Temperature-controlled Ablation Versus Conventional Ablation for Pulmonary Vein Isolation in the Treatment of AF: A Systematic Review and Meta-Analysis

Benjamin Clay [1,2] Balamrit S Sokhal [3,4] Sarah Zeriouh [5] Neil T Srinivasan [6,7]
Parag R Gajendragadkar [5,8] and Claire A Martin [5,9]

1. Department of Geriatrics, East Suffolk and North Essex NHS Foundation Trust, Ipswich, UK; 2. Department of Public Health and Primary Care, University of Cambridge, Cambridge, UK; 3. Department of Emergency Medicine, University Hospitals of North Midlands NHS Trust, Stoke-on-Trent, UK; 4. School of Medicine, Keele University, Stoke-on-Trent, UK; 5. Department of Cardiology, Royal Papworth Hospital NHS Foundation Trust, Cambridge, UK; 6. Department of Cardiac Electrophysiology, The Essex Cardiothoracic Centre, Basildon, UK; 7. Circulatory Health Research Group, Medical Technology Research Centre, School of Medicine, Anglia Ruskin University, Chelmsford, UK; 8. Nuffield Department of Population Health, University of Oxford, Oxford, UK; 9. Department of Medicine, University of Cambridge, Cambridge, UK

Abstract

Background: This study compared the efficacy and safety of temperature-controlled and conventional contact-force-sensing radiofrequency ablation catheters for pulmonary vein isolation (PVI) in AF. **Methods:** Seven studies (1,138 patients) were included. Randomised controlled trials and observational (single-arm and two-arm) studies that reported freedom from AF ≥3 months after PVI with temperature-controlled radiofrequency ablation catheters (Biosense Webster QDOT MICRO operating in QMODE or Medtronic DiamondTemp) were included. **Results:** Freedom from AF at a mean (± SD) follow-up of 9.0 ± 3.6 months did not differ significantly between temperature-controlled and conventional ablation (OR 1.22; 95% CI [−0.79, 1.64]; p=0.24). Total procedure duration (−13.5 minutes; 95% CI [−17.1, −10.0 minutes]; p<0.001) and total ablation duration (−8.9 min; 95% CI [−10.3, −7.5 min]; p<0.01) were significantly shorter for temperature-controlled ablation. There were no significant differences between temperature-controlled and conventional ablation in either the aggregated rates of procedural complications (OR 0.69; 95% CI [−0.15, 1.54]; p=0.11) or in the rate of any individual complication. **Conclusion:** Temperature-controlled ablation was found to be at least non-inferior to conventional ablation in all measures of efficacy and safety. Further randomised controlled trials are warranted to evaluate long-term rates of freedom from AF and patient comfort.

Keywords

AF, catheter ablation, radiofrequency, temperature-controlled, pulmonary vein isolation

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Correspondence: Benjamin Clay, Department of Public Health and Primary Care, University of Cambridge, Forvie Site, Robinson Way, Cambridge CB2 0SR, UK.
E: bjc61@cam.ac.uk

AF is a highly prevalent arrhythmia that may cause significant symptoms when uncontrolled and is a risk factor for further cardiovascular morbidity and mortality. Drug-refractory AF is commonly treated by catheter ablation, which aims to electrically isolate the pulmonary veins.[1,2] This is often achieved through the application of radiofrequency (RF) energy, which causes combined resistive and conductive heating of myocardial tissue, resulting in tissue damage/necrosis.

Long-term outcomes of RF ablation may be optimised by tighter control of the determinants of tissue heating to produce more consistent transmural lesions with a reduced prospect of electrical reconnection over time. Two novel RF ablation catheters, namely the Biosense Webster QDOT MICRO and the Medtronic DiamondTemp, have the potential to generate improvements in both safety and efficacy compared with current-generation contact-force-sensing catheters, such as the Biosense Webster ThermoCool SmartTouch and Abbott TactiCath Quartz. These potential benefits result from the ability of these catheters to continuously monitor target tissue temperature and automatically titrate power and/or the tip irrigation rate to produce consistent tissue heating at the desired level. The consistent level of tissue heating theoretically reduces the likelihood of tissue overheating and damage to nearby structures, which can lead to complications such as tamponade, oesophageal injury and phrenic nerve injury.

The aim of this systematic review and meta-analysis was to assess and aggregate the current evidence base regarding the efficacy and safety of temperature-controlled RF ablation compared with ablation with conventional contact-force-sensing catheters.

Methods

The review was conducted in accordance with the PRISMA guidelines and

the review protocol was prospectively registered at PROSPERO (CRD42024500474).

Search Strategy

The MEDLINE, Embase and Web of Science databases were searched from their inception up to 17 January 2024 with the following strategy: ablation AND (radiofrequency OR RF) AND (temperature-control or temperature control or qdot or diamondtemp) AND (atrial fibrillation OR AF OR a fib).

Focused Research Question

The PICO (Patient, Intervention, Comparator, Outcome) research question elements were defined as follows.

- Patient: Adults (aged ≥18 years) with a documented episode of AF lasting at least 30 s.
- Intervention: Temperature-controlled pulmonary vein isolation (PVI) with a novel RF ablation catheter. Novel temperature-controlled RF ablation catheters included only the QDOT MICRO ablation catheter (Biosense Webster) operating in QMODE and the DiamondTemp ablation catheter (Medtronic).
- Comparator: PVI with a conventional contact-force-sensing, non-temperature-controlled RF ablation catheter. Conventional catheters included, but were not limited to, the ThermoCool SmartTouch (Biosense Webster), ThermoCool SmartTouch SF (Biosense Webster) and the TactiCath Quartz (Abbott).
- Outcome: Documented episode of AF or other atrial tachyarrhythmia lasting at least 30 seconds at least 3 months after ablation.

Screening

After the removal of duplicates, two reviewers (BC and BSS) independently screened the abstracts of all returned results against prespecified inclusion and exclusion criteria. Randomised controlled trials and observational studies (single-arm and two-arm) that reported the rate of freedom from AF at least 3 months after PVI via temperature-controlled RF ablation were included. Studies that used a very-high-power, short-duration (vHPSD; e.g. QMODE+) ablation strategy were not included to allow accurate assessment of the temperature-control element without confounding by large differences in ablation strategy. In addition, a recent systematic review and meta-analysis assessing vHPSD versus conventional ablation has adequately assessed papers that use the QDOT MICRO in its vHPSD mode.[3] No specific additional searches were undertaken to identify grey literature. Unpublished articles were not excluded as long as they met the inclusion criteria and reported at least the primary outcome being assessed in this analysis. Conference abstracts were excluded due to the likelihood of a lack of sufficient methodological detail and to avoid the inclusion of overlapping populations with subsequently published articles. Animal studies, letters to editors, supplementary articles, review articles and case reports were also excluded.

A flow chart detailing the screening process is shown in *Supplementary Figure 1*.

Outcomes

The primary outcome assessed was freedom from AF, atrial flutter or other atrial tachyarrhythmias lasting for at least 30 s at least 3 months after ablation.

Secondary outcomes included the rate of repeat ablations during the follow-up period, procedural duration (minutes), fluoroscopy duration (minutes), RF ablation duration (minutes), the number of RF lesions, irrigation volume (ml), average RF power (W), average contact force (g) and the incidence of complications, including pericarditis, cardiac tamponade, atrio-oesophageal fistula formation, cerebrovascular accident, transient ischaemic attack, pulmonary vein stenosis, MI, thromboembolic event, death, vascular access or bleeding complications, phrenic nerve palsy, the formation of char or coagulum on the catheter tip and steam pops.

Data Extraction

Data detailing primary and secondary outcomes were collected as far as possible alongside characteristics of the study and the study population.

Study characteristics collected included study design, total sample size, the sample size in each treatment arm, participant inclusion criteria, the catheters used, planned temperature, power, contact force, ablation duration and irrigation rates for the catheters used, follow-up duration and follow-up modality.

Population baseline characteristics collected included the proportion of the population with paroxysmal AF, the time from onset of AF to ablation, age, male sex, left atrial size, the incidences of hypertension, diabetes and coronary artery disease and left ventricular ejection fraction (LVEF).

The risk of bias in the included studies was assessed by the Cochrane Risk of Bias 2 (RoB-2) Tool for randomised controlled trials and by the Newcastle-Ottawa Scale for two-armed observational studies.

Statistical Analyses

Only studies with both temperature-controlled and conventional treatment groups were included in comparative meta-analyses. All analyses used random-effects restricted maximum likelihood (REML) models. No quantitative assessment of heterogeneity was performed due to the small number of studies included, with summary statistics, such as I^2 are known to be inaccurate in these cases, with CIs of such point estimates of heterogeneity becoming very broad.[4–6] Forest plots are provided for the key comparative analyses to allow a qualitative, visual assessment of heterogeneity. ORs were used to quantify differences in binary outcomes. Unstandardised mean differences with assumed unequal group variances were used to quantify differences in continuous outcomes. Pooled-effects sizes were deemed statistically significant where the calculated p-value was <0.05. Continuous variables are presented as the mean ± SD. For the primary outcome, the effects of small studies and publication bias were assessed quantitatively using Egger's test and qualitatively through funnel plots and trim-and-fill analysis. A meta-regression was performed to assess the impact of population baseline characteristics (the proportion of the population with paroxysmal AF, age, sex, LVEF, hypertension and diabetes) on the rate of freedom from AF in the temperature-controlled group. Subgroup analyses were conducted to assess the impact of the model of temperature-controlled RF ablation catheter used (DiamondTemp versus QDOT MICRO) on freedom from AF. Pairwise comparisons of rates of specific procedural complications were made using ORs.

Statistical analyses were performed using IBM SPSS Statistics Version 28.

Results

Study Characteristics

Seven studies were included, comprising a total of 1,138 patients.[7–13] There was one randomised controlled trial,[8] three prospective comparative observational studies,[7,9,13] and three single-arm prospective observational studies.[10–12] The characteristics of the studies, treatment protocols and baseline participant characteristics are outlined in *Tables 1 and 2*. All

Table 1: Study Characteristics

Study	Design	Population size (n)	Population	Catheters	Catheter settings (target temperature, maximum power, target contact force, irrigation rate)	Antiarrhythmic drugs after ablation	Follow-up duration at endpoint (months)	Endpoint assessment modality	Newcastle-Ottawa scale	Cochrane RoB-2	Funding sources
Iwasawa et al. 2017[7]	Prospective observational	Total: 70 TC: 35 CF: 35	First-time ablation, drug-refractory symptomatic paroxysmal AF	DiamondTemp versus ThermoCool SmartTouch	TC: 60°C, 50 W, 8 ml/min CF: 35 W, >10 g, 30 ml/min	None routinely	6	14 days event monitor	8	N/A	None
Kautzner et al. 2021[8]	Randomised control trial	Total: 482 TC: 239 CF: 243	First-time ablation, drug-refractory symptomatic paroxysmal AF	DiamondTemp versus TactiCath Quartz	TC: 60°C, 50 W, 8 ml/min CF: 10–30 W, 20 g, 17–30 ml/min	None routinely	12	24-h Holter monitor	N/A	Overall: low risk	Medtronic
Potter et al. 2021[12]	Prospective observational (single-arm)	Total: 42 TC: 42 CF: 0	First-time ablation, symptomatic paroxysmal AF	QDOT MICRO	TC: 50°C, 45 W, 15 ml/min	None routinely	3	12-lead ECG	N/A	N/A	Biosense Webster
Guckel et al. 2022[9]	Prospective observational	Total: 113 TC: 45 CF: 68	First-time ablation, drug-refractory symptomatic paroxysmal AF	DiamondTemp versus ThermoCool SmartTouch SF	TC: 60°C, 50 W, 9 s, 9 ml/min CF: 50 W, 20 ml/min	None routinely	6	7-day Holter monitor	8	N/A	None
Starek et al. 2022[10]	Prospective observational (single-arm)	Total: 71 TC: 71 CF: 0	First-time ablation, drug-refractory symptomatic paroxysmal AF	DiamondTemp	TC: 60°C, 50 W, 8 ml/min	None routinely	12	Holter monitor, unclear duration	N/A	N/A	Medtronic
Neuzil et al. 2023[11]	Prospective observational (single-arm)	Total: 60 TC: 60 CF: 0	First-time ablation, symptomatic AF	DiamondTemp	TC: 60°C, 50 W, 8 ml/min	None routinely	12	24-h Holter monitor	N/A	N/A	Medtronic
Valeriano et al. 2023[13]	Prospective observational	Total: 300 TC: 150 CF: 150	First-time ablation, symptomatic AF	QDOT MICRO versus ThermoCool SmartTouch SF	TC: 47°C, 50 W, 4–15 ml/min CF: 25–35 W	None routinely	12	12-lead ECG	8	N/A	None

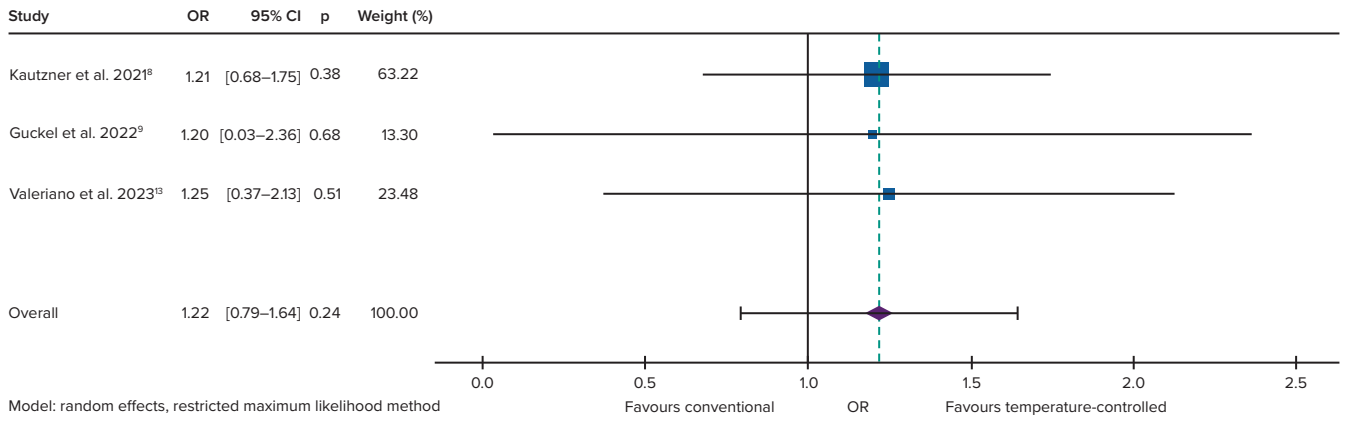
CF = conventional contact force-sensing catheter; TC = temperature-controlled catheter.

Table 2: Population Baseline Characteristics

Study	% With paroxysmal AF	Age (years)	% Male	Left atrial diameter (mm)	Hypertension (%)	Diabetes (%)	Coronary artery disease (%)	Congestive heart failure (%)	LVEF (%)
Iwasawa et al. 2017[7]	TC: 100 CF: 100	TC: 60 ± 10 CF: 63 ± 11	TC: 69 CF: 80	TC: 44 ± 4 CF: 40 ± 5	TC: 77 CF: 49	TC: 17 CF: 9	TC: 14 CF: 20	TC: 0 CF: 3	TC: 64 ± 4 CF: 63 ± 12
Kautzner et al. 2021[8]	TC: 100 CF: 100	TC: 62 ± 11 CF: 63 ± 10	TC: 56 CF: 58.8	TC: 40 ± 6 CF: 41 ± 7	TC: 52.3 CF: 56.8	TC: 8.4 CF: 11.5	TC: 11.3 CF: 11.9	TC: 2.5 CF: 1.2	TC: 59.8 ± 7.2 CF: 60.1 ± 7.1
Potter et al. 2021[12]	TC: 100	TC: 60.3 ± 12.6	TC: 62.8	TC: 38.5 ± 6.43	TC: 55.8	TC: 4.7	TC: 16.3	TC: 2.3	TC: 60.6 ± 5.38
Guckel et al. 2022[9]	TC: 100 CF: 100	TC: 66.04 ± 10.24 CF: 66.56 ± 11.52	TC: 87 CF: 91	TC: 45 ± 5.99 CF: 45.81 ± 12.14	TC: 80 CF: 81	TC: 27 CF: 28	TC: 16 CF: 29	TC: 20 CF: 37	TC: 52.17 ± 4.46 CF: 50.24 ± 7.59
Starek et al. 2022[10]	TC: 100	TC: 59 ± 11	TC: 60.6	TC: 44 ± 5	TC: 74.6	TC: 15.5	TC: 9.9	TC: 2.8	TC: 59.8 ± 7.3
Neuzil et al. 2023[11]	TC: 56.7	TC: 63.9 ± 10.2	TC: 71.7	TC: 44 ± 8	TC: 48.3	TC: 10	TC: 13.3	TC: 1.7	TC: 58.6 ± 7.7
Valeriano et al. 2023[12]	TC: 100 CF: 100	TC: 63.5 ± 10.5 CF: 64.4 ± 10	TC: 68.7 CF: 66	TC: 39.7 ± 6.3 CF: 40.5 ± 64	TC: 42 CF: 57.3	TC: 11.3 CF: 13.3	TC: 11.3 CF: 16.7	Not given	TC: 54.8 ± 6.1 CF: 55.1 ± 10

Unless indicated otherwise, data are given as the mean ± SD. CF = conventional contact force-sensing catheter; LVEF = left ventricular ejection fraction; SD = standard deviation; TC = temperature-controlled catheter.

Figure 1: Comparative Meta-analysis of Rates of Freedom From AF



participants underwent a first ablation procedure for symptomatic AF. Five studies used the Medtronic DiamondTemp catheter[7–11] and two studies used the Biosense Webster QDOT MICRO catheter.[12,13] Follow-up ranged from 3 to 12 months, with Holter monitors used to identify AF recurrence in four studies,[8–11] 12-lead ECG used in two studies,[12,13] and a 14-day event monitor used in one study.[7] No included study routinely gave antiarrhythmic drugs to patients after ablation. Bias assessment with the Newcastle-Ottawa scale for comparative observational studies and the Cochrane RoB-2 scale for randomised controlled trials demonstrated a low risk of bias in all studies assessed.

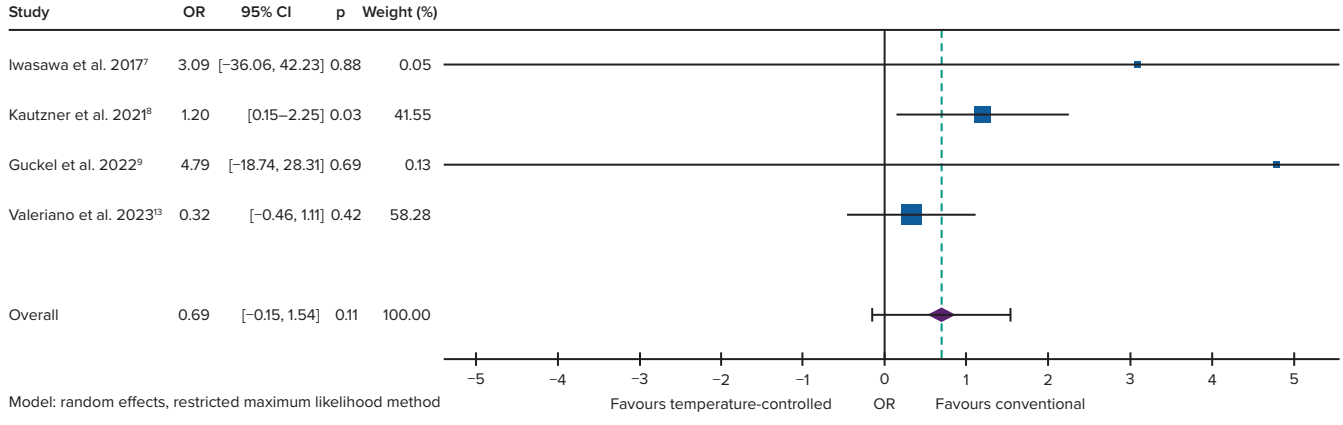
Freedom from AF

Follow-up occurred at a mean duration of 9.0 ± 3.6 months. Comparative meta-analysis demonstrated no significant difference in rates of freedom from AF at follow-up between temperature-controlled and conventional ablation (n=3 studies; OR 1.22; 95% CI [−0.79, 1.64]; p=0.24; *Figure 1*). Patients treated with temperature-controlled ablation had a pooled rate of freedom from AF at follow-up of 81.7% (n=3 studies; 434 patients). Patients treated with conventional ablation had a pooled rate of freedom from AF at follow-up of 78.1% (n=3 studies; 461 patients). Quantitative (Egger's coefficient=0.19; p=0.60) and qualitative measures (no additional studies imputed by trim-and-fill analysis, symmetrical funnel plot) of the impact of small study effects and publication bias revealed no significant effect (*Supplementary Table 1 and Supplementary Figure 2*).

When including non-comparative studies, a meta-analysis of proportions demonstrated a pooled rate of freedom from AF at follow-up of 79.9% for patients treated with temperature-controlled ablation (n=7 studies; 642 patients; 95% CI [73.3%, 86.5%]; *Supplementary Figure 3*). Meta-regression revealed no significant impact of age (p=0.75), sex (p=0.67), hypertension (p=0.36), diabetes (p=0.24), coronary artery disease (p=0.40), or LVEF (p=0.94). A significant association was found for left atrial diameter (p<0.01) in the temperature-controlled group, with smaller left atrial diameters being associated with higher rates of freedom from AF at follow-up.

Subgroup analysis demonstrated a lower rate of freedom from AF between patients treated with the DiamondTemp catheter (76.0% freedom at a mean follow-up of 9.6 ± 3.3 months, n=5 studies, 450 patients) and patients treated with the QDOT MICRO catheter (88.5% at a mean follow-up of 7.5 ± 6.4 months, n=2 studies, 192 patients).

Figure 2: Comparative Meta-analysis of Total Complication Rates



Secondary Procedural Outcomes

Rates of repeat ablation during follow-up were not significantly different between groups (n=3 studies; OR 0.93; 95% CI [0.51, 1.69]; p=0.81). Total procedural duration was significantly shorter for temperature-controlled than conventional ablation (n=3 studies; mean difference −13.5 minutes; 95% CI [−17.1, −10.0 minutes]; p<0.001). Fluoroscopy duration was not significantly different between groups (n=3 studies; mean difference −0.5 minutes; 95% CI [−1.4, 0.4 minutes]; p=0.31). Total RF ablation duration was significantly shorter in patients treated with temperature-controlled ablation catheters than those treated with conventional catheters (n=3 studies; mean difference −8.9 minutes; 95% CI [−10.3, −7.5 minutes]; p<0.01). The total number of lesions was not significantly different between groups (n=3 studies; mean difference −3.9; 95% CI [−8.9, 1.1]; p=0.13).

Complications

Comparative meta-analysis demonstrated no significant difference in total complication rates between groups (n=4 studies; OR 0.69; 95% CI [−0.15, 1.54]; p=0.11; *Figure 2*). There were no significant differences in the incidence of any individual complication between temperature-controlled and conventional ablation (*Table 3*).

When including non-comparative studies, meta-analysis of proportions revealed a pooled total complication rate of 3.4% for patients treated with temperature-controlled ablation (n=7 studies, 642 patients; 95% CI [0.9%, 5.9%]; *Supplementary Figure 4*).

Subgroup analysis demonstrated a near-significant difference (OR 2.65; 95% CI [0.91, 7.74]; p=0.08) in total rates of complications between patients treated with the DiamondTemp catheter (5.3%, n=5 studies, 450 patients) and patients treated with the QDOT MICRO catheter (2.1%, n=2 studies, 192 patients).

Discussion

This systematic review and meta-analysis is the first to compare temperature-controlled AF ablation with novel temperature-controlled catheters to conventional ablation using contact-force-sensing catheters.

Temperature-controlled ablation was associated with no statistically significant difference in freedom from AF at a mean follow-up of 9 months relative to conventional ablation (80.9% versus 77.4%, respectively). The pooled rate of freedom from AF in all patients treated with temperature-controlled ablation of 79.9% is comparable to the rates observed in major randomised controlled trials such as FIRE AND ICE, which reported 78.6% (n=294/374) freedom from AF in patients treated with cryoballoon ablation,[14] and ADVENT, which reported 83.3% (n=254/305) freedom from AF in patients treated with pulsed-field ablation.[15]

Egger's test for funnel plot symmetry was performed to estimate the risk of publication bias on the assessment of the primary outcome. This analysis demonstrated no significant effect and was supported by visual assessment of the plot, which demonstrates tight clustering of individual study effect sizes around the overall effect size.

Meta-regression demonstrated no significant association with participants' baseline age, sex, hypertension, diabetes, coronary artery disease and LVEF. A significant association was found between smaller left atrial diameter and higher freedom from AF at follow-up – an effect that has been previously characterised.[16]

Subgroup analysis identified higher freedom from AF in patients treated with the Biosense Webster QDOT MICRO catheter than the Medtronic DiamondTemp catheter (88.54% versus 76.00%, respectively). The lack of

Table 3: Individual Complication Rates

Complication	Temperature-controlled ablation	Conventional ablation	P-value
Pericarditis	3/639 (0.47%)	5/491 (1.02%)	0.29
Tamponade	4/638 (0.63%)	3/439 (0.61%)	0.97
Atrio-oesophageal fistula	0/642 (0.00%)	0/496 (0.00%)	0.90
Stroke	1/641 (0.16%)	1/495 (0.20%)	0.86
Transient ischaemic attack	3/639 (0.47%)	1/495 (0.20%)	0.47
Pulmonary vein stenosis	0/642 (0.00%)	0/496 (0.00%)	0.90
MI	0/642 (0.00%)	0/496 (0.00%)	0.90
Thromboembolism	0/642 (0.00%)	0/496 (0.00%)	0.90
Death	0/642 (0.00%)	0/496 (0.00%)	0.90
Vascular access and bleeding	9/633 (1.42%)	6/490 (1.22%)	0.78
Phrenic nerve injury	1/641 (0.16%)	0/496 (0.00%)	0.61
Coagulum formation	0/484 (0.00%)	0/428	0.95
Char formation	0/484 (0.00%)	0/428 (0.00%)	0.95
Steam pops	7/548 (1.28%)	3/425 (0.71%)	0.39

Data show the number of patients with the complication/total number of patients and percentages in parentheses.

a direct comparison between the two temperature-controlled catheters within any single study and with the small overall number of studies included in the analysis make this result difficult to verify. There is also potential for significant confounding due to multiple factors. Operator proficiency may have varied between the two catheters, with the QDOT MICRO catheter having been more widely used in the clinical literature due to its application in vHPSD ablations.[17–25] Another potential contributor to this result is the difference in assessment of recurrence at follow-up, with both QDOT studies using a 12-lead ECG at follow-up, whereas all DiamondTemp studies used a Holter monitor or event monitor for at least 24 hours. Therefore, episodes of AF could have been missed by the QDOT studies, resulting in an overestimation of the rate of freedom from AF. In addition, the mean follow-up duration was 2.1 months shorter for the QDOT than DiamondTemp studies, with rates of freedom from AF likely to have decreased in the QDOT studies in the following months. If these results were genuine, one potential explanation could be lack of contact-force sensing in the DiamondTemp catheter, which could potentially allow a higher-quality lesion formation with the QDOT MICRO and a more durable ablation.

Temperature-controlled ablation was shown to yield significant decreases in total procedural duration and RF ablation duration (13.50 minutes and 8.90 minutes, respectively) compared with conventional ablation. These results are likely to reflect differences in ablation strategies between treatment groups, with most studies using slightly higher-powered and shorter-duration applications in their temperature-controlled group. This result is unlikely to reflect a difference in lesion diameter because the number of lesions per patient was not significantly different between groups.

No significant differences between temperature-controlled and conventional ablation were found when considering other secondary outcomes, including rates of repeat ablation during follow-up and fluoroscopy duration. The lack of significant difference in fluoroscopy duration despite the significant reduction in total procedural duration in the temperature-controlled group implies that temperature-controlled catheters were not significantly faster in gaining access to the pulmonary veins after initial vascular access was gained.

The majority of the total reduction in procedure time (−13.5 minutes) can be accounted for by the significant mean reduction in ablation time (−8.9 minutes). However, approximately 4 minutes of mean time saved is unaccounted for by this analysis. Given that fluoroscopy duration cannot account for this gap, other procedural components, including vascular access, electrophysiological mapping and assessment of the completion of PVI, may be quicker in temperature-controlled ablation. These factors were not assessed by this analysis.

Complications were rare in both groups, with no significant difference in aggregated rates of complications between temperature-controlled and conventional ablation. The majority of complications in both groups were related to vascular access and bleeding, with no instances of procedure-related mortality in any study. The pooled rate of complications (including death and stroke) in patients treated with temperature-controlled ablation of 3.4% is lower than the equivalent rate seen in the FIRE AND ICE cryoballoon group (8.6%; n=32/374)[14] and comparable to the ADVENT pulsed field ablation group (2.3%; n=7/305).[15]

There was a small difference in total complication rates between the temperature-controlled catheter models (DiamondTemp 5.3% versus QDOT MICRO 2.1%; p=0.08). This result is primarily due to differences in the rates of two specific complications between catheters. First, seven instances of steam pops were reported in one study using the DiamondTemp catheter, with none reported in any other study using either temperature-controlled catheter.[8] Second, vascular access and bleeding complications were reported a total of eight times in three of the five studies using DiamondTemp,[8–10] compared with only one instance of such complications in the two studies using QDOT MICRO.[12]

When considering the real-world impact of the findings of this analysis, the demonstrated benefits of temperature-controlled ablation over conventional ablation in PVI are limited. The primary benefit found was a small but significant reduction in total procedure time of 13.5 minutes. The demonstrated benefits may only be sufficient to motivate adoption in some centres, particularly those where the associated financial implications and requisite operator proficiency are not likely to be significant barriers. A recent systematic review and meta-analysis comparing vHPSD and conventional ablation using both the QDOT MICRO operating in QMODE+ and the Abbott FlexAbility SE catheters demonstrated significant benefits in freedom from AF and procedural duration compared with a conventional ablation strategy.[3] As a result, centres are more likely to consider adopting temperature-controlled catheters in order to perform vHPSD ablations rather than for conventional ablation strategies, given the robustly demonstrated improvement in freedom from AF. Alternatively, given the recent advances and promise in pulsed field ablation, many centres may choose to invest limited time and financial resources into this technology instead.[15,26–28]

Limitations

The number of studies included was small, with only four comparative studies included, limiting the accuracy of the results. In particular, there is a notable deficiency of randomised controlled trials assessing temperature-controlled PVI versus conventional PVI. Several studies in the wider literature used the QDOT MICRO catheter in its QMODE+ ablation mode, which is not truly temperature-controlled, instead only using its thermocouples to avoid tissue overheating during vHPSD ablations.[17–25]

The forest plots and Egger's tests for publication bias were limited by low statistical power due to the small number of studies included. No grey literature studies met the criteria for inclusion in the analysis, so there is potentially some degree of publication bias that could not be assessed due to the rigour of the screening process.

One of the four comparative studies included did not report rates of freedom from AF in the conventional ablation group, preventing its inclusion in a comparative meta-analysis of this outcome.[7] No study reported rates of freedom from AF at follow-up durations longer than 12 months. It is known that the recurrence rate continues to rise over time; therefore, studies with follow-up durations of ≥5 years are desirable. Two studies assessed freedom from AF at follow-up simply through a 12-lead ECG, which is very likely to miss episodes of paroxysmal AF and result in overestimation of the rate of freedom from AF.[12,13] Future studies should endeavour to assess freedom from AF with 24-hour Holter monitors in all patients as standard. A 12-lead ECG is not sufficient to claim freedom from AF given the sporadic and unpredictable occurrence of instances of AF, particularly given that the majority of patients enrolled in PVI trials have paroxysmal AF rather than persistent or permanent AF.

The meta-regression analysis was limited in its power by the small number of studies included. Conventional regression analyses are able to use

more highly granular data at the level of the individual patient, whereas meta-regression can only assess for associations between the study population's averaged characteristic and a given outcome, with analysis becoming more powerful with a higher number of included studies, rather than a large number of included patients necessarily.

Conclusion

Temperature-controlled RF ablation results in a non-inferior rate of freedom from AF at follow-up and significant decreases in total procedural time and RF ablation time compared with conventional ablation. The incidences of complications do not differ significantly between temperature-controlled and conventional ablations. Further randomised controlled trials are needed to assess for benefits in other procedural characteristics, patient comfort and long-term rates of freedom from AF. ❑

Clinical Perspective

- Temperature-controlled ablation is non-inferior to conventional ablation with regard to freedom from AF in the medium term after PVI.
- Temperature-controlled ablation is associated with a small but significant decrease in total procedure time compared with conventional ablation.
- Procedural complications are similarly uncommon between temperature-controlled and conventional ablation.
- The demonstrated benefits of temperature-controlled ablation may not be sufficient to prompt some centres to pursue this technology over conventional ablation.

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