STUDIES OF MICROWAVE THERMAL BALLOON ANGIOPLASTY IN RABBITS

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ABSTRACT

The study into the technique of microwave (2.45 MGz) thermal balloon angioplasty has established a correlation between recorded temperature and observed injury. In addition, a trend pointing toward an inverse relationship between intimal proliferation and medial injury has been observed. Angioplasty was performed on 30 normal New Zealand white rabbits, providing 60 iliac arteries for histopathologic analysis. The angioplasty catheter consists of a 3.0mm angioplasty balloon with an intrinsic thermocouple placed on the interior surface of the mid-portion of the balloon A 0.023 inch coaxial cable was used to deliver the microwave power, and a slot antenna configuration was chosen for the radiating element

METHODS

Microwave/Angioplasty System

The angioplasty catheter (Figure 1) consisted of a 3.0mm angioplasty balloon with an intrinsic thermocouple placed on the interior surface of the mid-portion of the balloon. The microwave antenna was a 0.023 inch diameter coaxial cable with a gap antenna at the distal end. This was coupled to a 2450 MHz microwave generator with a power output ranging up to 60 watts. The antenna was placed in the through lumen of the angioplasty catheter and positioned so that the gap antenna was aligned with the thermocouple of the angioplasty balloon.

Angioplasty Procedure

Angioplasty was performed on 30 normal male and female adult New Zealand rabbits ranging from 4.5 to 5.5 kg. After induction of general anesthesia with Acepromazine, Xylazine, and Ketamine, both femoral arteries were isolated under sterile conditions. The angioplasty/microwave system was then placed in the appropriate femoral artery and advanced retrograde to the external iliac artery under fluoroscopic guidance. Once in place, angioplasty was performed using the specified parameters. Study variables included inflation pressure (1 or 5 atm.), target temperature (50, 70, or 90 degrees centigrade), and microwave energy duration (30 or 60 seconds). Thirty animals were chosen to provide 60 iliac arteries for analysis, at least four vessels for each possible permutation of time, temperature and pressure, as well as 8 vessels that underwent conventional angioplasty without heating. Following angioplasty, the catheter was removed and the femoral artery ligated.

Histologic Analysis

One week after angioplasty, the animals were again anesthetized and the inferior vena cava and abdominal aorta were isolated. After heparinization, animals were sacrificed with an overdose of Pentobarbital and the aorta was perfused with 10% formalin at 100 mmHg for thirty minutes. Following this, the external iliac arteries were dissected out and sent for histologic analysis.

Each vessel was embedded in paraffin and sectioned at four millimeter intervals, then stained with Hematoxylin-Eosin, Trichrome, and Verhoeff's stains. Each vessel was examined by a pathologist who was blinded to the conditions of each angioplasty. Medial injury for each section was qualitatively graded on a scale of one to five, with one representing medial reaction and five representing full thickness medial necrosis. In addition, medial injury was expressed as the percent of the total vessel circumference involved. The product of the depth of injury and percent circumference (x 100) was defined as the medial injury index (MII). For each vessel, the MII for all vessel sections was averaged to yield the mean MII. Intimal proliferation was graded on a scale of one to four, and also expressed as a percent of vessel circumference. The intimal proliferation index (IPI) was defined as the product of the two (x100). The mean IPI was computed by averaging the IPI of all vessel sections for a given vessel.

RESULTS

A strong correlation was observed between mean medial injury index and peak temperature (Figure 2). It should be noted that below 60 degrees centigrade, no more medial injury was observed than was seen in conventional angioplasty. A plot of mean IPI and mean MII suggests an inverse relationship between intimal proliferation and medial injury (Figure 3).

The longitudinal distribution of medial injury is shown in Figure 4. Medial injury falls off to close to control at a distance of 1.2 cm. from the point of peak medial injury.

Microwave duration and inflation pressure had no effect on intimal proliferation or medial injury. Similar results were obtained, Figures 5, 6, when the rabbits were sacrificed following the microwave balloon angioplasty procedure. It should be stressed that this preliminary study, done one week following the procedure, is a first attempt to define the biologic effects of intravascular microwave energy and determine optimal angioplasty parameters for further study. Also, effects in the normal rabbit may be different when compared to the atherosclerotic rabbit, and are more difficult to extrapolate to humans.

CONCLUSIONS

Microwave thermal balloon angioplasty is an effective means of delivering intravascular thermal energy with measurable histopathologic effects that vary linearly with temperature. Further studies, which will include artetiographic and histologic analysis, as well as *in vitro* study of vessel mechanics and contractility,in both normal and atherosclerotic rabbits four weeks after angioplasty are currently under way. In addition, studies are currently in progress which relate to temperature profiling as a function of antenna configuration, and to temperature variation along the coaxial cable as a function of tissue loading.

ACKNOWLEDGEMENTS

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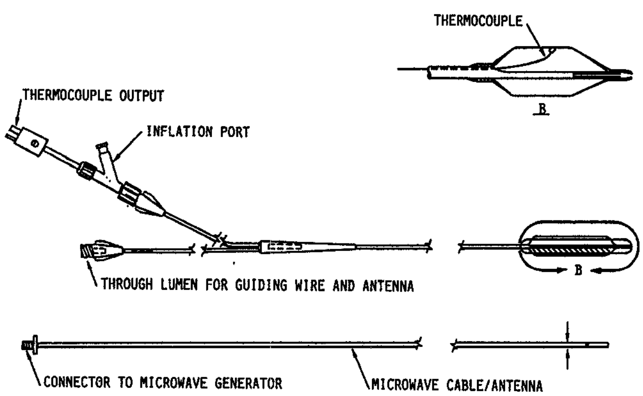

Figure 1

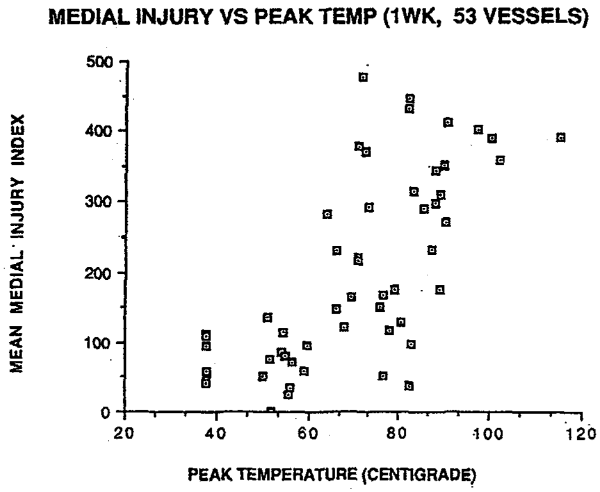

Figure 2

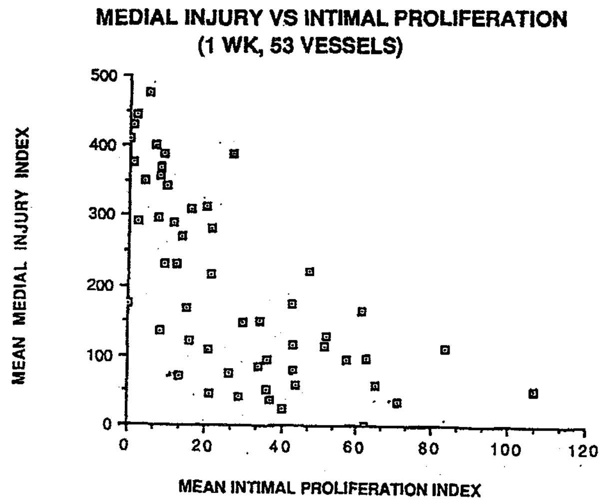

Figure 3

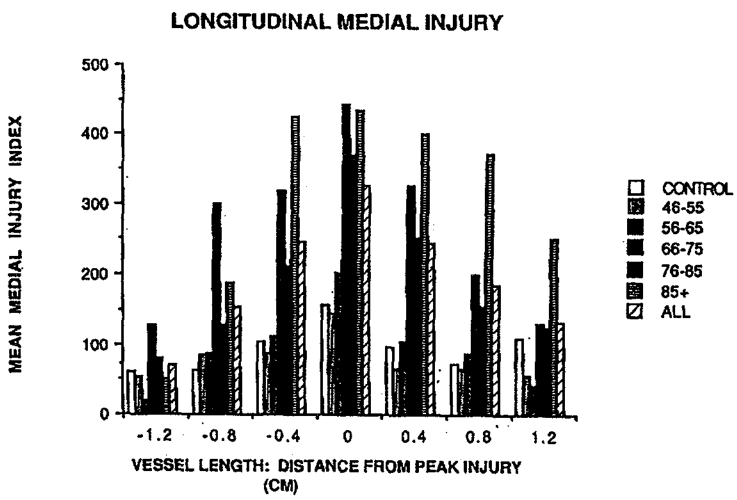

Figure 4

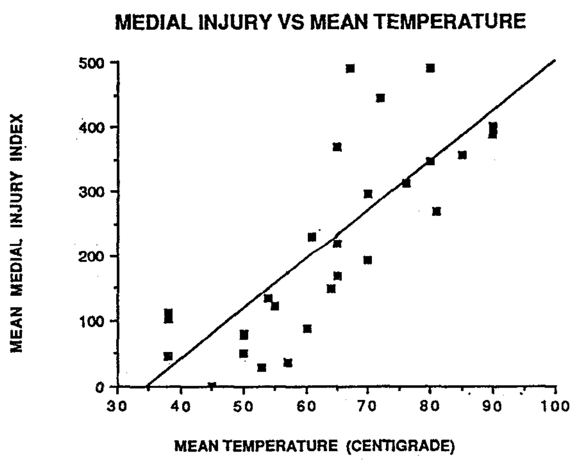

Figure 5

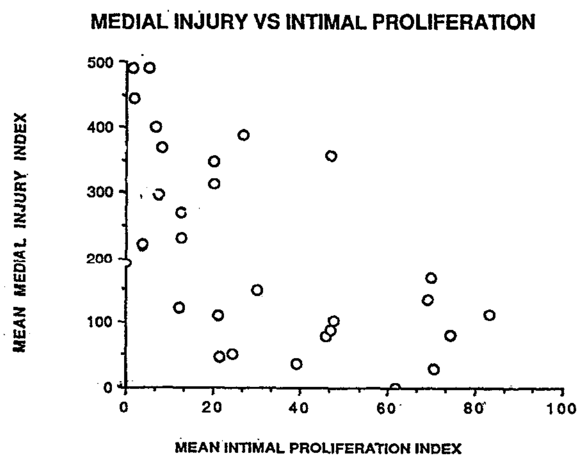

Figure 6