PERCUTANEOUS TRANSLUMINAL MICROWAVE ANGIOPLASTY CATHETER

A. Rosen (*), P. Walinsky (*), D. Smith (*), Y. Shi (*), Z. Kosman (*),
A. Martinez (*), H. Rosen (*), F. Sterzer (**), D. Mawhinney (**),
A. Presser (**), J-S. Chou (***), P. Goth (***), G. Lowery (***).

(*) Thomas Jefferson University, Philadelphia, Pennsylvania
(**) MMTC, Princeton, New Jersey
(***) Baxter Healthcare Corporation, Edwards LIS Division, Irvine, California

ABSTRACT

Microwave balloon angioplasty (MBA) combines traditional angioplasty techniques with microwave heating as an ancillary modality to help open narrowed arteries and reduce the occurence of restenosis. MBA was used in anesthetized rabbits to induce tissue modification in the endothelium and media. Results of initial in-vitro and in-vivo experiments are presented, and the potential advantages of adding microwave heating to balloon angioplasty are discussed.

INTRODUCTION

Coronary artery disease is a leading cause of mortality and morbidity in the United States. Each year, several hundred thousand people die of acute myocardial infarction, and a still larger number suffer the chronic effects of coronary artery disease. Occlusion of coronary arteries by atheromatous plaque results in obstruction of blood flow necessary to supply oxygen and nutrients to cardiac muscle. Thus, injury to, or death of affected cardiac muscle can ensue. Techniques to restore blood supply to regions of the heart affected by coronary artery stenosis are varried, and range from medical therapy for less severe cases, to coronary artery bypass surgery for far advanced situations.

Percutaneous transluminal balloon catheter angioplasty has become a popular alternative therapy to open heart surgery since it carries less risk, and is less expensive, than surgery. This method involves the insertion of a catheter, tipped by a deflated balloon, into the lumen of an artery partially occluded by plaque. The balloon is then inflated to enlarge the lumen and thus re-establish coronary blood flow.

In this paper, we describe a microwave balloon angioplasty catheter and its in-vitro and in-vivo effects on arterial tissue. Microwave energy, producing heat at the end of a balloon angioplasty catheter, can cause softening of an arterial plaque prior to, or during inflation of the balloon. This process may result in more effective and longer lasting dilatation of previously stenosed arteries. Furthermore, there is a thermal compression of the three layers of the artery. Such thermal compression has potentially beneficial effects, including a decrease in arterial elastic recoil. (1,2)

MICROWAVE DELIVERY SYSTEM AND INITIAL IN-VITRO RESULTS

The microwave system consists of a 2450 MHz signal generator (capable of delivering up to 50W), a directional coupler, and two power meters to measure forward and reflected power. A thin flexible coaxial cable, 0.034" in diameter, which fits within a conventional balloon angioplasty catheter, is terminated by a radiating antenna. The radiating antenna is formed by removing a length of the center conductor creating a slot, fig. (1). A thermocouple is inserted into the lumen of the catheter (the same opening through which the cable/antenna is inserted), and epoxied to the outer portion of the balloon as shown in fig. (2a). The coaxial antenna is positioned within the balloon, and microwave energy is broadcast to surrounding arterial tissue. Tissue temperatures of 90 degrees centigrade have been achieved during a procedure. Fig. (2b) depicts the microwave delivery system.

The temperature increase and heating pattern of this slot antenna were measured by placing the antenna between two saline-soaked sponges. A liquid crystal sheet that changes color in the temperature range of 25-30 degrees centigrade was placed on the heated face of each sponge. The sponges were heated for 30 seconds with a net input power of 5 Watts at a frequency of 2450 MHz to measure temperature elevation (3). The heating pattern of the antenna was bi-directional and uniform over about 1 cm in length.

Having determined the heating properties of the antenna system, we applied microwave energy directly to the myocardium of a dog in an open chest experiment. No arrhythmia was observed. Fig. (3) depicts the histologic findings, consisting of a discrete area of tissue disruption, to a depth of 2-3 mm, which followed the application of microwave energy through a coaxial cable and radiating antenna.

Centrally, the lesion contains a zone of severe thermal destruction with resulting coagulation necrosis. The extent of the

CH2725-0/89/0000-0167$01.00 © 1989 IEEE

coagulation necrosis gradually decreases towards the periphery of the lesion, where normal myocardial tissue is seen. The outer zones of tissue damage retain some connective tissue architecture despite the destruction of myocardial tissue, and a few surviving fibroblasts are visible. These experiments, coupled with previous experience with microwave coaxial applicators for use in thermotherapy of brain tumors (4) indicate that sufficient energy can be introduced into the stenotic lumen of a cardiac artery via a special microwave transmission line/antenna system embedded in a catheter. Such a system may be used to heat and soften the plaque and, with the help of a balloon, to increase the flow through the lumen.

IN-VIVO MICROWAVE BALLOON ANGIOPLASTY ON RABBIT ARTERIAL TISSUE

The MBA procedure is similar to a normal catheterization, where a catheter wire is guided through the artery to the site of the lesion. Studies were performed on New Zealand White Rabbits, which were anesthetized with AcePromazine and Ketamine. The balloon catheter was introduced along the guide wire into the carotid artery, and positioned in the iliac artery or the distal abdominal aorta. Once the position of the balloon catheter was established (using fluoroscopy and contrast material next to the site of the plaque, for example), the guide wire was removed, and the same lumen was used to insert the coaxial microwave system. The antenna was positioned in the center of the balloon. The balloon was inflated at 2 atmospheres for 15 seconds, and the microwave generator was then turned on. The fluid inside the balloon (deionized water) and the balloon itself are transparent to microwave energy, thus allowing for direct tissue volume heating to occur without loss of energy. Microwave power of between 10-15 Watts was delivered for 30-45 seconds, heating tissues to 70-90 degrees centigrade. Temperature was monitored by a thermocouple on the surface of the balloon adjacent to the gap antenna. At the end of power delivery, the balloon inflation was maintained for an additional 30 seconds, allowing the tissue to cool down. Deflation of the balloon immediately after the delivery of microwave power has resulted in balloon rupture. The animals were sacrificed 3-4 hours after the microwave thermal balloon angioplasty. After fixation in formalin, H & E, trichrome, and VVG stains were performed. These preliminary studies have demonstrated that there is coagulation necrosis of both intima and media, Fig. (4). This effect was variable in circumferential extent, possibly related to changes in the small slot antenna caused by tortuosity of the vessels negotiated.

These studies demonstrate the feasibility of using microwave energy to induce thermal modification of vascular tissue. This modality shows promise as an ancillary means of treating acute dissections, reducing arterial elastic recoil as evident in the in-vitro measurements, Fig. (5a,5b), forming a biological stent, Fig. (6), decreasing plaque resistance to dilatation, and approaching the difficult problem of restenosis.

CONCLUSION

Preliminary studies utilizing microwave balloon angioplasty at 2450 MHz were conducted. Local temperatures were raised to 90 degrees centigrade with a power of 15 Watts input into the 0.032" diameter coaxial cable, producing localized tissue modifications in both dog myocardium _in-vitro_ and rabbit arteries _in-vivo._

ACKNOWLEDGEMENT

Special appreciation is due to Daniella Tamches Rosen for her invaluable contribution.

REFERENCES

1. A. Rosen, P. Walinsky, "Percutaneous transluminal microwave catheter angioplasty," United States Patent Number 4,643,186, February 17, 1987.

2. P. Walinsky, A. Rosen, A.J. Greenspon, "Method and apparatus for high frequency ablation," United States Patent number 4,641,649, February 10, 1987.

3. T.L. Borok, A. Winter, J. Laing, R. Paglione, F. Sterzer, I. Sinclair, J. Plafker, "Microwave hyperthermia radiosensitized iridium-192 for recurrent brain malingnancy," Medical Dosimetry, Vol. 13, pp. 29-36.

4. A. Winter, J. Laing, R. Paglione, F. Sterzer, "Microwave hyperthermia for brain tumors", Neurosurgery, Vol. 17, No. 3, 1985.

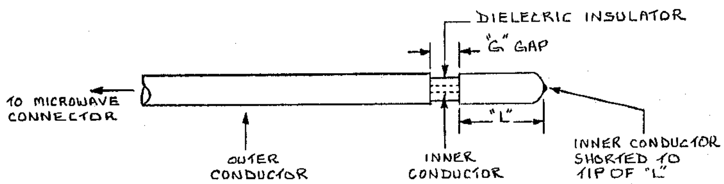

Fig. 1 Semi-rigid coaxial cable/antenna assemblies.

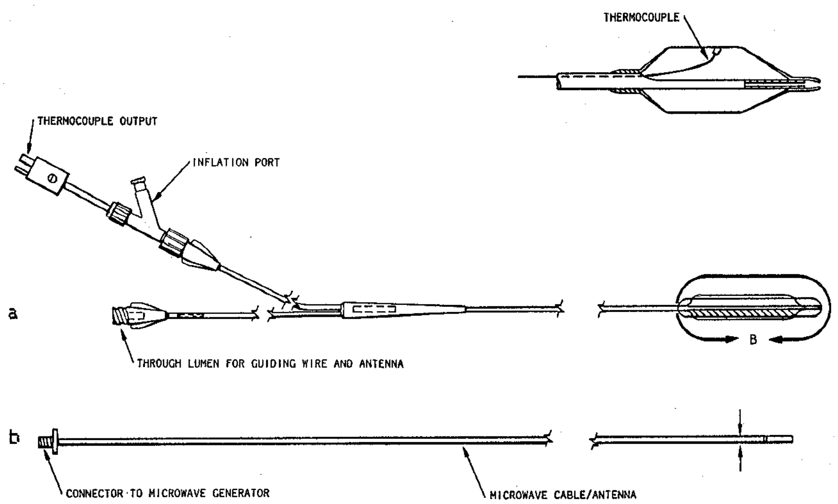

Fig. 2 a. Balloon catheter.

b. Microwave delivery system.

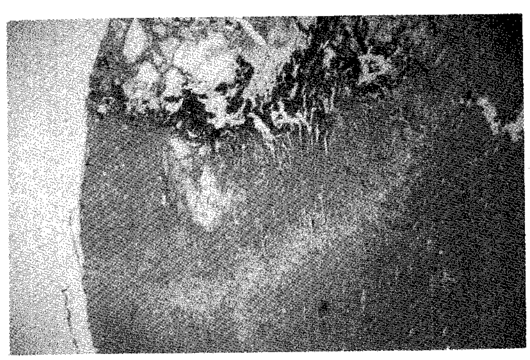

Fig. 3 Histological section of dog myocardium following thermal disruption by microwave energy.

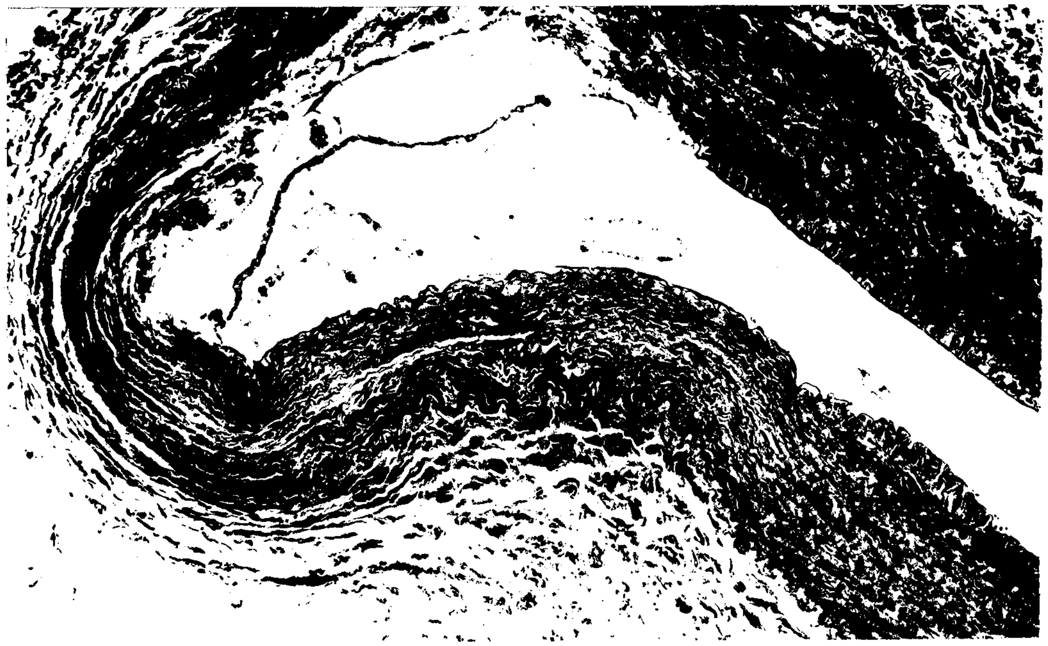

Fig. 4 Histological section of rabbit illiac artery following in-vivo microwave balloon angioplasty.

a

b

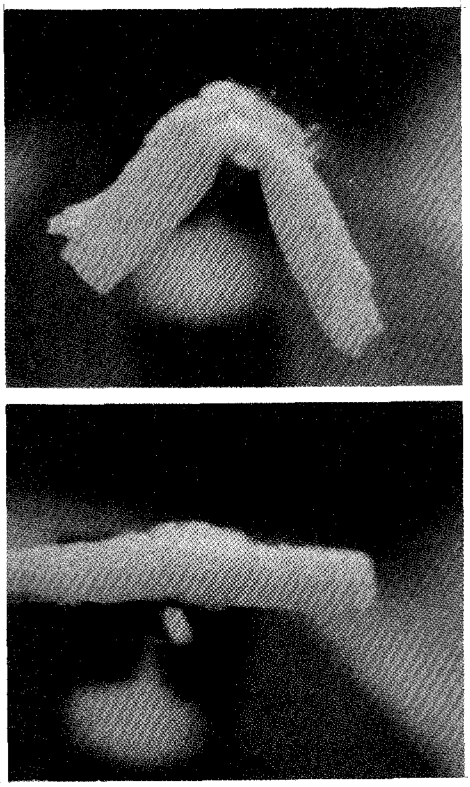

Fig. 5 Lateral view of rabbit artery before (above) and after (below) in-vitro balloon microwave angioplasty.

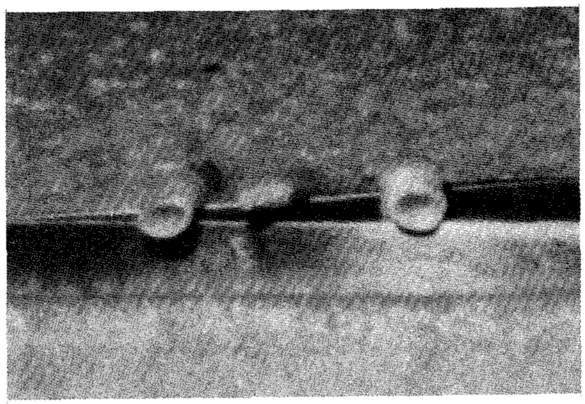

Fig. 6 Luminal view of rabbit artery before (center) and after (sides) in-vitro balloon microwave angioplasty.