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ORIGINAL RESEARCH

Comparison of real-world clinical and economic outcomes between the ThermoCool® SF and ThermoCool® catheters in patients undergoing radiofrequency catheter ablation for atrial fibrillation

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Introduction: This study evaluated the real-world clinical and economic outcomes associated with the use of the ThermoCool® Surround Flow (SF) and ThermoCool® catheters in atrial fibrillation (AF) ablation.

Methods: Adults with AF who underwent catheter ablation between January 1, 2013, and December 31, 2016, in a hospital outpatient setting were identified from the Premier Healthcare Database. Using a search strategy of hospital-charge descriptors, patients were classified into two mutually exclusive groups: ThermoCool® SF catheter and ThermoCool® catheter. A generalized estimating equation was used to compare index admission cost. Survey logistic regression was used to compare the incidence of inpatient readmission, direct-current cardioversion (DCCV), and repeat ablation. Multivariable analyses were adjusted for hospital clustering and demographic, procedural, hospital, and comorbidity characteristics.

Results: There were 1,014 and 463 patients in the ThermoCool® SF and ThermoCool® groups, respectively. The ThermoCool® SF group had significantly lower odds of all-cause (odds ratio [OR] 0.45; 95% CI 0.27–0.76) and cardiovascular-related readmissions (OR 0.45; 95% CI 0.21–0.96), and DCCV (OR 0.61; 95% CI 0.42–0.88) than the ThermoCool® group. In patients susceptible to fluid overload, the ThermoCool® SF group had significantly lower odds of 12-month all-cause (OR 0.42; 95% CI 0.23–0.75), cardiovascular-related (OR 0.31; 95% CI 0.10–0.92), and AF-related readmissions (OR 0.18; 95% CI 0.04–0.80), and DCCV (OR 0.52; 95% CI 0.31–0.87) than the ThermoCool® group.

Conclusions: Using the ThermoCool® SF catheter for AF ablation was significantly associated with improved clinical outcomes compared with the ThermoCool® catheter.

Keywords: atrial fibrillation, radiofrequency ablation, irrigated-tip catheter, ThermoCool® Surround Flow catheter, ThermoCool® catheter

Introduction

Approximately 2.3 million individuals have been diagnosed with atrial fibrillation (AF) in the USA.[1] The incidence of AF increases with age, and with a growing elderly population, the prevalence of AF is anticipated to rise. The prevalence of AF is expected to more than double by the year 2050, with 15 million individuals predicted to have the disease.[1,2] The estimated national annual cost associated with AF ranges from $6 billion

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to $26 billion.[3,4] This significant economic burden indicates the importance of effective management of symptoms and complications in patients with AF.[3,4]

Radiofrequency (RF) catheter ablation is an effective, non-pharmacological, and minimally invasive treatment option for patients with AF. Irrigated RF catheters use a small tip, which preserves flexibility and mobility during RF ablation while maintaining power delivery.[5,6] They also maintain a low electrode temperature, which allows creation of longer and deeper lesions, in contrast to non-irrigated tip catheters.[7–11]

Introduced in the latter half of the last decade, the ThermoCool® catheter (Biosense Webster, Inc., Irvine, CA, USA) includes six small irrigation holes at the distal end of its 3.5-mm tip. Use of the ThermoCool® catheter is associated with shorter procedure and fluoroscopy times, and lower rates of AF recurrence and complications than other irrigated and non-irrigated RF catheters.[12–18] Introduced in 2012, the ThermoCool® Surround Flow (SF) catheter (Biosense Webster, Inc.) features 56 tiny irrigation holes distributed evenly around the entire 3.5-mm tip to provide uniform cooling. When compared to the ThermoCool® catheter, this advanced, porous tip design allows more consistent irrigation at a lower rate of infusion and with less saline used. It may be noted that both the ThermoCool® SF catheter and the ThermoCool® catheter are non-contact force catheters. By reducing the volume of fluid delivered, the ThermoCool® SF catheter may lower the risk of fluid-related complications in patients with comorbidities sensitive to excess fluid delivery. This reduction may have an economic impact, as fluid overload is associated with costly complications and an increase in length of stay (LOS) and hospital costs.[19–22]

Clinical studies comparing the efficacy and safety of the ThermoCool® SF and ThermoCool® catheters have shown that the ThermoCool® SF catheter improves efficiency by reducing the total volume of infused saline solution, incidence of early pulmonary vein (PV) reconnections, total time for PV isolation, and duration of RF energy application.[23,24] The ThermoCool® SF catheter has also been shown to have a safety profile comparable to, or better than, the ThermoCool® catheter.[23–26] However, there is limited real-world evidence comparing economic and clinical outcomes among the ThermoCool® SF catheter and the ThermoCool® catheter. Thus, the objective of this study was to assess and compare the real-world clinical and economic outcomes of ThermoCool® SF catheter use with ThermoCool® catheter use in AF patients undergoing RF ablation.

Methods

Study design and data source

This retrospective, observational cohort study used hospital billing records from January 1, 2012, through December 31, 2016, in the Premier Healthcare Database, which includes records from over 700 participating US hospitals.[27] The use of the Premier database was reviewed by the New England Institutional Review Board (IRB); full IRB approval was not required, as the study did not involve identifiable human participants.

Study cohort

Billing records from the Premier database were first screened for patients with a primary, secondary, or admitting diagnosis of AF who had an index ablation between January 1, 2013 and December 31, 2016. A text search strategy using the name and model number of the ThermoCool® SF catheter and ThermoCool® catheter was applied to hospital charge descriptors to detect patients who underwent an index ablation using either catheter. Identified patients were then categorized into two mutually exclusive groups: 1) ThermoCool® SF catheter, and 2) ThermoCool® catheter. The primary analysis cohort included patients who had an index ablation procedure during an outpatient admission. As AF ablation increasingly moves towards an outpatient setting, we included outpatient admissions as primary analysis.

Additional criteria for study inclusion were patients aged ≥18 years at the time of their index hospital admission, providers with at least 12 months of pre-index inpatient and outpatient data in the Premier database, and patients with non-zero cost listed during their index admission. To account for provider experience, patients had to have undergone their index ablation procedure at a hospital that had performed >10 procedures with the catheter used during their index ablation in the 12-month pre-index period.

Patients were excluded if they had any catheter other than a ThermoCool® SF catheter or ThermoCool® catheter listed during the index ablation procedure, or if they had any of the following during the 12-month pre-index period: a catheter ablation procedure; implantation of a pacemaker or implantable cardioverter defibrillator; surgical cardiac ablation; valvular procedure; atrioventricular nodal ablation; or left atrial appendage occlusion.

Selected covariates

Patient demographics included age (18–49 years, 50–59 years, 60–69 years, 70 years and above); sex (male, female); race (White, other); and marital status (married, single, other).

Comorbid conditions included Deyo modification of the Charlson Comorbidity Index (CCI) score[28,29] and CHA_2DS_2-VASc score for risk of stroke in patients with AF. Specific comorbidities included obstructive sleep apnea, obesity, diabetes, hypertension, COPD, renal disease, congestive heart failure, atrial flutter, valvular disease, cardiomyopathy, cardiomegaly, ischemic heart disease, peripheral vascular disease, and pulmonary circulation disorders. Payer (commercial, Medicaid, Medicare, other) and year of RF ablation (2013, 2014, 2015, 2016) were also covariates of interest.

Provider characteristics included hospital bed size (<300, 300–399, 400–499, ≥500), hospital's prior mean ablation volume per month (≤10, >10 and ≤20, >20 and ≤30, >30), geographical region (Midwest, Northeast, South, West), physician specialty (cardiovascular [CV] vs non-CV), and hospital type (teaching, non-teaching).

Study outcomes and statistical methods

The primary independent variable was the type of catheter, ThermoCool® SF catheter or ThermoCool® catheter, used in the index ablation. Study outcomes included index ablation admission cost (total cost and supply cost), and 12-month hospital readmissions (all-cause, CV-related, AF-related), direct current cardioversions (DCCV), and repeat ablation. For index ablation admission outcomes, the study period went from 2013 to 2016, while for readmission outcomes, the study period went from 2013 to 2015 (to allow for 12-month readmission assessment).

Bivariate analyses were conducted with the Student's *t*-test and chi-squared test to examine any differences in selected covariate characteristics between the ThermoCool® SF and ThermoCool® groups of patients. Categorical outcomes are presented as percentages.

Multivariable adjusted analyses were conducted to examine study outcomes. Index admission costs of index ablation procedure were compared using a generalized estimating equation (GEE) with exchangeable correlation structure with log link and gamma distribution function. Survey logistic regression was used to compare the 12-month incidence of inpatient readmission, DCCV, and repeat ablation. Results are presented as exponentiated ratios (ERs) or odds ratios (ORs) with 95% confidence intervals (CIs). For all-cause, CV-related, and AF-related hospital readmissions, the patient sample was restricted to include patients with continuous inpatient data during the 12-month post-index period. For DCCV and repeat ablation, the patient sample was restricted to include patients with continuous inpatient and outpatient data during the 12-month post-index period. Regression analysis was adjusted for hospital-level clustering, patient demographics, comorbid conditions, index procedure characteristics, and provider characteristics.

Subgroup analyses

A subgroup analysis for all outcomes was conducted on the cohort of patients susceptible to fluid overload. Patients susceptible to fluid overload included those who had congestive heart failure, valvular disease, renal failure, cardiomyopathy, peripheral vascular disease, pulmonary circulation disorder, hypertension, and/or ischemic heart disease.

Sensitivity analyses: one

Considering the issue of selection bias that is inherent in observational research, we conducted propensity score matching as part of sensitivity analysis to better control for any such bias. There were three sets of propensity matching conducted. First, we conducted propensity matching on the sample of ThermoCool® SF and ThermoCool® group that constituted the final sample. This was done to examine outcomes (total cost, supply cost) associated with index admission. Second, to examine inpatient readmission outcome (all-cause, CV-related, AF-related), we applied the criteria that the provider wherein the patient had index admission should be continuously providing data to Premier database for the subsequent 12-month period. Since hospitals could fall in and out of Premier database, it was necessary to apply this criterion to make sure that there is no differential in provider data availability in the 12-month follow-up period, which otherwise could lead to measurement bias. Third, for DCCV and ablation that can occur in either inpatient or outpatient setting, we conducted propensity matching on sample of patients who had index admission in hospitals that continuously provided both inpatient and outpatient data in the subsequent 12-month follow-up period.

Propensity matching was conducted using nearest neighbor technique without replacement and 0.10 caliper, with all study covariates included in the logistic propensity model. The balance of covariates was assessed using standardized differences, with any difference more than 25% considered to be significant. We then used GEE with exchangeable correlation structure and log link and gamma distribution function for cost comparison, and survey logistic regression for 12-month inpatient readmission, DCCV, and repeat ablation comparison in the matched sample. As with the multivariable analysis as part of the original analysis, regression analysis in the propensity-matched sample was adjusted for hospital-level clustering.

Sensitivity analyses: two

We also conducted sensitivity analysis wherein the patient sample included patients who underwent RF ablation in either an outpatient or inpatient setting. Results for the sensitivity analysis cohort are presented in the Supplementary Material. For patients who had their RF ablation in an inpatient setting, LOS, and room and board cost were assessed and compared between the two treatment groups. GEE with exchangeable correlation structure with log link and negative binomial distribution for LOS and with gamma distribution function for room and board cost was used. Bivariate, unadjusted data are presented as mean values; multivariable-adjusted data are presented as ERs and 95% CIs.

Statistical analyses were conducted using SAS for Windows, Version 9.4 (SAS Institute Inc., Cary, NC, USA). Descriptive statistics were reported for all study variables. A two-sided P of <0.05 was the threshold for statistical significance in all analyses.

Ethics approval

The use of Premier was reviewed by the New England Institutional Review Board (IRB) and was determined to be exempt from broad IRB approval, as this research project does not involve identifiable human subjects research, and therefore did not require patient consent.

Results

Study cohort

A total of 67,656 patients who had a primary, secondary, or admitting diagnosis of AF for index ablation performed between January 1, 2013, and December 31, 2016, were identified in the Premier database. After screening for eligibility, the outpatient cohort included 1,014 ThermoCool® SF patients and 463 ThermoCool® patients (Figure 1; Step 8a). The cohort of outpatients susceptible to fluid overload included 765 ThermoCool® SF patients and 319 ThermoCool® patients (Figure 1; Step 8b). The sample sizes included in the analyses for each study outcome are presented in the footnotes of the corresponding tables.

Significant differences in study characteristics were observed between the two treatment groups (Table 1). The ThermoCool® TC group had significantly more patients with a CHA_2DS_2-VASc score of 0 than the ThermoCool® SF group (ThermoCool® SF 13.91% vs ThermoCool® 18.14%; P=0.0355). The ThermoCool® SF group had significantly more patients with diabetes (ThermoCool® SF 17.36% vs ThermoCool® 12.96%; P=0.0324), hypertension (ThermoCool® SF 63.91% vs ThermoCool® 57.88%; P=0.0270), atrial flutter (ThermoCool® SF 34.42% vs ThermoCool® 23.97%; P<0.0001), and valvular disease (ThermoCool® SF 20.41% vs ThermoCool® 12.10%; P=0.0001) than the ThermoCool® group.

Primary analyses

Results from Student's t-test indicated unadjusted mean total costs to be significantly lower in the ThermoCool® SF group than the ThermoCool® group (ThermoCool® SF: $20,160 vs ThermoCool®: $22,525; P<0.0001) (Table 2). After multivariable adjustment using GEE, the mean total costs were similar between the ThermoCool® SF and ThermoCool® groups (ThermoCool® SF: $21,753 vs ThermoCool®: $23,483; ER 0.93 [95% CI 0.84–1.03]) (Table 2).

Unadjusted mean supply costs were significantly lower in the ThermoCool® SF group than the ThermoCool® group (ThermoCool® SF: $9,705 vs ThermoCool®: $10,686; P<0.0001) (Table 2). After GEE adjustment, mean supply costs were similar between the treatment groups (ThermoCool® SF: $9,218 vs ThermoCool®: $8,877; ER 1.04 [95% CI 0.92–1.17]) (Table 2).

In the unadjusted analysis, all-cause, CV-related, and AF-related hospital readmissions were similar between the ThermoCool® SF and ThermoCool® catheters (Table 2). After multivariable adjustment using survey logistic regression, the ThermoCool® SF group was associated with 55% lower odds of all-cause readmission (OR 0.45 [95% CI 0.27–0.76]) and 55% lower odds of CV-related readmission (OR 0.45 [95% CI 0.21–0.96]) than the ThermoCool® group in the 12-month period after the index ablation (Table 2). When comparing outcomes during the blanking period (0–3 months), the ThermoCool® SF group had 58% lower odds of all-cause readmission (OR 0.42 [95% CI 0.22–0.79]) and 62% lower odds of CV-related readmission (OR 0.38 [95% CI 0.15–0.95]) than the ThermoCool® group (Table 2).

Before adjusting for covariates, the ThermoCool® SF group had a significantly lower occurrence of DCCV than the ThermoCool® group at all time points (Table 2). After multivariable adjustment, results for DCCV significantly favored the ThermoCool® SF group over the ThermoCool® group, with 39% lower odds at 0–12 months (OR 0.61 [95% CI 0.42–0.88]), 45% lower odds at 0–3 months (OR 0.55 [95% CI 0.34–0.89]), and 45% lower odds at 4–12 months (OR 0.55 [95% CI 0.33–0.92]) (Table 2). There were no differences in repeat ablation between the ThermoCool® SF and ThermoCool® groups during any period in the unadjusted or adjusted analysis (Table 2).

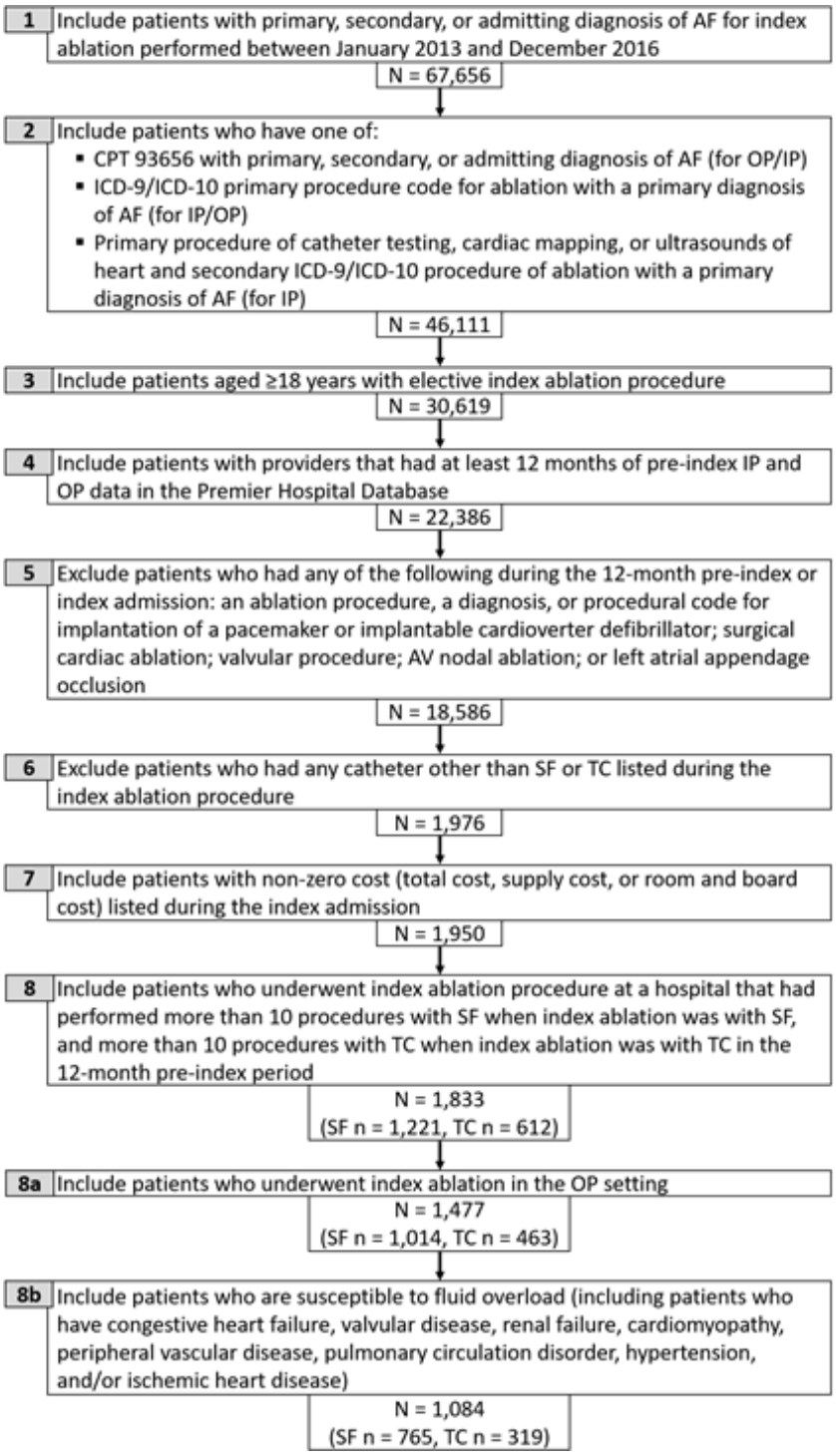

Figure 1 Patient selection diagram – a stepwise diagram detailing the eligibility criteria and results for patients with AF identified in the Premier Healthcare Database who had an index ablation during the study period.

Abbreviations: AF, atrial fibrillation; AV, atrioventricular; IP, inpatient; N, number of total eligible patients; n, number of eligible patients; OP, outpatient; SF, ThermoCool® Surround Flow; TC, ThermoCool®.

Subgroup analyses

Study characteristics for the cohort of outpatients susceptible to fluid overload are presented in Table 1. In AF patients susceptible to fluid overload, adjusted mean total costs were similar between treatment groups (ThermoCool® SF: $21,296 vs ThermoCool®: $22,924; ER 0.93 [95% CI 0.82–1.05]) (Table 3). Also, there was no significant difference in the adjusted mean supply cost between the groups (ThermoCool® SF: $9,222 vs ThermoCool®: $8,493; ER 1.09 [95% CI 0.94–1.25]) (Table 3).

Table 1 Summary of cohort characteristics

	Outpatients			Outpatients susceptible to fluid overload		
	SF (%)	TC (%)	*P*-value	SF (%)	TC (%)	*P*-value
Total cohort (N)	1,014	463		765	319	
Patient characteristics						
Age, y						
18–49	10.55	10.37	0.9143	8.10	6.58	0.3906
50–59	22.29	19.22	0.1821	19.61	5.63	0.8540
60–69	38.17	39.74	0.5642	39.74	38.24	0.6463
70+	28.99	30.67	0.5125	32.55	36.05	0.2660
Sex						
Female	35.90	32.61	0.2192	36.60	32.92	0.2478
Race						
White	91.22	88.12	0.0623	92.16	90.28	0.3104
Other	8.78	11.88		7.84	9.72	
Marital status						
Married	75.74	69.33	0.0094	75.82	72.10	0.1994
Single	22.49	25.92	0.1493	23.01	24.45	0.6088
Other	1.78	4.75	0.0011	1.18	3.45	0.0113
CCI score						
0	59.27	63.28	0.1433	48.76	52.04	0.3251
1	25.44	22.89	0.2915	31.11	28.53	0.3990
≥2	15.29	13.82	0.4629	20.13	19.44	0.7941
CHA_2DS_2-VASc score						
0	13.91	18.14	0.0355	3.79	5.02	0.3569
1	28.60	26.35	0.3711	26.67	27.59	0.7558
≥2	57.50	55.51	0.4743	69.54	67.40	0.4870
Comorbidities						
OSA	19.63	17.93	0.4410	22.09	22.88	0.7752
Obesity	12.52	9.50	0.0923	14.64	10.66	0.0801
Diabetes	17.36	12.96	0.0324	21.83	16.93	0.0679
Hypertension	63.91	57.88	0.0270	84.71	84.01	0.7738
COPD	11.64	10.37	0.4735	14.38	12.54	0.4240
Renal disease	4.14	2.59	0.1409	5.49	3.76	0.2333
CHF	15.09	14.25	0.6757	20.00	20.69	0.7966
Atrial flutter	34.42	23.97	<0.0001	36.99	25.39	0.0002
Valvular disease	20.41	12.10	0.0001	27.06	17.55	0.0009
Cardiomyopathy	7.99	6.91	0.4702	10.59	10.03	0.7845
Cardiomegaly	4.14	4.97	0.4730	5.36	6.27	0.5535
IHD	17.55	15.12	0.2454	23.27	21.94	0.6362
PVD	3.94	3.89	0.9582	5.23	5.64	0.7826
PCD	3.25	2.59	0.4918	4.31	3.76	0.6780
Procedure characteristics						
Payer						
Commercial	48.42	42.55	0.0358	44.97	39.18	0.0799
Medicaid	1.38	2.59	0.1006	1.31	3.13	0.0416
Medicare	46.55	48.60	0.4646	51.37	52.98	0.6297
Other	3.65	6.26	0.0241	2.35	4.70	0.0402
Year of admission						
2013	37.67	46.22	0.0019	38.30	45.45	0.0287
2014	33.73	33.05	0.7966	35.03	33.86	0.7106
2015	20.32	15.77	0.0383	19.35	15.05	0.0937
2016	8.28	4.97	0.0226	7.32	5.64	0.3182
Provider characteristics						
Hospital bed size						
<300	3.75	9.72	<0.0001	4.05	10.34	<0.0001
300–399	45.76	13.82	<0.0001	45.23	13.79	<0.0001
400–499	32.35	41.25	0.0009	36.21	40.75	0.1592
≥500	18.15	35.21	<0.0001	14.51	35.11	<0.0001

(*Continued*)

Table 1 (*Continued*)

	Outpatients			Outpatients susceptible to fluid overload		
	SF (%)	**TC (%)**	***P*-value**	**SF (%)**	**TC (%)**	***P*-value**
Prior mean ablation volume per month						
≤10	6.61	17.49	<0.0001	6.67	16.93	<0.0001
>10 and ≤20	44.28	18.14	<0.0001	41.57	16.30	<0.0001
>20 and ≤30	26.92	34.99	0.0016	25.62	34.48	0.0031
>30	22.19	29.37	0.0029	26.14	32.29	0.0399
Geographical region						
Midwest	8.38	29.59	<0.0001	8.50	34.48	<0.0001
Northeast	11.05	9.29	0.3064	10.33	6.58	0.0522
South	61.05	20.09	<0.0001	65.49	21.63	<0.0001
West	19.53	41.04	<0.0001	15.69	37.30	<0.0001
Physician specialty, CV	81.36	53.13	<0.0001	83.92	54.23	<0.0001
Non-teaching hospital	76.73	39.09	<0.0001	77.65	35.11	<0.0001

Abbreviations: CCI, Charlson Comorbidity Index; CHA_2DS_2-VASc, congestive heart failure, hypertension, age ≥75 years (double weight), diabetes mellitus, stroke (double weight), vascular disease (coronary artery disease, peripheral artery disease, aortic atherosclerosis), age 65–74 years, female sex; CHF, congestive heart failure; COPD, cardiopulmonary disease; CPD, cardiopulmonary disease; CV, cardiovascular; IHD, ischemic heart disease; NA, not applicable; OSA, obstructive sleep apnea; PCD, pulmonary circulation disorders; PVD, peripheral vascular disorders; SF, ThermoCool® Surround Flow; TC, ThermoCool®; y, years.

Table 2 Total and supply costs, hospital readmissions (all-cause, CV-related, AF-related), cardioversion, and repeat ablation in the outpatient cohort

Total and supply costs[a]	**Bivariate unadjusted analysis**			**Multivariable adjusted analysis**			
	SF (mean)	**TC (mean)**	***P*-value**	**SF (mean)**	**TC (mean)**	**ER**	**95% CI**
Analysis cohort (n)	1,014	463					
Total cost	$20,160	$22,525	<0.0001	$21,753	$23,483	0.9263	0.8365–1.0259
Supply cost	$9,705	$10,686	<0.0001	$9,218	$8,877	1.0385	0.9196–1.1726
Readmissions[b]	**SF (%)**	**TC (%)**	*P*-value	**OR**		**95%** CI	
Analysis cohort (n)	833	365					
All-cause							
0–12 months	12.73	16.99	0.050	0.449		0.266–0.755	
0–3 months	6.96	9.86	0.085	0.415		0.218–0.789	
4–12 months	7.44	7.67	0.890	0.581		0.287–1.177	
CV-related							
0–12 months	7.08	10.14	0.073	0.445		0.207–0.956	
0–3 months	3.72	6.03	0.074	0.381		0.152–0.952	
4–12 months	3.96	4.11	0.904	0.660		0.182–2.389	
AF-related							
0–12 months	4.20	6.03	0.171	0.403		0.136–1.192	
0–3 months	2.04	4.11	0.041	0.342		0.092–1.275	
4–12 months	2.40	1.92	0.604	0.590		0.071–4.931	
DCCV and repeat ablation[c]							
Analysis cohort (n)	819	342					
DCCV							
0–12 months	14.29	23.98	<0.0001	0.607		0.420–0.878	
0–3 months	9.89	18.42	<0.0001	0.547		0.337–0.889	
4–12 months	6.59	11.70	0.0037	0.551		0.330–0.919	
Repeat ablation							
0–12 months	12.09	9.65	0.2328	0.854		0.359–2.033	
0–3 months	3.54	3.22	0.7823	0.531		0.163–1.726	
4–12 months	8.91	7.02	0.2873	0.989		0.439–2.225	

Notes: [a]Cost (total and supply) includes only those costs associated with the index ablation procedure. [b]Patient sample restricted to providers with continuous inpatient data during the 12-month post-index period. [c]Patient sample restricted to providers with continuous inpatient and outpatient data during the 12-month post-index period.
Abbreviations: AF, atrial fibrillation; CV, cardiovascular; DCCV, direct-current cardioversion; ER, exponentiated ratio; OR, odds ratio; SF, ThermoCool® Surround Flow; TC, ThermoCool®.

Table 3 Total and supply costs, hospital readmissions (all-cause, CV-related, AF-related), cardioversion, and repeat ablation in the outpatient cohort susceptible to fluid overload

Total and supply costs[a]	**Bivariate unadjusted analysis**			**Multivariable adjusted analysis**			
	SF (mean)	**TC (mean)**	***P*-value**	**SF (mean)**	**TC (mean)**	**ER**	**95% CI**
Analysis cohort (n)	765	319					
Total cost	$20,495	$22,677	<0.0001	$21,296	$22,924	0.9290	0.8231–1.0485
Supply cost	$9,711	$10,819	0.0013	$9,222	$8,493	1.0858	0.9416–1.2521
Readmissions[b]	**SF (%)**	**TC (%)**	*P*-value	**OR**		**95%** CI	
Analysis cohort (n)	631	250					
All-cause							
0–12 months	12.68	18.00	0.0413	0.416		0.231–0.748	
0–3 months	6.66	9.60	0.1346	0.303		0.156–0.587	
4–12 months	7.77	8.80	0.6111	0.723		0.321–1.928	
CV-related							
0–12 months	6.34	10.80	0.0243	0.307		0.102–0.923	
0–3 months	2.85	6.00	0.0266	0.075		0.032–0.176	
4–12 months	3.80	4.80	0.5006	0.873		0.193–3.944	
AF-related							
0–12 months	3.49	6.40	0.0550	0.180		0.041–0.797	
0–3 months	1.27	4.40	0.0039	0.035		0.011–0.112	
4–12 months	2.22	2.00	0.8403	0.527		0.049–5.667	
DCCV and repeat ablation[c]							
Analysis cohort (n)	617	232					
DCCV							
0–12 months	14.10	26.29	<0.0001	0.516		0.305–0.871	
0–3 months	9.56	20.26	<0.0001	0.396		0.226–0.694	
4–12 months	6.48	12.93	0.0023	0.500		0.269–0.930	
Repeat ablation							
0–12 months	10.86	9.05	0.4414	0.815		0.460–1.443	
0–3 months	3.08	2.16	0.4690	0.449		0.226–0.891	
4–12 months	7.94	7.33	0.7659	0.879		0.477–1.620	

Notes: [a]Cost (total and supply) includes only those costs associated with the index ablation procedure. [b]Patient sample restricted to providers with continuous inpatient data during the 12-month post-index period. [c]Patient sample restricted to providers with continuous inpatient and outpatient data during the 12-month post-index period.
Abbreviations: AF, atrial fibrillation; CV, cardiovascular; DCCV, direct-current cardioversion; ER, exponentiated ratio; OR, odds ratio; SF, ThermoCool® Surround Flow; TC, ThermoCool®.

Multivariable adjusted results for the 12-month period after index ablation showed 58% lower odds of all-cause readmission (OR 0.42 [95% CI 0.23–0.75]), 69% lower odds of CV-related readmission (OR 0.31 [95% CI 0.10–0.92]), and 82% lower odds of AF-related readmission (OR 0.18 [95% CI 0.04–0.80]) in the ThermoCool® SF group than in the ThermoCool® group (Table 3). When restricted to the blanking period (0–3 months), the ThermoCool® SF group had 70% lower odds of all-cause readmission (OR 0.30 [95% CI 0.16–0.59]), 92% lower odds of CV-related readmission (OR 0.08 [95% CI 0.03–0.18]), and 96% lower odds of AF-related readmission (OR 0.04 [95% CI 0.01–0.11]) than the ThermoCool® group (Table 3). For DCCV, adjusted results showed lower odds of DCCV in the ThermoCool® SF group than in the ThermoCool® group at all time periods: 48% lower odds at 0–12 months (OR 0.52 [95% CI 0.31–0.87]), 60% lower odds at 0–3 months (OR 0.40 [95% CI 0.23–0.69]), and 50% lower odds at 4–12 months (OR 0.50 [95% CI 0.27–0.93]) (Table 3). Multivariable analysis also revealed the odds of repeat ablation to be 55% lower in the ThermoCool® SF group than in the ThermoCool® group at 0–3 months (OR 0.45 [95% CI 0.23–0.89]) (Table 3).

Sensitivity analyses: One

As part of propensity matching for index admission cost (total cost, supply cost) comparison, 168 patients emerged in each of the ThermoCool® SF and ThermoCool® group (Supplementary Appendix 1). When assessing post-match balance of covariates, there were no standardized differences greater than 25%. In this propensity-matched sample, bivariate analysis revealed the total cost to be significantly lower for the ThermoCool® SF group as compared to the ThermoCool® group ($19,729 vs $22,038; *P*=0.0022). Results from GEE analysis did not reveal a significant difference in total

cost in this propensity-matched sample of the two groups (ThermoCool® SF: $21,287 vs ThermoCool®: $23,330; ER 0.91 [95% CI 0.81–1.01]). No significant difference in supply cost emerged in the matched sample in both bivariate analysis (ThermoCool® SF: $11,523 vs ThermoCool®: $11,481; *P*=0.9394) and GEE analysis (ThermoCool® SF: $9,832 vs ThermoCool®: $9,787; ER 1.00 [95% CI 0.87–1.15]) (Supplementary Appendix 4).

When comparing inpatient readmissions, 144 patients emerged in each of the ThermoCool® SF and ThermoCool® group (Supplementary Appendix 2). There were no standardized differences greater than 25% when assessing the post-match sample balance of covariate. For all-cause readmission, bivariate analysis of the propensity matched sample revealed the ThermoCool® SF group to have significantly lower rate of 0–12 month (9.72% vs 21.53%, *P*=0.0058) and 0–3 months readmission (4.17% vs 15.28%, *P*=0.0015) as compared to the ThermoCool® group. Logistic regression analysis revealed the ThermoCool® SF group to have 61% (OR 0.39 [95% CI 0.20–0.75]) lower odds of 0–12 months all-cause readmission and 76% (OR 0.24 [95% CI 0.13–0.43]) lower odds of 0–3 months all-cause readmission. No significant difference among the two groups in 4–12 months all-cause readmission emerged in both bivariate and logistic regression analysis. As per CV-related inpatient readmission, the ThermoCool® SF group was found to have significantly lower rate of 0–12 months (3.47% vs 11.81%, *P*=0.0078) and 0–3 months (1.39% vs 7.64%, *P*=0.0106) readmission rate as compared to the ThermoCool® group. The ThermoCool® SF group was found to have 73% (OR 0.27 [95% CI 0.09–0.75]) lower odds of 0–12 months and 83% (OR 0.17 [95% CI 0.04–0.64]) lower odds of 0–3 months CV-related readmission. The two matched groups did not differ in terms of 4–12 months CV-related readmission. In terms of AF-related inpatient readmission, the ThermoCool® SF group had significantly lower rate of 0–12 months readmission (2.08% vs 9.03%, *P*=0.0101) and 0–3 months readmission (1.39% vs 6.94%, *P*=0.0183). Results from logistic regression revealed the ThermoCool® SF group to have 79% (OR 0.21 [95% CI 0.05–0.78]) lower odds of 0–12 months AF-related inpatient readmission and 82% (OR 0.18 [95% CI 0.05–0.65]) lower odds of 0–3 months AF-related inpatient readmission as compared to the ThermoCool® group. Bivariate and logistic regression analysis revealed no difference in 4–12 months AF-related inpatient readmission among the matched groups (Supplementary Appendix 4).

A total of 272 patients were identified for the two groups (136 each) for DCCV and repeat ablation assessment using propensity matching. Standardized differences for all covariates were less than 25% for the post-match sample (Supplementary Appendix 3). The ThermoCool® SF group had significantly lower rate of 0–3 months DCCV (10.29% vs 19.85%, *P*=0.0276). Logistic regression revealed the ThermoCool® SF group to have 44% (OR 0.56 [95% CI 0.34–0.92]) lower odds of 0–12 months DCCV, and 54% (OR 0.46 [95% CI 0.30–0.69]) lower odds of 0–3 months DCCV. Bivariate and logistic regression analysis revealed no difference in 4–12 months DCCV among the matched groups. As per 0–12 months, 0–3 months, and 4–12 months repeat ablation, no significant difference in bivariate and logistic regression analysis was observed in the post-match ThermoCool® SF group and ThermoCool® group (Supplementary Appendix 4).

Sensitivity analyses: two

Study characteristics for the cohort of both inpatient and outpatient ablation are presented in Supplementary Appendix 5. When comparing outcomes for patients with AF undergoing RF ablation either in an inpatient or outpatient setting, significant differences in all-cause readmission and DCCV emerged (Supplementary Appendix 6). Results after adjustment for covariates showed that the combined inpatient and outpatient cohort had 40% lower odds of all-cause readmission in the ThermoCool® SF group than in the ThermoCool® group during the 0–12-month period (OR 0.60 [95% CI 0.42–0.88]) and 41% lower odds during the 0–3-month period (OR 0.59 [95% CI 0.41–0.86]) (Supplementary Appendix 6). After adjustment, inpatients and outpatients in the ThermoCool® SF group had 32% lower odds of DCCV at 0–12 months (OR 0.68 [95% CI 0.49–0.95]) and 37% lower odds at 0–3 months (OR 0.63 [95% CI 0.41–0.96]) than those in the ThermoCool® group (Supplementary Appendix 6). Differences in other outcomes, including total cost, supply cost, room and board cost (for inpatients only), LOS (for inpatients only), CV-readmission, AF-readmission, and repeat ablation did not emerge significant (Supplementary Appendix 6**.** for inpatients and outpatients, Supplementary Appendix 7 for inpatients only).

Discussion

Real-world evidence comparing the advanced irrigated ThermoCool® SF catheter with conventional irrigated catheters is limited. As RF catheter technology for AF ablation evolves, evidence supporting the incremental improvement in outcomes associated with newer technology is critical from a patient, provider, and societal perspective. We conducted a retrospective comparative analysis of health and

cost outcomes in AF patients from the Premier database who underwent index ablation with either a ThermoCool® SF catheter or ThermoCool® catheter. The Premier database provided a large, robust, and nationally representative sample size that allowed analysis of outcomes after the ThermoCool® SF catheter and ThermoCool® catheter technologies were used in the real-world setting. The patient sample was large enough to allow for analyses of patients who had an index ablation in the outpatient setting and a subgroup of those patients susceptible to fluid overload. Overall, results showed that RF ablation with the ThermoCool® SF catheter significantly improved outcomes related to hospital readmissions, DCCV, and repeat ablation compared with the ThermoCool® catheter, particularly in patients susceptible to fluid overload. No significant difference in index admission cost was observed between use of the advanced, irrigated ThermoCool® SF catheter and the earlier-generation ThermoCool® catheter. Results from the two sensitivity analyses were generally consistent with the primary analysis where we used multivariable analysis and focused only on patients undergoing ablation in an outpatient setting.

The comparison of study characteristics among AF patients receiving ablation using the ThermoCool® SF catheter as compared to the ThermoCool® catheter revealed underlying differences in the two cohorts. Patients who had ablation using the ThermoCool® SF catheter had higher prevalence of diabetes, hypertension, atrial flutter, and valvular disease as compared to those having ablation using the ThermoCool® catheter. These differences generally persisted across sensitivity analysis samples studied. The higher comorbid burden among the ThermoCool® SF catheter cohort likely reflects an underlying channeling of severe patients to more advanced catheter. It also highlights that any comparison of the two catheters in a real-world setting should use methodological approaches like propensity matching to adjust for the underlying selection bias. Though such approaches are unlikely to completely remove selection bias, they would help alleviate the impact of such baseline differences on study results.

Radiofrequency ablation with the ThermoCool® SF catheter has been shown to provide clinical benefits in patients with AF.[23,24] Evidence from randomized trials show that the ThermoCool® SF catheter significantly reduces irrigation volume and significantly improves procedural efficiencies compared with the ThermoCool® catheter, in addition to providing comparable long-term freedom from AF.[23,24] Our study's real-world findings highlight additional benefits associated with ThermoCool® SF catheter use, particularly the significantly lower odds for all-cause and CV-related hospital readmissions and DCCV with the ThermoCool® SF catheter than the ThermoCool® catheter at follow-up periods up to 12 months. This is the first study to demonstrate, from a real-world perspective, the clinical advantage of reduced fluid delivery associated with the ThermoCool® SF catheter when compared to traditional RF irrigated catheters. In our study, we used both multivariable regression analysis as part of primary outcome analysis, and performed sensitivity analysis wherein propensity matching was used to alleviate selection bias that may have affected primary analysis study results. Unlike clinical trials wherein randomization controls for selection bias, observation data is susceptible to such bias due to lack of randomization. Though it is difficult to fully control for selection bias without randomization, a common method to alleviate its effect in observational research is through propensity matching. Also, by performing three sets of propensity matching based on underlying outcomes being assessed (cost, inpatient readmissions, DCCV and repeat ablation), we attempted to alleviate both selection and measurement bias in our study. The results from sensitivity analysis mirrored those from primary outcome multivariable analysis. In the propensity-matched sample, as with the original multivariable adjusted analyses, the ThermoCool® SF catheter group was found to have significantly lower odds of all-cause and CV-related inpatient readmissions and DCCV.

Patients with AF who have comorbidities that increase susceptibility to fluid overload are at increased risk of serious and costly complications after an RF ablation procedure, including pulmonary edema, pleural effusion, and congestive heart failure.[19–22,24,30] In a recent retrospective study of the Premier database, inpatients with fluid overload had a 29% longer length of stay and a 43% higher per-visit hospital cost than those without fluid overload.[19] In the current study, analysis of a subgroup of patients susceptible to fluid overload showed that the ThermoCool® SF catheter significantly reduced odds of all-cause, CV-related, and AF-related hospital readmissions compared with the ThermoCool® catheter in the 12-month post-index period. Further, ThermoCool® SF patients were observed to have lower odds of repeat ablation during the 0–3-month blanking period. Given that a substantial proportion (~74% as found in our study) of AF patients have comorbidities that may place them at a higher risk of fluid overload, the use of the ThermoCool® SF catheter instead of traditional RF irrigated catheters in such a vulnerable subgroup could lead to meaningful improvements in outcomes. Though we did not assess post-index cost in our study, the improved clinical outcomes demonstrated

with the use of the ThermoCool® SF catheter may translate into economic savings for patients, providers, and payers.

Though ThermoCool® SF patients had improved 12-month outcomes, those benefits accrued primarily from the improved outcomes that occurred during the 0–3-month blanking period. Clinical studies have shown significantly less freedom from AF in patients with early recurrence than in those without early recurrence.[31–33] In a study of 234 symptomatic AF patients who received RF ablation, 46% of patients with early recurrence were free from AF recurrence at a median follow-up of 12 months, in contrast to 68% of patients without early recurrence.[33] Similarly, in another study of patients with AF (N=110), significantly fewer patients with early recurrence (31%) were free from AF than those without early recurrence (85%; $P<0.001$) at a mean follow-up of 208 days after index RF ablation.[32] Results from the study suggest that the benefits accrued during the blanking period from the use of the ThermoCool® SF catheter as compared to the ThermoCool® catheter persist until at least 1 year after RF ablation.

Study limitations

Limitations of the current study include those that are inherent with a retrospective follow-up study design, including the possibility of inadvertent patient selection bias and unidentified confounding variables. Though we used multivariable analyses to adjust for measured confounders, there could be other factors influencing outcomes that could not be adjusted. Patients who may have had a readmission at a different hospital would not have been captured in the Premier database. At the time of the analysis, the Premier database did not have a searchable unique device identifier. A non-standardized text field search strategy was created to identify the catheter used in the index ablation, which may have led to miscoding. The operator's level of experience was not considered in the regression analyses as it is unavailable in the database, and may have been an unidentified covariate. In addition, the fact that the ThermoCool® SF catheter is a newer technology as compared to the ThermoCool® catheter, variation in adoption and experience in these catheters could influence study results. The fact that we adjusted for year in our analysis, we would likely have alleviated any such influence. Study results could have been affected by billing and coding errors in the database records. As our data period was from primarily ICD-9 era (wherein ICD-9-CM diagnosis code of 427.31 refers to AF), information on AF type (paroxysmal, persistent, etc.) was also not available. Clinical parameters including fluid volume associated with catheter ablation, RF delivery time, lesion size including lesion depth and diameter could not be ascertained using Premier database. Lastly, the underlying objective of this study was to examine and compare the effectiveness profile of the advanced porous tip ThermoCool® SF catheter with the first-generation standard irrigated ThermoCool® catheter, and as such we did not assess adverse events among the two catheter groups. In their multicenter randomized control study comparing the safety and efficacy of the ThermoCool® SF catheter with ThermoCool® catheter, Bertaglia et al[23] found no complication in the former group and one occurrence of cardiac tamponade and vascular complication each in the latter group (complication rate 0/54 vs 2/52; $P=0.003$). The better safety profile of the ThermoCool® SF catheter may explain to some extent the improved outcomes differential observed with this catheter in our study, though that effect is likely to be minimal.

Conclusion

In AF patients who received index ablation in an outpatient setting, ThermoCool® SF catheter use was associated with significantly better clinical outcomes than ThermoCool® catheter use. Patients undergoing RF ablation using the ThermoCool® SF catheter had significantly lower all-cause readmissions, CV-related readmissions, and DCCV in the 12-month period after the index ablation than in patients undergoing RF ablation using the ThermoCool® catheter. In patients susceptible to fluid overload, RF ablation with the ThermoCool® SF catheter additionally reduced AF-related hospital readmission and repeat ablation. Results suggest that the reduced fluid delivery of the ThermoCool® SF catheter likely translates into clinically significant improvements in outcomes among AF patients.

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Disclosure

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