RF and Microwave Ablation for the Treatment of Ventricular Tachycardia

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ABSTRACT

Current radiofrequency (RF) ablation technology is limited by small lesion size. In order to enhance the size of RF-induced LV endocardial lesions we evaluated the effects of an enlarged distal electrode tip and increased RF power on lesion volume. Steerable electrode catheters with distal electrode tips of 4-12mm were studied in anesthetized dogs at power settings of 20-100 watts. Temperature (T) was continuously monitored from a thermistor located at the tip of the catheter. RF energy (500kHZ, unmodulated) was applied between the tip of the catheter and a large skin electrode at four separate LV sites in each animal. Microwave ablation catheters with whip and helical antennae configurations were also tested with network analysis, temperature profiling in a phantom model and in vivo.

RF lesion volume increased with increasing delivered power and enlarged tip size. Average tip T correlated with measured lesion volume (r=0.66). Microwave catheters produced volume heating but the magnitude of heating was less than that observed for RF catheters. Catheter ablation of ventricular tachycardia may be enhanced by this technology.

Introduction

Catheter ablation using radiofrequency energy (RF) has become the non-pharmacologic treatment of choice for patients with refractory supraventricular tachycardia. [1] By contrast, catheter ablation in patients with ventricular tachycardia (VT) has a much lower success rate. [2] Extrapolation from data obtained from patients with sustained ventricular tachycardia post myocardial infarction surgically treated with subendocardial resection suggests that effective ablation of ventricular arrhythmias is likely to require significantly larger lesions than those produced by currently employed RF electrodes.

An important disadvantage of current RF ablation is the focal and discrete nature of the endocardial lesion. Studies of RF ablation in vitro have shown that the size of the electrode-tissue interface can influence lesion formation. [3] However a recent study failed to demonstrate any incremental lesion size with electrode catheters greater than 4 mm in length. [4] The aim of the present study was to determine: 1) the feasibility of RF ablation in the canine left ventricle utilizing large tip electrodes (up to 12 mm) and high applied power, 2) the influence of tip size, tip temperature and applied power on lesion volume, and 3) whether microwave energy offers promise as an alternative energy source.

METHODS

RF Catheter Ablation Protocol

Eighteen adult mongrel dogs of either sex, weighing 15-25 kg, were narcotized with 2 mg/kg of subcutaneous morphine sulfate 30 minutes prior to intravenous administration of sodium pentobarbital (30 mg/kg). The animals were endotracheally intubated and sedated with 1-2 cc of pentobarbital as needed. Hemostatic sheaths were introduced into the right common carotid artery and right internal jugular vein using a cut down procedure. Under fluoroscopic guidance a temporary pacing electrode was positioned in the right ventricular apex. Electrode catheters used for cardiac ablation were 7 French with a tip size of either 4 mm, 8 mm, or 12 mm (EP Technologies, Sunnyvale, Cal.). A thermistor for recording of tissue temperature, located at the tip of the electrode, was exposed to the surface but thermally insulated from the surrounding electrode by a polyamide plastic sleeve. A total of four lesions were created in each animal at disparate sites: apical, posterior, lateral, and septal LV. In each animal, a single catheter at one power setting was used to create all four lesions. Adequate contact between probe and endocardium was verified electrically using unfiltered unipolar intracardiac electrograms recorded from the tip of the ablation electrode. Probe contact was also inspected fluoroscopically before and at 15 second intervals during RF ablation.

Radiofrequency energy using continuous, unmodulated current at 500 KHz (EP Technologies, Sunnyvale, Cal) was applied between thetip of the ablation probe and a ground electrode positioned on the animal's posterior chest. The RF generator allowed for continuous digital and graphic monitoring of applied power, electrode tip temperature, and impedance. The generator was adjusted to discontinue RF power delivery with an impedance rise above 300 Ω.

Endocardial lesions were created at power settings of at 20, 40, 60, 80, and 100 watts. Following a rise in impedance the catheter was removed from the animal, inspected, and cleared of any tissue debris prior to further testing. If an impedance rise was consistently noted at a particular power setting, no further testing at higher power was done with that size electrode.

Tissue Preparation and Measurement of Lesion Volume: Following the ablation procedure, the animals were observed carefully for evidence of hemodynamic instability and sedated as

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necessary. Approximately 2 hrs. following the procedure, the animals were sacrificed, and the heart was rapidly explanted and immersed in iced saline. The left ventricle was dissected free of other structures, frozen at -70° C, and then sliced into 2 mm sections along the short axis. Sections were incubated in nitro-blue tetrazolium (0.5 mg/ml in Sorrenson's Buffer [pH=7.4]) at 37° C for 15 minutes and then fixed in 10% formalin solution. The perimeter of each lesion was traced onto plastic transparency sheets and the area planimetered using a digitizing pad. If a lesion was noted on only a singe side of a given 2 mm slice, the thickness of that lesions was assumed to be 1 mm. Lesion volume was then calculated according to the equation:

$V = \Sigma\ [A_n] \times [T_n]$

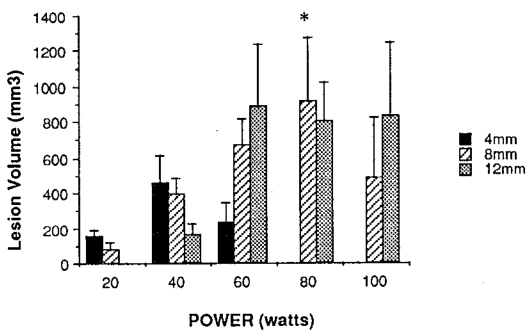
where V= total lesion volume, A_n= the mean planimetered lesion area for each slice, and T_n = the thickness of the given slice.

Statistical analysis

Continuous variables are expressed as mean ± SD. ANOVA was used to define the relationships among power, lesion volume, and tip size. Correlations between continuous variables were tested with use of the Pearson correlation coefficient (r). A p value < 0.05 was considered significant.

RESULTS

Lesion Volume

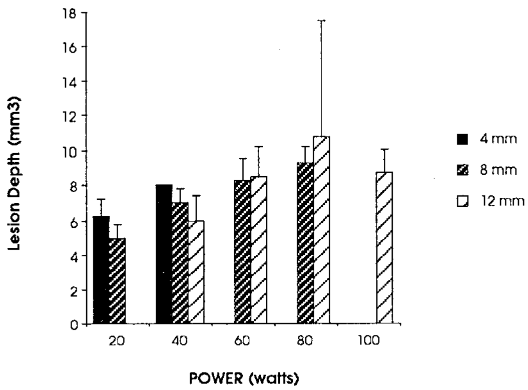


The effects of power and electrode size on lesion volume is illustrated in the following figure:

A direct relationship between applied power and lesion volume was evident for each size electrode tested. Lesion volume increased as power delivery to the endocardium increased. An optimal power setting existed for each catheter, above which, lesion volume either decreased (4 mm, 8 mm catheters) or remained stable (12 mm catheter) due to a rise in impedance. Higher power (60-80 watts) was required to optimize lesion volume with the 8 mm and 12 mm catheters, than with the 4 mm catheter (40 watts). Maximal lesion size with an 8 mm electrode was approximately twice the size of the maximal lesion with a 4 mm electrode (914±362 mm^3 vs 446±150 mm^3, *$p<0.01$). For the 8 mm catheter there was good correlation between applied power and lesion volume at power settings of 20 to 80 watts (r= 0.7). Power above 80 watts was associated with a rise in impedance and a fall in lesion volume.

Lesions created with a 12 mm electrode were no different than those from an 8 mm electrode. Minimal lesions were seen with large tip electrodes at powers less than 40 watts. This was particularly evident with the 12 mm catheter as no lesions were produced using 20 watts of energy.

Lesion depth was measured along the horizontal short axis from endocardial surface to the most distant point of necrosis in the



subepicardium. Average lesion depth measured 9 mm for each of the three catheters tested at their optimal power setting. Therefore the increase in observed lesion volume with large tipped catheters was not due to better tissue penetration of RF energy.

Thermistor tip temperature during ablation

Average and maximal temperatures increased significantly with increasing power delivery, and predictably plateaued when maximal tip temperatures of approximately 100° C were achieved. Thermistor tip temperatures of 100° C were nearly always associated with an abrupt rise in catheter impedance and concomitant discontinuation of power delivery from the RF generator. Conversely, a rise in impedance was never noted when tip temperature was below 100° C. Significantly more power was necessary to achieve a similar tip temperature with the 12 mm electrode as compared with the 4 mm tip. For example, 20 watts of power delivered to the 4 mm tip resulted in a maximal thermistor tip temperatures of 63° C, while a power of 60 watts delivered to the 12 mm tip was required to attain a similar temperature.

The relationship between average tip temperature and lesion size was analyzed. Lesion size correlated well with average tip temperature (r= 0.7) when power applications not associated with a rise in impedance were analyzed. Minimal lesions were seen when tip temperatures of less than 45° C were recorded.

Acute rises in impedance were frequently seen during catheter ablation, and were always associated with thermistor tip temperatures of approximately 100° C. Rarely however, temperatures in excess of 100° C could be maintained without rises in impedance. Acute impedance rise was not seen with 20 watts of power in any of the three catheters tested. The highest delivered power in the 4 mm and 8 mm electrodes (60W and 100W respectively) resulted in impedance rise with each ablation attempt. Gross inspection of the electrode following an impedance rise commonly revealed adherent tissue and/or thrombus formation.

The duration of applied power was commonly less than the anticipated 60 seconds because of impedance rises. Not infrequently, however, large lesion volume was seen following relatively brief power applications (i. e. 10-20 seconds). For instance, impedance rise occurred, on average, 8 seconds following power onset in the 8 mm/100 watt ablations. Lesion volume however, was relatively high (487 mm^3), and suggests that high electrode temperature, even for very brief periods, may produce significant cardiac lesions.

Complications

10 animals experienced 17 episodes of ventricular fibrillation during the ablation protocol. All but one of these animals was successfully resuscitated. A single ablation on the septum of one animal (8 mm/40W) resulted in a very large lesion (1119 mm^3), complete heart block and incessant ventricular fibrillation. A second animal (60W/4 mm) could not be resuscitated following a single septal ablation complicated by asystole. Unlike the previous animal described, lesion volume was small (195 mm^3). In all cases, ventricular fibrillation occurred either during or immediately following power delivery. Ventricular fibrillation was seen in 2/12 (17%) lesions created with a 4 mm electrode, 2/20 (10%) lesions with an 8 mm electrode, and 6/24 (25%) lesions with a 12 mm electrode (p=NS).

RF Ablation: Discussion

Catheter ablation using RF current, creates discrete areas of coagulation necrosis without destruction of surrounding normal tissue. Although several potential mechanisms for cellular injury due to radiofrequency energy exist, the predominant mechanism is most likely thermal injury due to resistive heating of tissue. RF current follows a path of least resistance from electrode tip to a thin rim of tissue which is in immediate contact with the electrode surface. The amount of direct electrical (resistive) heating at any distance from the electrode can be described as 1/R4, where R is the distance from the surface of the electrode. As a result, a relatively small volume of tissue is exposed to direct electrical, or resistive heating, while the majority of thermal damage is created via passive (conductive) heating of contiguous tissue. Heating of tissue (resistive and conductive) causes dessication of intracellular and extracellular water and ultimately, coagulation necrosis. By contrast, microwave radiates energy into tissue producing volume heating rather than conductive heating.

The size of the RF-induced lesion is determined by many factors, including electrode size. Recent in-vitro work demonstrated that the volume of tissue which is directly (resistively) heated by RF current can be increased by increasing the electrode-tissue interface, as well as increasing the electrode radius. Haines et al., using a model of perfused and superfused canine right ventricular free wall, observed a strong correlation between electrode radius and lesion radius in both the transverse and transmural dimensions. [3]

Although there is good in-vitro evidence to suggest that lesion volume is critically dependent on electrode size, an in-vivo study by Langberg and coworkers suggested that maximal lesion size was attained with an electrode tip size of 4 mm. [4] In that study constant power was applied to electrode catheters of 2 to 10 mm in length until a total of 500 joules had been delivered or a rise in impedance occurred. Maximal lesion volume was produced with the 4 mm electrode (mean volume= 326 mm^3), while electrode lengths beyond 4 mm produced progressively smaller lesions. The authors also suggested that lesion volume produced by the larger electrodes may have been significantly limited by inadequate power delivery. Since resistive heating is a function of power density (power per unit of electrode surface area), power density will decrease with a constant power input as electrode surface area increases. To determine the effects of electrode size on lesion volume, it is necessary to vary power output so that power density at each electrode length is similar.

The present study, demonstrates that increased electrode size enhances lesion volume during RF catheter ablation provided sufficient power is applied. Data from the tip thermistor shows that small lesions are seen with large tip electrodes at relatively low power due to an inability to achieve adequate tissue heating. As predicted, relatively high power was required to maintain high electrode power density and thus tip temperature in the larger electrodes.

For each catheter tested, increasing power output was associated with an increase in lesion volume. For the 8 mm catheter this appeared to be a linear relationship for power outputs of 20-80 watts. However that standard deviation of the lesion volume increased substantially as power increased from 20 to 80 watts (45.3 to 362) Therefore, a high variability in lesion formation is expected at higher power. A stable electrode/tissue interface may be more difficult to achieve at high power with larger tip electrodes. For each electrode tested power application was limited due to a rise in impedance occurring within 10 seconds of power initiation. An impedance rise was associated with tip temperatures in excess of 100° C. and coagulum formation at the electrode surface. Impedance rise, in itself, did not preclude large lesion creation. Further studies will be required to determine the time course of lesion development and the effect, if any, of impedance rise occurring 10-20 seconds after power initiation.

The utility of tip temperature monitoring as a predictor of lesion size is well established. [5] In the present study, a strong correlation existed between average tip temperature and lesion volume. Radiofrequency ablation guided by tip temperature rather than applied power may be associated with the delivery of more current and, therefore, larger lesion formation without the risk of an impedance rise.

Complications

A relatively high percentage of ablation attempts were associated with significant arrhythmias. Over 50% of animals experienced at least one episode of ventricular fibrillation. Although VF was commonly seen during or immediately following RF delivery, all but one animal was successfully defibrillated. No significant arrhythmias were seen during the two hour observation period. Although electrode size appeared not to be associated with the risk of VF, larger lesion volume was strongly correlated with this complication.

Clinical Implications

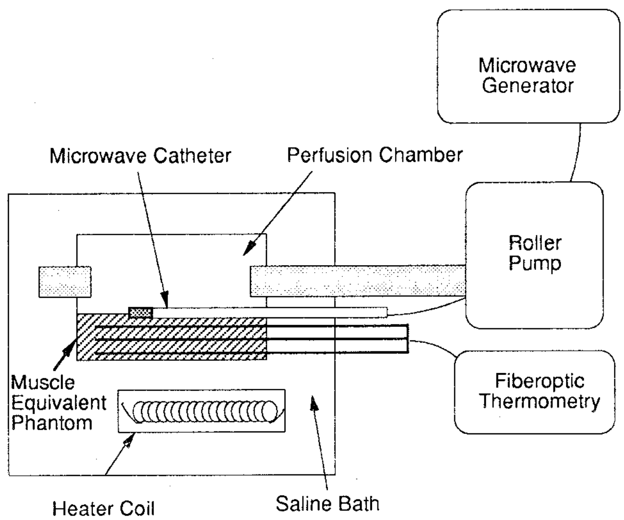
Cardiac ablation using RF energy has been shown to be safe and effective nonpharmacologic therapy for supraventricular tachycardia. Equal success has not been achieved in patients with ventricular tachycardias on the basis of coronary artery disease. One of the reasons for this may be the small size and depth of conventional RF lesions. Further refinements in RF electrode design, such as as enlarged electrode tip which increase lesion volume at higher applied power, may help facilitate transcatheter ablation of these tachyarrhythmias.

Microwave Catheter for Cardiac Ablation

A steerable cardiac ablation catheter (EP Technologies, Inc) utilizing a coaxial cable (0.06 in. OD) with helical and whip antennae designs were analyzed at frequencies of 915 MHz and 2450 MHz. Antenna length varied between 4 and 19 mm. Catheter designs for microwave ablation catheters were evaluated using three techniques: network analysis, phantom model, and LV ablation to measure lesion size. The optimal frequency and antenna design for cardiac ablation is the major objective of the present investigation.

1. Network analysis- Network analysis of each catheter design manufactured was performed. Such analysis demonstrated the great variability in tuning of these microwave catheters. Microwave ablation catheters have suffered from imperfect tuning leading to inefficient radiation of energy. Consequently, there is generation of heat along the length of the catheter rather than radiation of energy into tissue. Such network analysis underscores the critical importance of proper tuning of microwave catheters prior to any further studies in vitro or in vivo.

2. Phantom model- A flow model using a muscle equivalent phantom was created.



Flow-Phantom Model for Cardiac Ablation Catheters

A perfusion chamber containing a muscle equivalent phantom was constructed and placed in a saline bath held at 37° C. The muscle equivalent phantom consisted of TX150, polyethylene powder, NaCl, and water. The ablation catheter was placed on the surface of the phantom material. Temperature measurements were performed using a 12 channel Luxtron fiberoptic thermometry system. Probes were placed beneath the surface of the phantom. Saline at a constant temperature of 37° C was infused at a flow rate of 4 L/min across the surface of the phantom. This model simulates the heart where the phantom material has the dielectric properties of cardiac muscle and the saline the properties of blood.

Temperature curves were plotted from probes placed 1mm, 2.5 mm, 5 mm, and 7.5 mm from the point of maximal heating on the microwave catheter. Thermal profiling of these catheters demonstrated volume heating. Heating following 20 watts of delivered power occurred simultaneously at 1 mm and 2.5 mm suggesting a volume heating effect. Conductive heating was also present due to the increased temperature at the cathter phantom-interface. The magnitude of heating with the microwave catheters was smaller when compared to the RF ablation catheters.

3. In-vivo LV ablation- In-vivo LV ablation using microwave catheters was performed using a protocol similar to that described with radiofrequency. Eighty watts of power was delivered for a total of 5 minutes. Mean lesion size measured 435±236 mm^3 which was similar in size to lesions created with small tipped RF catheters.The microwave ablation catheters, as presently designed, are not capable of producing lesions larger than RF catheters.

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