Microwave Thermal Angioplasty in the Normal and Atherosclerotic Rabbit Model

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Abstract—**The results of using Microwave (2450 MHz) Balloon Angioplasty (MBA) in normal and diseased animal model (rabbits) are described. In atherosclerotic rabbits, MBA at 85°C results in an enhanced lumen diameter compared to Conventional Balloon Angioplasty (CBA) immediately post balloon angioplasty.**

Introduction

Although angioplasty has become an acceptable modality in cardiology, significant problems and unresolved issues still exist in conventional angioplasty. The development of thermal angioplasty has become an area of great interest. Until recently, however, it was restricted to laser intervention. As many as 30% of patients who have undergone successful angioplasty develop restenosis. There are also many patients in whom the immediate results of balloon angioplasty are less than optimal because of vessel recoil, dissection, or thrombus. A second or third balloon inflation may therefore be required.

These complications exaccerbate some of the instability of the vessel and can result in acute closure. As early as 1987 [1] we had suggested the use of microwave energy to perform thermal angioplasty. In addition, we had speculated that microwave energy penetrating the media would reduce artery recoil as well as intimal proliferation, both of which are major problems in both balloon and laser balloon angioplasty. In this letter, we describe a microwave thermal balloon angioplasty (MBA) with emphasis on results obtained in the atherosclerotic rabbit.

A. Microwave/Angioplasty System [1]–[4]

The angioplasty catheter (Fig. 1) consisted of a 3.0 mm angioplasty balloon with a 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 an antenna at the distal end. This was coupled to a 2450 MHz microwave generator with a power output ranging up to 100 watts. The antenna was placed in the center lumen of the angioplasty catheter and was aligned with the thermocouple of the angioplasty balloon.

B. Experimental Procedure

After induction of general anesthesia with ACE promazine, 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.

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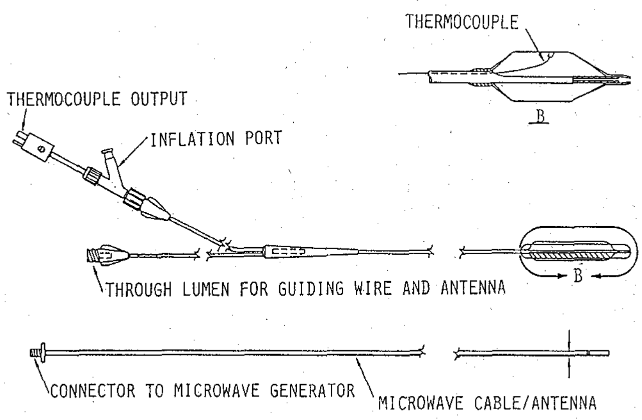

Fig. 1. Microwave delivery system.

In the study of normal rabbits, variables included inflation pressure (1 or 5 atm), temperature (50, 70 or 90° centigrade), and microwave energy duration (30 or 60 seconds). In the atherosclerotic model, each animal was its own control with one side treated with conventional balloon angioplasty (no microwave heating), and the other side with conventional angioplasty combined with microwave heating. Target temperatures in the atherosclerotic model were 70° and 80° C.

C. Results – Normal Model

The results of tests performed on normal rabbits [4] have demonstrated that microwave balloon angioplasty is an effective means of delivering intravascular thermal energy. One week after angioplasty, there are measurable histopathologic effects that vary linearily with temperature, and suggest an inverse relationship between medial injury and intimal proliferation, Fig. 2 and Fig. 3.

Medial (muscle portion of the vessel) 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 ($\times 100$) was defined as the medial injury index (MII). For each vessel, the MII for all vessel sections was averaged to yield the mean MII. Internal proliferation (regrowth of the vessel resulting in decreased lumen diameter) 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 ($\times 100$). The mean IPI was computed by averaging the IPI of all vessel sections for a given vessel.

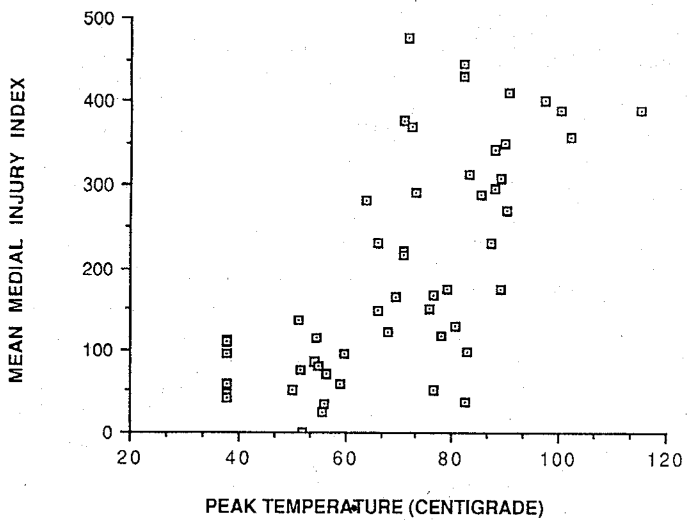

Fig. 2. Medial injury vs. peak temperature (1 wk, 53 vessels).

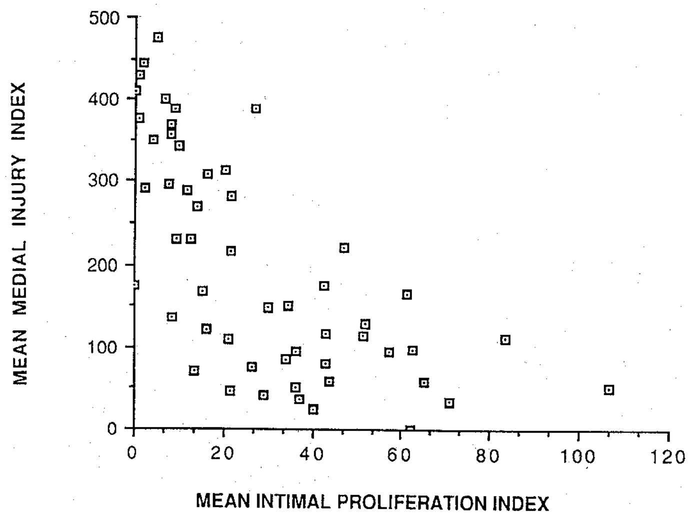

Fig. 3. Medial injury vs. intimal proliferation (1 wk, 53 vessels).

D. Results – Atherosclerotic Model

After the conclusion of our studies on normal rabbits, a series of atherosclerotic rabbits were prepared. Endothelial denudation was performed by inserting a balloon catheter down the iliac artery and abrading the arterial wall to create endothelial damage. The rabbits were then continued on a high cholestrol and high fat diet for six weeks, during which time atherosclerosis of the iliac vessels was produced (Fig. 4).

We have evaluated the effects of microwave thermal balloon angioplasty in 16 atherosclerotic rabbits, comparing its results with those of conventional balloon angioplasty, (CBA), performed in external iliac arteries. Balloon inflation lasted one minute in the vessels treated with MBA, with temperature raised to 70°C or 85°C for 30 seconds. Analysis was performed on angiograms pre (Fig. 4), immediately post (Fig. 5), and four weeks post angioplasty (Table I).

Histologic evaluation at four weeks revealed increased intimal fibrosis with formation of circular and longitudinal layers of myointimal cells and decrease in foamy cells in MBA vs. CBA treated vessels. The vessel diameter was significantly enhanced by the use of MBA at 85°C, as compared to CBA. Differences were not only evident immediately after BA, but appeared to be persistant up to four weeks after BA (Table I).

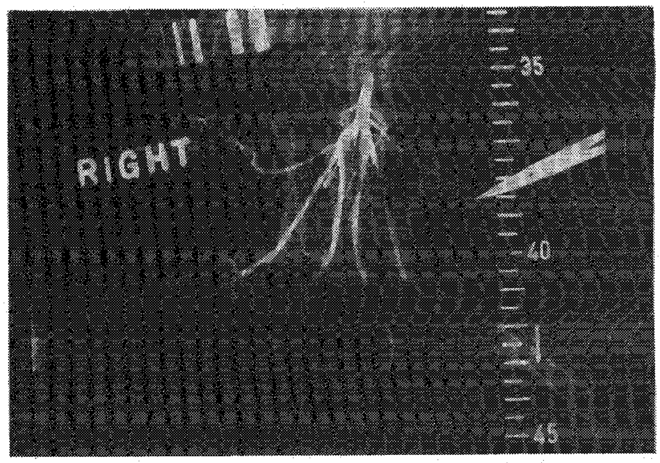

Fig. 4. Atherosclerosis of iliac vessels.

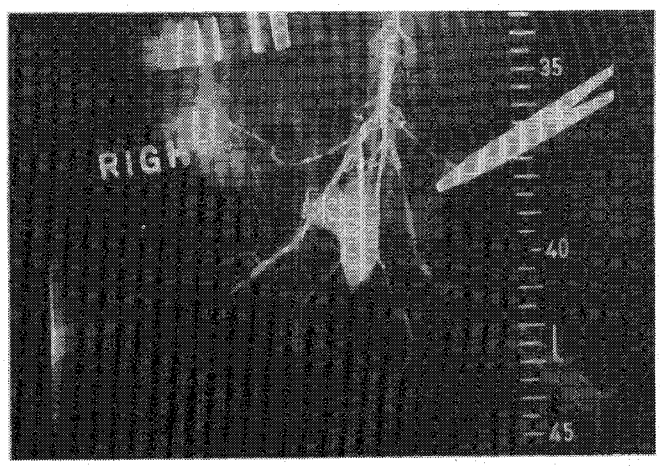

Fig. 5. Iliac vessels following treatment: The right iliac vessel (on left as one observes the figure), has been treated with microwave balloon angioplasty; left iliac bessel (on right of figure), has been treated with conventional balloon angioplasty.

TABLE I
COMPARISON OF THE CHANGE, IN mm, OF THE MEAN DIAMETER (D), TO THE PRE-BA DIAMETER

Temperature	Change in Mean Diam. Immediately Post		Change in Mean Diam. Four Weeks Post	
of MBA	MBA	CBA	MBA	CBA
70°C	+0.48	+0.29	−0.06	−0.30
85°C	+0.87	+0.47	+0.58	+0.40

$p < 0.05$ MBA versus CBA. ($P < 0.05$ indicates that the probability is less than 5% that the differences between the MBA and CBA results are due to random chance.)

CONCLUSION

Pathological changes found in the media of normal rabbits ranged from inflamatory cell infiltration to loss of smooth muscle cells with medial thinning. Variable degrees of intimal proliferation were seen. A linear relationship between peak or mean temperature and injury to the media was observed, with an inverse relationship between intimal proliferation and medial injury suggested at one week following the procedure. In the atherosclerotic models, MBA at 85°C resulted in an enhanced linear diameter compared to CBA immediately post BA, as well as in suggested improvement four weeks post BA.

Acknowledgment

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