

Features:

Cooled Tip Catheter Ablation

- Linda Moulton

Just over a decade ago, the advent of tip temperature monitoring during radiofrequency (RF) energy delivery marked the beginning of a second generation of ablation catheter technology and furthered the success of catheter ablation as a therapeutic tool. RF generators were designed with a closed-loop feedback system to automatically adjust power output to avoid temperatures that would cause coagulation formation on the ablation catheter tip.

Initially, it was recognized that as long as the tip was located at sites of good blood flow, the tip temperature rarely reached a level resulting in coagulum formation. On the other hand, if the tip was wedged in an area of inadequate blood flow, the system's "impedance" rapidly rose and power output would abruptly fall to the extent that the lesion was inadequate. This problem prompted interest in whether constant cooling of the ablation catheter tip might result in more effective lesion production and led to the development of the next generation of ablation catheter technology. This article will review the physiology of RF ablation, the use of cooled radiofrequency ablation, clinical trials, and current available systems.

Radiofrequency Ablation: What Happens?

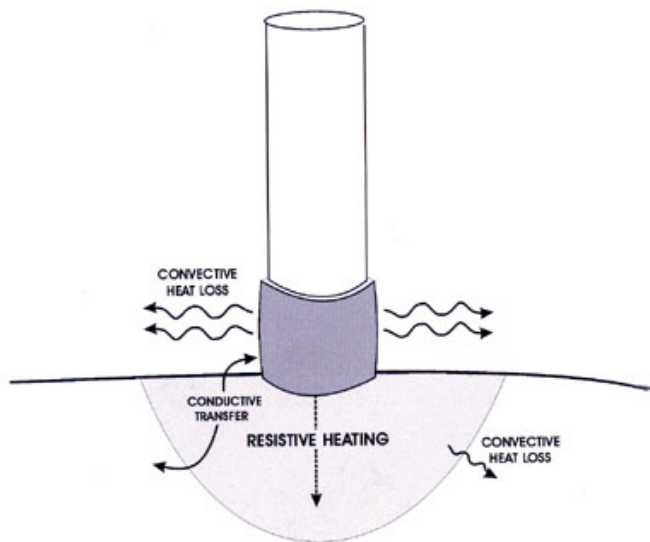


Figure 1. Tissue heating with radiofrequency current. An ablation catheter tip is shown delivering current to tissue. Resistive heating is occurring within the millimeter beyond the catheter tip. The radiant heat which takes place during this process helps to give rise to the conductive heating that occurs beyond, and contributes most to lesion size. The conductive heat transfer back to the catheter tip results in a detectable rise in electrode surface temperature. Convective heat loss occurs by the presence of tissue blood flow acting as a heat sink, thereby detracting from lesion production.

Radiofrequency current is alternating electrical current at a range between 350–750 kHz between an electrode catheter tip resting on the endocardium and a grounding patch placed on the body surface. The grounding patch or plate, also known as a dispersive electrode, has a much greater surface area than the catheter tip. This "dispersive" effect minimizes any heat delivered to the skin as current flows through the patch. In contrast, the small surface area of the catheter tip is associated with very high "current density" which produces the desired effect of intensifying heat production in the area around the electrode.

Heating of the tissue around the catheter tip occurs in two phases (Figure 1). First, there is resistive heating, in which a mere millimeter of tissue beyond the catheter tip is heated. With resistive heating, an impedance change occurs between the metallic electrode (low impedance) and the tissue (high impedance). The region of tissue undergoing resistive heating becomes the source of radiant heat which results in tissue damage. It also gives rise to the second phase of heating, known as conductive heating, in which heat transfer to adjacent areas promotes tissue destruction. This conductive heat transfer is also sensed by a thermistor probe located inside the catheter tip and provides the basis for tip temperature monitoring. The resulting lesion size is determined by the balance of tissue conductive heat generation and convective heat loss carried away by tissue blood flow. Thus, lesion volume can be influenced by tissue blood flow within an area deep to the catheter tip.

Radiofrequency current is delivered at power outputs in the range of 25–50 watts. There is a direct relationship between tissue temperature achieved and the size of the resultant lesion. An increase in RF current causes an increase in resistive heating and therefore an increase in tissue temperature. Maximum tissue temperature occurs close to the tip of the ablation electrode and rapidly falls off within a very short distance from the tip. Tissue destruction occurs when temperature exceeds 50 °C, with an ideal range between 60 °C and 70 °C. The increase of radiofrequency current will increase lesion size up to a point. When temperature exceeds 100 °C, tissue dessication, steam and coagulum formation around the electrode tip will occur. Prior to the introduction of tip temperature monitoring, the RF generator would abruptly shut off when resistance to current reached such a high level due to coagulum formation — much like a fuse will blow when a certain level of “safe” current is exceeded. To prevent this, most RF generators have been designed to include a feedback mechanism preventing tip temperature from exceeding 100 °C, thus decreasing the chance of such impedance rises. However, the consequence of such feedback is the risk that power output may fall to levels incapable of producing an effective lesion. An increase in delivery time becomes possible; however current often is limited, and desirable temperature may not be achieved.

Another approach has been the development of larger tip ablation catheters, which require higher outputs, and are capable of forming larger lesions than the standard 4 mm tip catheters. Disadvantages of the 8 mm tip have included a decreased resolution of electrograms, greater catheter stiffness, and therefore decreased compliance and maneuverability.

Cooled Ablation

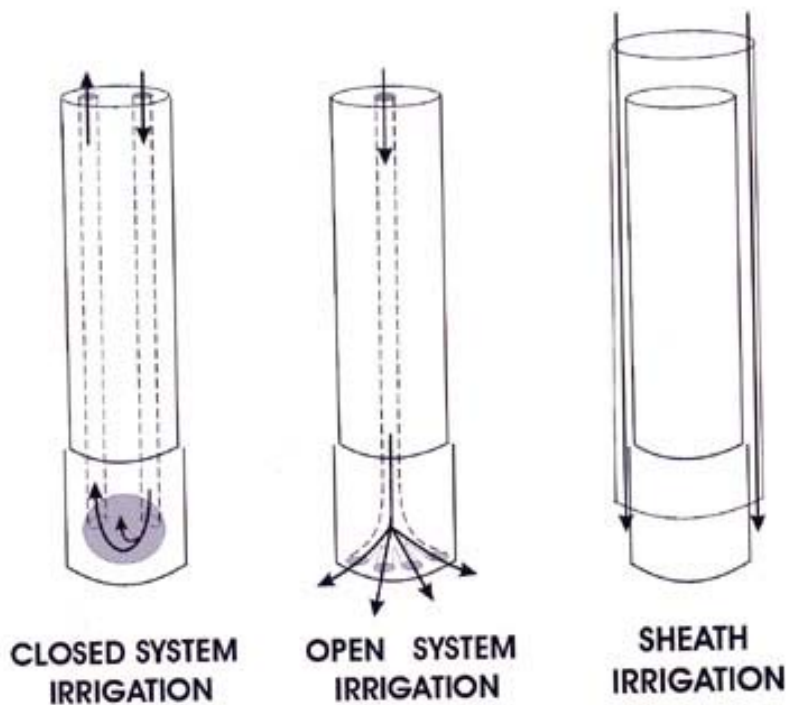


Figure 2. Three models for cooled ablation. The three major approaches to cooled ablation are illustrated. (A) the closed system in which internally irrigated saline remains confined to a catheter-pump apparatus; (B) the open irrigation model illustrating the internal flow of saline through the catheter tip into the blood pool; (C) the open-system sheath model showing saline flowing externally between the sheath and catheter.

Use of saline perfusion or irrigation of the ablation tip in order to cool the tip during radiofrequency delivery was first reported in 1988.¹ This technique was found to result in fewer impedance rises, a decrease in coagulum risk, the ability to lengthen RF application times, and achievement of larger lesion size.

Three catheter designs for tip cooling have been investigated at length. The first type, perhaps the low tech version, uses a long sheath of slightly larger diameter than the ablation catheter. The ablation catheter is advanced through the sheath and saline flows externally around the ablation catheter and bathes the tip-tissue interface and surrounding tissue. This is an "open system" in which saline is continuously infused and empties into the blood pool. A disadvantage of this system is the sheath itself, the presence of which limits potential sites on which it may be used. The second type of system is a method of internal irrigation through the catheter tip, also an open system. Saline is conducted down the body of the catheter and is forced out of holes in the porous catheter tip. This has been described as a showerhead or sprinkler design (Cordis Webster/Medtronic). The third also involves internal perfusion of the catheter tip. Saline is perfused via a pump mechanism through the catheter tip, turns around within the catheter tip, and returns back to the pump. This represents a closed system because no saline is infused into the blood pool (Chilli®, EPT/Boston Scientific). An illustration of all three systems is seen in Figure 2.



Figure 3. The Chilli® Catheter (EP Technologies/Boston Scientific).

The benefit of cooled ablation systems lies in the potential for greater current delivery for greater periods of time, while decreasing the potential for coagulum formation on the electrode surface and the unwanted impedance rise. Studies comparing standard radiofrequency ablation to cooled tip

ablation in animal models have found that powers of < 50 watts for a closed system and < 20 watts for an open one produce lesions with greater depth, width and volume than standard systems.^{2–5}

Researchers have sought to compare the three types of systems to look at both safety and efficacy. A study by Demazumder et al.⁶ utilized an in vitro model. They found that larger lesion sizes could be achieved with showerhead or sheath models; however the risk of crater and complex lesion formations was increased, suggesting that further studies were needed.



Fig 4. CircuCool™ Pump And Model 1000TC Generator (EP Technologies/Boston Scientific).

The open systems allow regulation of flow rate, potentially impacting on lesion size. The greater flow rates allow greater tissue cooling to take place and therefore greater lesion size.⁷ Demazumder et al.⁸ examined the effect of the fluid type used in direct irrigation on the size of lesion produced during ablation, in an in vitro model. Iced saline was found to have no advantage. The effect of room temperature saline and blood were about equally effective. Dextrose was found to impede power delivery, resulting in smaller lesions. The use of saline did not prevent tissue boiling. Boiling, however, did not prevent lesion growth.

Hypertonic saline was used in canine prostate tissue in another study, and was shown to increase lesion size. This was thought to be due to its greater conductivity than blood, thus resulting in lowering of impedance at the catheter tip.⁹ Applicability with the human population in an EP lab setting is probably limited however, due to potential for hypertonic saline causing volume overload in heart failure and other compromised patients.

Clinical Trials

Trials using cooled tip ablation have been conducted with a variety of arrhythmia populations. The following represents just a few. Nabar et al.¹⁰ studied 8 patients who had undergone unsuccessful prior ablations for ventricular tachycardia (VT). An open-system, saline-irrigated tip catheter (Thermo-Cool, Cordis Webster) was used. Five of the 8 patients were free of arrhythmias post ablation with the use of antiarrhythmic drugs, through 6.5 ± 4 -month follow-up. In another study of 146 patients with VT, a closed system (Chilli®, Cardiac Pathways) was capable of eliminating the clinical VT among 106 patients and was associated with 75% long term survival. Ablation with this device was found to be more cost-effective than the use of amiodarone.¹¹

Jais et al.¹² studied 13 patients in whom isthmus ablation for atrial flutter had been unsuccessful with conventional radiofrequency application. An open-system irrigated tip catheter was used and cured twelve patients. Flow rate used during actual energy delivery was 17 ml/minute and between ablations the rate was 3 ml/minute. Target temperature was 50 °C and power limits used were 50 watts for 60 seconds. In another study with the atrial flutter population, 8 mm tip conventional ablation catheters were compared to a closed-system cool tip catheter and the results were found to be comparable.¹³

A group of four patients with right posteroseptal accessory pathways and no structural heart disease who had failed at least two prior ablation attempts were ablated with the closed system (Chilli®, Cardiac Pathways). Ablation was successful in all four, with no recurrence after several months.¹⁴

Potential Disadvantages of Cooled Tip Ablation

Some disadvantages of cooled tip ablation have been suggested. One of these involves the fact that maximum temperature in the deeper tissues during ablation cannot be monitored.¹⁵ Also, there is a risk of steam pops from a boiling process with gas expansion as lesions deepen. This could lead to a risk of perforation. Steam pops usually vent through the endocardium, and use with thicker tissues are less likely to cause problems. However, use of the cooled tip catheters on thinner tissue sites pose greater risks of perforation. Of further consideration is the potential damage that could occur to coronary arteries when deeper lesions are formed.

What's Available?

The only cool tipped system currently on the market is the Chilli®, a 4-mm tip ablation catheter and its CircuCool™ pump system (EP Technologies/Boston Scientific) (Figures 3 and 4). The Chilli® is a closed system utilizing an injection pump mechanism which interfaces only with an EPT Model 1000TC Generator. Temperature sensing occurs through the use of a thermocouple. The temperature displayed by the device is the temperature of the cooled electrode. A study by Wharton, Wilber, Calkins et al.¹⁶ suggests that impedance rises can be predicted with temperatures of 45–65 °C in this system, thus providing some helpful monitoring guidelines. Safety recommendations include limiting impedance setting not to exceed 200 ohms and temperature cut-off not greater than 100 °C.

The pump mechanism is small and can be attached to an IV pole. The system is approved for use with D5W. The flow rate achievable is 0.6ml/second or 36 ml/minute. The FDA has approved the system for ventricular tachycardia ablations only.

Cooled tip ablation brings yet another tool to the arrhythmia war. Though the currently approved system is approved for use only in ventricular tachycardias, there may be great promise for use in refractory atrial flutters, atrial tachycardias which originate in areas of thickened muscle or in which the arrhythmogenic focus is broad, and epicardial or deep posteroseptal accessory pathways.

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