narrowing and flow rate before insonification were 73.2±11.7 %, and 88.6±57.4 ml/min, respectively. Mean pressure gradient before ultrasonic exposure was 89.5±22.8 mmHg. After recanalization, mean pressure gradient was reduced to 45.2±23 mmHg ($p<0.001$). Mean % luminal diameter narrowing improved to 48.8±12.5% ($p<0.001$) and increase in mean flow rate was 109.7±78%, $p<0.001$. 95% of debris particles had a diameter <12.23 μ, range 4.8-12.42μ. Arterial perforation occurred in 3/13 arteries (23%) and in all 3 occurred before ultrasound application. Mechanical breakage of wire occurred in 5 cases (38%).We conclude that ultrasonic recanalization of human coronary arteries *in vitro* is feasible. Debris sizes are sufficiently small to minimize the hazard of embolization. However, for eventual human application, improvement in wire flexibility is needed.

INTRACARDIAC ECHOCARDIOGRAPHIC GUIDANCE AND MONITORING DURING AORTIC AND MITRAL BALLOON VALVULOPLASTY: IN VIVO EXPERIMENTAL STUDIES

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To evaluate the potential of *intracardiac* two-dimensional echocardiography during balloon valvuloplasty, we used a modified 5 MHz ultrasound probe (with 2-D echo and color Doppler capabilities) for intracardiac imaging during simulated aortic valve (AoV) and/or mitral valve (MV) balloon valvuloplasty in 8 dogs. The ultrasound probe was introduced into the RA to image both right and left heart structures. By manipulating the tip with a distal control, we were able to obtain excellent 2-D echo images of the AoV and MV, LV and RV, and LA and RA. The morphology and motion of both valves could be clearly delineated in a short-axis and in a modified long-axis orientation. LV cavity size and function could be assessed in similar imaging planes. As the AoV balloon catheter was advanced, it could be seen in the aorta and then across the valve. The catheter positioning could be constantly imaged by ICE. During balloon valvuloplasty, the balloon inflation and deflation could be seen. Associated changes in LV size and function could be ascertained. Following balloon valvuloplasty, the presence and degree of aortic insufficiency when it occurred could be gauged by color Doppler. During mitral balloon valvuloplasty, the position of the balloon was visualized well by ICE in its long-axis, before, during and following inflation and deflation. We conclude that *intracardiac* 2-Dimensional and Doppler echocardiography from the right atrium with a lower frequency transducer allows constant visualization of left heart structures; when refined, this imaging approach could be useful in assessing the morphology of aortic and mitral valves, in guiding balloon valvuloplasty, in monitoring changes in the valvular integrity and ventricular function, and in the detection of complications such as valvular insufficiency.