

## Considerations In Selecting a Cooled Ablation Technology: Impact of Fluid Infusion into the Patient

### INTRODUCTION

Catheter-based radiofrequency (RF) ablation has become the standard of care for patients with certain types of cardiac arrhythmias. Cooled-catheter cardiac ablation systems are a fairly recent development of this technology.

Cooled-catheter ablation involves active cooling of the catheter tip at the electrode tip/tissue interface. Active cooling is intended to impede coagulum formation at the tip electrode, allowing (if desired) the delivery of higher energy and the creation of larger, deeper lesions.

Catheter manufacturers have developed various means of actively cooling the ablation electrode during cardiac RF ablation procedures. In an **internally-cooled** version, the cooling fluid is pumped to the tip electrode



Figure 1  
Internal Cooling

via one lumen in the catheter and is then returned to the pump via a second lumen (Figure 1). In this case, the fluid recirculates and does not enter the bloodstream of the patient. This cooled ablation technology, embodied in the Chilli® Catheter (1999) and recently the Chilli II™ Catheter (2004) has been used in thousands of clinical procedures since its introduction.

In an **open-irrigated** approach, cooling fluid (typically saline) is pumped from a source through a lumen in the catheter and is infused directly into the patient's bloodstream through a set of small holes in the distal end of the tip electrode



Figure 2  
Open Irrigation

(Figure 2). The potential impact of fluid infusion should be a factor when choosing a cooled-catheter ablation technology.

### POTENTIAL RISK OF FLUID INFUSION

In normal patients, homeostatic mechanisms regulate the balance of fluids between the intravascular (plasma and red blood cells within the blood vessels) and extravascular (outside the blood vessels) compartments.<sup>1</sup> The total blood volume in the intravascular compartment is approximately 5 liters. Infusing a typical volume of 500ml saline or albumin (equivalent to approximately 10% of total blood volume) into the circulation may affect the fluid balance between all fluid compartments.<sup>2</sup>

Administration of a volume load over a relatively short period of time, such as saline irrigation, produces an elevation in venous and capillary pressures, which requires the lymphatic and renal systems to keep pace with the additional fluid load.<sup>1,3</sup>

However, if the capacity of these systems is exceeded, the excess fluid will begin to accumulate in the extravascular spaces, causing edema.<sup>3</sup> Other potential consequences of fluid delivery resulting from volume overload and/or electrolyte imbalance may range from patient discomfort to acute neurological effects to acute heart failure.<sup>3,5</sup>

**Potential Consequences of Excessive Volume Load due to Saline Irrigation<sup>3</sup>**

- increased respiratory rate, dyspnea, agitation
- increased venous/capillary pressure
- breathing difficulties
- edema (especially pulmonary edema)
- tachycardia
- heart failure

**Fluid Infusion in Open-Irrigated Ablation**

The clinical significance of fluid infusion from an open-irrigated ablation system is dependent upon several factors, including the volume of fluid and the time over which it is infused, the type of fluid used for the infusion, the manner in which patient fluid levels are managed, and the characteristics of the individual patient.

In the clinical trials supporting the FDA approval of one open-irrigated ablation catheter, the following data was collected:<sup>5</sup>

**Procedural Data for an Open-Irrigated ablation Catheter**

**# RF Applications/ Procedure**

Mean 19 ± 16  
Range 1 - 86

**Total Saline Infused by Catheter**

Mean 1.0 ± 0.6 liters  
Range 0.06 - 3.8 liters

It should be noted that this clinical study involved the treatment of patients with *Type 1 atrial flutter*. For more complicated ablation procedures that are typically associated with more RF deliveries and longer procedure times, the volume of fluid infused into the bloodstream could be expected to increase significantly.

Estimates of the volume of fluid infused can be made by applying the manufacturer’s recommended infusion rates<sup>5</sup> to a range of procedure times and number of RF deliveries.

**Projected Volume of Saline Infused During Open Irrigated Procedure<sup>5</sup>**

Scenario	“Catheter-In” Time*	# of 60-sec RF Lesions	Total Volume Saline (liters)
FDA Clinical Trial for Flutter <sup>5</sup>	n/a	n/a	1.0 + 0.6
FDA Clinical Trial for VT <sup>6</sup>	n/a	n/a	1.5 + 0.8
<b>Projected Volumes</b> -----			
2-hour Procedure	120 mins	25	0.62 – 0.94**
		50	1.04 – 1.64**
3-hour Procedure	180 mins	50	1.11 – 1.76**
		75	1.49 – 2.46**
4-hour Procedure	240 mins	75	1.61 – 2.58**
		100	1.98 – 3.28**
Irrigant: 0.9% Saline, Heparinized (1 u/ml)		Irrigation Rates: <sup>6</sup>	
		Standby / Mapping	2 ml/min
		0-30 Watts (RF)	17 ml/min
		31-50 Watts (RF)	30 ml/min

\* Time that the ablation catheter is in the patient’s body.

\*\*Smaller number is based on 17 ml/min irrigation rate during RF, larger number is based on 30 ml/min irrigation rate during RF. 2ml/min assumed during standby.

### Potential Electrolyte Imbalance

In addition to the added fluid volume from the saline infusion, risk of electrolyte imbalance should be considered and levels should be monitored pre-, during and post-procedure. Each liter of normal saline solution contains 9 grams of sodium chloride, which includes 3.6 grams of sodium. This can be problematic for patients with hypertension or heart failure, who are often advised to restrict their total daily sodium intake to 2.4 grams. Another consideration is that each liter of saline solution contains 1,000 units of heparin. Though this ratio is generally considered safe for most patients, it is advisable to monitor activated coagulation times during lengthy procedures with open-irrigated catheters.<sup>3</sup>

### Patient Risk Factors and Management

Most patients will respond to the fluid volume infused from the open irrigated-catheter by excreting it through the kidneys (and thus increasing urine output), which may not pose a major management challenge during the procedure. *However, many patients who undergo ablation procedures have underlying risk factors or comorbid conditions that reduce their ability to handle this additional fluid volume load, making them susceptible to developing pulmonary edema, acute heart failure, or other complications.*<sup>3</sup> Therefore,

fluid intake and output should be continuously monitored during a procedure.

Depending upon the patient, and procedural details, fluid management may include the use of urinary catheters, diuretic agents, close management of electrolyte levels, or more involved measures as needed. In patients with conditions such as renal disease, congestive heart failure (CHF), or pre-existing neurological impairment, patient management may be additionally complicated.

Awareness and management of the fluid volume load is important in *all* patients prior to, during and after open-irrigated RF ablation procedures.<sup>3</sup>

#### **Risk Factors that may Predispose Patients to Complications from Use of an Open-Irrigated Catheter<sup>3</sup>**

- history of CHF
- aortic and mitral valve disease
- renal insufficiency
- diabetes mellitus
- multi-systemic condition (autoimmune disease)
- advanced age

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