Reduced Post-Ablation Chest Pain with Active Esophageal Cooling

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November 10, 2023

Abstract

Introduction: Post-ablation chest pain is a common occurrence in patients after radiofrequency (RF) pulmonary vein isolation (PVI) ablation for the treatment of atrial fibrillation (AF), with a reported incidence of up to 50%. Pain can be caused by pericarditis, vagal plexus thermal injury, gastroparesis, or local inflammation. Active esophageal cooling is FDA cleared for reducing the likelihood of ablation-related esophageal injury resulting from RF cardiac ablation procedures, but cooling has also been reported to have pleiotropic effects which may mitigate inflammation and reduce the likelihood of post-ablation chest pain. The aim of this study is to quantify the change in incidence of post-ablation chest pain after the adoption of active esophageal cooling during RF ablations. **Methods**: Data from a community hospital registry were obtained for the 12 months prior to (pre-adoption), and the 12 months after adoption (post-adoption) of active esophageal cooling in December 2021 during RF ablations. Type of ablation was recorded, along with patient's age, post-ablation symptoms, and type of prophylactic treatment utilized. Incidence rates of chest pain before and after adoption of esophageal cooling were then compared. **Results**: Data were reviewed from 183 patients. In the pre-adoption cohort, patients were given 2 weeks of daily sucralfate and pantoprazole, with an additional 4 weeks in cases with persisting symptoms. In this group, 90 patients (66.7% persistent AF) with a mean age of 69.6 years (SD $\pm$ 10.34) received PVI, with 62 (68.9%) receiving roof lines, 60 (66.7%) receiving floor lines, and 41 (45.6%) reporting post-ablation chest pain requiring extension of treatment to 6 weeks. In the post-adoption cohort, 2 days of sucralfate and pantoprazole was given, and a total of 93 patients (75.2% persistent AF) with a mean age of 68.3 years (SD $\pm$ 10.28) received PVI, with 79 (84.5%) receiving roof lines, 75 (80.6%) receiving floor lines, and none reporting post-ablation chest pain ($p<0.0001$). **Conclusion**: Adoption of active esophageal cooling was associated with a significant reduction in post-ablation chest pain despite increased use of posterior wall isolation and decreased use of prophylactic treatment.

1 Introduction

Atrial fibrillation (AF) is the most commonly diagnosed form of cardiac arrhythmia today [1] and its prevalence is expected to increase to 12.1 million cases by the year 2030.[2]While radiofrequency (RF) ablation is an effective treatment for AF, it can cause unintentional injury to surrounding tissue as a result of undesired conductive heating.[3] One symptom of injury is chest pain resulting from acute pericarditis, vagal plexus thermal injury, gastroparesis, or local inflammation.[4,5]Post-ablation chest pain often results in the need for further treatment, and on average, incurs longer hospital stays and higher hospital charges for patients.[6]

A number of studies have investigated methods to reduce this complication. For example, colchicine has been evaluated for its potential role as a prophylactic medication.[75] While a non-randomized study found colchicine to be effective, [8] a randomized study found it ineffective and reported significant gastrointestinal

side effects.[9] As such, effective prophylactic treatment regimens remain unclear, while instances of post-ablation chest pain remain high, with reports ranging from 10% to more than 50% of patients experiencing post-ablative chest pain.[5,7,10,11]

The use of active esophageal cooling has been cleared by the Food and Drug Administration (FDA) to reduce the likelihood of ablation-related esophageal injury resulting from RF cardiac ablation procedures.[12-16] In general, cooling is known to have pleiotropic effects, primarily through mitigation of the activity of inflammatory mediators.[17,18] These decreased local inflammatory effects may decrease chest pain from multiple etiologies. To examine this hypothesis further, we aimed to quantify the effect of active esophageal cooling on the rate of post-ablation chest pain by examining the incidence of patient-reported symptoms before and after adoption of active esophageal cooling.

2 Methods

2.1 Data Collection

After IRB review (Advarra #Pro00067967), patient data from a community hospital registry containing all patients treated by a single provider were obtained for the 12 months before (pre-adoption) and 12 months after the adoption of active esophageal cooling (post-adoption) during RF ablation. The data collected included the extent of ablation, whether it involved only pulmonary vein isolation (PVI) or if additional posterior wall isolation (PWI) was performed, patients' post-ablation symptoms, and the type of prophylactic treatment utilized. Post-ablation chest pain was broadly considered to include thoracic discomfort, whether or not a formal diagnosis of pericarditis was made.

2.2 Luminal Esophageal Temperature Monitoring

Prior to the adoption of esophageal cooling in December 2021, multi-sensor luminal esophageal temperature (LET) monitoring (CIRCA Scientific, S-cath, Englewood, CO) was utilized. Settings for the multi-sensor LET monitoring system were such that alarms were triggered for any increase of 1°C over baseline temperature.

2.3 Active Esophageal Cooling

In the post-adoption cohort, active esophageal cooling was performed using a dedicated cooling device (ensoETM, Attune Medical, Chicago, IL) which is FDA cleared to reduce the likelihood of ablation-related esophageal injury resulting from RF cardiac ablation procedures. The device is a closed-loop multi-lumen silicone tube placed in the esophagus similar to a standard orogastric tube, and connected to a standard water blanket heat exchanger commonly available in the hospital**(Figure 1).** Distilled water circulates through the device at 2.4 L/minute and at a temperature of 4°C. Due to the nature of the device, there is no temperature sensor to monitor the temperature of the esophagus. As such, there are no temperature alarms and therefore no need to interrupt RF delivery.

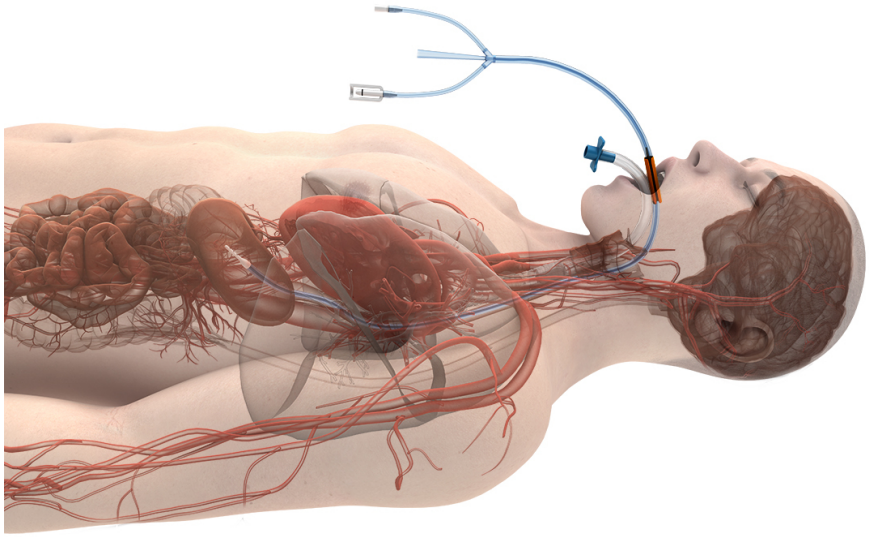

Figure 1: Schematic of active esophageal cooling device (ensoETM, Attune Medical, Chicago, IL), with permission.

2.4 Statistical Analysis

Rates of post-ablation chest pain among patients were compared before and after the implementation of active esophageal cooling. Fisher's exact test was used with a two-sided level of 0.05 to compare groups by chest pain and the use of roof and floor lines. For all analyses, R statistical computing software was utilized.

3 Results

3.1 Patient Characteristics

Data from 183 patients undergoing RF PVI ablation were reviewed. No patients in the 24 month timeframe reviewed were excluded and patient ages in the two groups were similar. In the pre-adoption cohort, the average age was 69.6 years (SD $\pm$ 10.34), and in the post-adoption cohort, the average age was 68.3 years (SD $\pm$ 10.28)(p = 0.420).

3.2 Ablation Protocol

Patients were treated under general anesthesia. Wide area circumferential PVI with additional PWI was performed as determined necessary by the operator. Anticoagulation was administered with a heparinized target activated clotting time of >300 seconds. The CARTO® mapping system (Biosense Webster, Inc., Diamond Bar, CA) was used to obtain electroanatomical maps and create a three-dimensional geometry. Intracardiac echocardiography was used, as was an irrigated ablation catheter with contact force sensing (ThermoCool® SmartTouch® Surround Flow (STSF) catheter, Biosense Webster, Inc., Diamond Bar, CA). Power settings were 50 W, with a Visitag Surpoint® ablation index (Biosense Webster, Inc.) of 350 to 400 units on the posterior wall, and 450 to 550 units on the anterior wall, lateral wall, and septum targeted.

3.3 Procedure Characteristics

In the pre-adoption cohort, all patients were treated with 2 weeks of daily sucralfate and pantoprazole after ablation, with an additional 4 weeks added in case of persisting symptoms. In the post-adoption group, prophylactic treatment was changed to 2 days of sucralfate and pantoprazole after ablation. In the post-adoption cohort, 79 (84.5%) patients received roof lines, while only 62 patients (68.9%) received roof lines in the pre-adoption cohort **(Table 1 and Figure 2).**Similarly, in the post-adoption cohort, 75 (80.6%)

patients received floor lines, while only 60 (66.7%) patients received floor lines in the pre-adoption cohort **(Table 1 and Figure 2).**

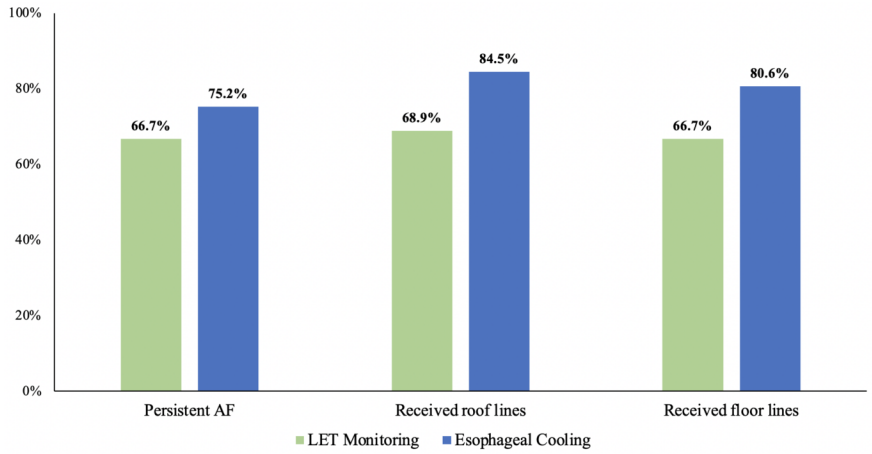

Figure 2. Procedural characteristic of each procedural cohort.

	LET Monitoring	**Esophageal Cooling**	**p-value**
Number of Patients	90	93	ns
Patient Age (years)	69.6 (SD ± 10.34)	68.3 (SD ± 10.28)	p=0.420
Reported Chest Pain	45.6%	0%	p<0.0001
Persistent AF	66.7%	75.2%	p=0.250
Received roof lines	68.9%	84.5%	p=0.013
Received floor lines	66.7%	80.6%	p=0.043

Table 1: Summary of findings. Of 183 patients, 90 received RF ablation with LET monitoring and 93 received RF ablation with esophageal cooling. In the pre-adoption cohort the average age was 69.6 years (SD ± 10.34), 45.6% (41 patients) reported chest pain, 66.7% (60 patients) had persistent AF, 68.9% (62 patients) received roof lines, and 66.7% (60 patients) received floor lines. In the post-adoption cohort the average age was 68.3 years (SD ± 10.28), 0% (0 patients) reported chest pain (p<0.0001), 75.2% (70 patients) had persistent AF (p=0.250), 84.5% (79 patients) received roof lines (p=0.013), and 80.6% (75 patients) received floor lines (p=0.043).

3.4 Outcomes

In the pre-adoption cohort, 41 of the 90 patients (45.6%) reported post-ablation chest pain requiring extension of treatment to 6 weeks**(Figure 3)** and in the post-adoption cohort, none of the 93 patients reported post-ablation chest pain (p<0.0001).

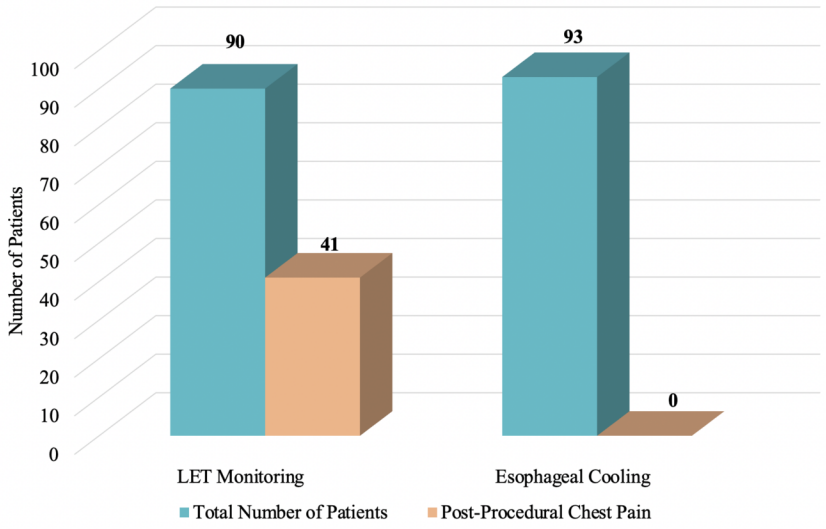

Figure 3. Out of 90 patients, 41 (45.6%) reported chest pain in the LET monitored group. Out of the 93 patients that underwent ablations with active esophageal cooling, none reported post-procedural chest pain ($p<0.0001$).

4 Discussion

This is the first analysis of the role active esophageal cooling may play in reducing the incidence of post-ablative chest pain following RF ablation. After adoption, a significant reduction in post-ablation chest pain was found, despite an increased use of posterior wall ablation beyond standard PVI. These findings are in agreement with an operator survey presented recently, in which electrophysiologists reported a 58% reduction in patient complaints of post-ablative chest pain after adopting active esophageal cooling.[19] Another recent analysis of 175 patients found that chest pain was reported by 18% of patients treated with LET monitoring, but only 6% of patients treated with active esophageal cooling (P=<0.001).[20]

Limited data exist showing any method to be successful in preventing post-procedural chest pain, despite its high frequency of occurrence.[5,7] Nakhla et al.[5]examined the incidence of post-ablation acute pericarditis among 2,215 patients. Overall, 10.2% of the patients experienced suspected post-ablation acute pericarditis, defined as chest pain requiring treatment with anti-inflammatory drugs.[5]

Multiple studies have sought to establish prophylactic treatment protocols for acute procedure-related pericarditis, but effective treatment regimens remain elusive.[11] In a prospective study of 1,075 patients undergoing RF ablations, prophylactic use of colchicine given at 0.3 mg twice daily ranging from 7 days to 1 month prior to ablation was found to reduce the incidence of post-ablation chest pain.[8] However, the study was neither randomized nor blinded, which may limit the generalizability of its findings. In contrast, a randomized study of 139 patients did not demonstrate a clear relationship between post-ablation acute pericarditis and prophylactic colchicine use.[9] This study observed no difference in incidence of chest pain in patients given 0.6 mg of colchicine twice daily and patients receiving standard post-ablation care without colchicine. However, there was a significant increase in gastrointestinal side effects in the group that received colchicine. Additionally, a retrospective observational study of 205 patients found that when colchicine was given at 0.6 mg twice daily for two weeks prior to a procedure it was not associated with a significant reduction in post-ablation chest pain, acute pericarditis, hospitalization, or AF recurrence rates.[21] However, colchicine was associated with increased gastrointestinal side effects.[21]Despite significant energy and resources dedicated to elucidating a definitive prophylactic treatment for post-ablation chest pain, little progress has been made. The use of active esophageal cooling may offer a simple and readily available option to address this problem.

In addition to improving patient quality of life, the reduction in the incidence of post-ablation chest pain through the use of esophageal cooling may in turn reduce the cost of medical care for patients. In a review of the National Inpatient Sample from 2009 to 2014, the incidence of post-ablation acute pericarditis hospitalizations was reported to have almost tripled, rising from a frequency of 46 hospitalizations in 2009 to 130 hospitalizations in 2014.[6] These hospitalizations resulted in higher mean cost spent on care compared to patients who did not experience post-ablation acute pericarditis.[6]

As with any retrospective review, unmeasured confounders may exist that bias the results; however, the focus on a single operator using the same ablation technique and tools over the timeframe analyzed may serve to minimize this source of bias. Moreover, factors that are associated with increased post-ablation chest pain, such as the use of additional posterior wall ablation, were found to have increased after the adoption of cooling. Our data came from a single-site community hospital, and as such, variation in staff experience, procedural approaches, and other factors may affect the generalizability of the results. Nevertheless, these findings are in agreement with survey data and recently presented data from other hospital systems, which may serve to support the reliability of the conclusions.

5 Conclusions

Adoption of esophageal cooling during RF ablations was associated with a significant reduction in post-ablation chest pain despite increased use of PWI and decreased use of prophylactic treatment.

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