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ORIGINAL ARTICLE

Radiation Exposure Optimisation During AF Ablations Utilising the Cryoballoon Ablation System

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Background Radiation risk minimisation during cardiac catheterisation, particularly atrial fibrillation (AF) ablation procedures, requires a multifaceted approach involving both technique and technology.

Objective To evaluate radiation dose associated with cryoballoon compared to conventional radiofrequency (RF) AF ablation procedures.

Methods Consecutive patients undergoing AF ablation were collected in a single-centre registry. Radiation and procedural data for index AF ablation procedures using four ablation techniques were compared: RF ablation with and without the anti-scatter grid (RF Grid and RF Gridless), and cryoballoon ablation utilising first and second-generation Medtronic Arctic Front Cryoballoons (Cryo; Arctic Front, Medtronic, Minneapolis, MN, USA), with and without 3D imaging during fluoroscopy (Cryo 3D and Cryo).

Results We studied 418 patients; 30 RF Grid, 68 RF No Grid, 12 Cryo 3D and 308 Cryo. The dose area product (DAP; Gy cm^2), adjusted for patient standardised weight of 80 kg, was significantly higher for the Cryo 3D (21.91) and RF Grid (7.31) than the Cryo (2.13) and RF Gridless (3.31) groups; as a result, Cryo 3D was discontinued and RF Grid was only used when clinically required. Comparing the remaining groups, DAP for Cryo was significantly lower than RF Gridless ($p < 0.001$) mainly attributable to a difference in fluoroscopy use (13.2 vs. 17.3 mins; $p < 0.001$). Cryo procedure time was also significantly shorter (80 mins vs. 133 mins; $p < 0.01$).

Conclusion Cryoballoon AF ablations can be performed efficiently using Gridless fluoroscopy techniques achieving significant reduction in radiation exposure and procedure time while maintaining safety and efficacy. In this observational study, cryoballoon AF ablations compare favourably to conventional RF ablations in terms of these parameters.

Keywords Atrial fibrillation • Ablation • Radiofrequency • Cryoballoon • Fluoroscopy • Radiation

Introduction

Catheter ablation for the treatment of atrial fibrillation (AF) has emerged as an important alternative to pharmacological therapy. Ablation offers advantages including AF symptom control, medication reduction and associated side effects, and reduced hospitalisation visits. Consequently, the number of AF ablations performed globally has increased over the last decade. AF ablations, however, are not without risks; the extensive use of imaging to guide catheter positioning has

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resulted in AF ablations being ranked amongst the highest radiation risk procedures in routine clinical use [1]. Radiation utilisation poses a risk to the patient, operator, and health professionals directly involved in the procedure [2].

Published studies have previously demonstrated that reduction in radiation exposure can be achieved by several simple, highly effective, methods. Careful attention to imaging system configuration (balancing dose rate and clinically appropriate image quality) coupled with use of low frame rates and minimal use of high-dose digital acquisition can limit radiation risk to patients undergoing diagnostic and therapeutic electrophysiology (EP) procedures. Limiting fluoroscopic screening to the posterior-anterior (PA) orientation [1,3], removal of the anti-scatter grid (gridless) during EP procedures [3] and use of transoesophageal echocardiography (TOE) and intracardiac echocardiography (ICE) [4] can also have a significant impact on AF ablation procedure radiation dose.

In this retrospective cohort study, we evaluated radiation exposure being optimised over time during routine AF ablations utilising the first and second generation cryoballoon ablation system (Cryo; Arctic Front, Medtronic, Minneapolis, MN, USA) to achieve pulmonary vein isolation (PVI) and compare it to conventional radiofrequency (RF) AF ablation. Our evaluation confirms the safety and efficacy of this technique through the implementation of a real-time monitoring program designed to detect potentially negative changes in clinical outcome.

Material and Methods

Patient Population

Procedural, technical, and demographic data for consecutive AF ablation procedures performed at St. Andrew's War Memorial Hospital between February 2012 and December 2017 using RF and Cryo ablation technologies were collected prospectively in an observational registry designed for quality assurance and outcomes research purposes. While patients both in their index ablation procedure or a retreatment for previously failed ablation were tracked in the registry, only index ablation procedures (n = 418) were included in the present analysis to simplify data interpretation. Procedures were performed by a single operator in a single EP laboratory, thereby minimising imaging system and clinical team practice variation. The UnitingCare Health Human Research Ethics Committee reviewed and approved this research and did not require individual patient consent.

Pre-Ablation Investigations

Computed tomographic (CT) scanning with left atrium (LA) model construction of pulmonary veins (PV) was routinely performed prior to the patient undergoing the initial AF ablation using the Siemens Artis Imaging platform (Erlangen, Germany). The estimated exposure of 0.6-1.0 mSv was based on the standard protocol used for these cases. Knowledge of the PV anatomy prior to the ablation procedure assisted in selecting the most appropriate ablation technique. For example, a left common PV anatomy might be considered more appropriate to be treated with RF, as would a history of documented atrial flutter. Transoesophageal echocardiography was performed on patients in AF at the time of admission, and those deemed to be at high risk for formation of LA thrombus did not go on for ablation. Intracardiac echocardiography was not used in these patients and therefore did not influence radiation doses.

Ablation Procedure

Catheter ablation proceeded using a commonly employed technique as described elsewhere [5]. Briefly, patients underwent general anaesthesia, uninterrupted warfarin therapy, pressure and oesophageal temperature monitoring was performed. The right femoral vein was accessed, and fluoroscopic and haemodynamic guidance was used for transseptal puncture.

For each Cryo procedure, the Cryo catheter was passed into the LA, positioned in the PV antrum, and contrast dye was injected to assess PV occlusion with fluoroscopy. When occlusion was confirmed, at least two cryo-applications of 180–240 seconds were applied to each PV.

For each RF ablation procedure, the irrigated-tip mapping and ablation catheter (FlexAbility Irrigated, St. Jude Medical, St. Paul, MN, USA or Thermocool SmartTouch, Biosense Webster, Diamond Bar, CA, USA) was introduced into the LA and a three dimensional (3D) model was generated using the electro anatomical (EA) mapping systems and merged to guide catheters. Targeting the ipsilateral PVs with RF lesions, a wide area, circumferential, antral PVI procedure was performed.

At the completion of all ablation procedures, entrance and exit block was confirmed with pacing manoeuvres. Pulmonary vein isolation was considered complete upon observed elimination of PV potentials in sinus rhythm and upon PV to LA dissociation 20 minutes after the ablation. In-hospital complications were recorded. Patients were usually sent back to their referring physicians for longer term follow-up.

Gridless Imaging Technique

All procedures were performed on a Siemens Artis Zee, Biplane imaging platform (Erlangen, Germany). To specifically optimise the system for EP cases, it was configured with a detector input dose rate mode; digital acquisition was minimised, or avoided entirely; fluoroscopic frame rates reduced and preferentially performed in the PA projection; and routine removal of the anti-scatter grid (gridless) from the cardiac imaging system, which has been previously validated as a safe imaging technique for EP procedures, including AF ablation [3]. Gridless imaging can be efficiently performed at any time and changed at physician discretion to alter the image quality as necessary (e.g., in larger patients or during transseptal punctures).

Radiation and Clinical Outcome Data Collection

Radiation use following each procedure was documented from system-reported total case fluoroscopy time (FT), the number of digital frames acquired, and the total procedural dose-area-product (DAP). These metrics, derived directly from the imaging system, are consistent with those recommended by Miller et al. (2004) for use in quality improvement processes [6].

In addition to these standard technical metrics, the effective dose (E) for each procedure was estimated and compared [7]. For each procedure, E has been estimated using a DAP to E conversion factor of 0.14 mSv/Gy cm^2 (for a PA projection) [3]. To account for variations in system output due to patient size, a correction factor, derived using the method described by Chapple et al. (1995), was applied to the DAP for each case [8]. For this study, however, median patient characteristics of 173 cm and 80 kg (giving an effective diameter of 24.3 cm) were used in place of the standard mean values of 170 cm and 70 kg (effective diameter of 22.9 cm).

Statistical Analysis

Unless otherwise stated, continuous variables are summarised as median and interquartile (Q1–Q3) range as not all data fields were normally distributed. Categorical variables are presented as frequencies and percentages. Descriptive statistics were calculated by imaging group: RF with grid, Cryo with 3D imaging, RF with no grid (RF Gridless), and Cryo. For two sample comparisons involving continuous variables, the Mann–Whitney U test for independent samples were used; for tests comparing three or more groups, the Kruskal Wallis test was employed. The Pearson $\chi 2$ test or Fisher's exact test was used to compare categorical variables for RF Gridless and Cryo groups only. All tests were two-sided, and significance was defined at the 0.05 level. Kaplan-Meier curves comparing Cryo and RF Gridless were generated and compared using the log-rank (Mantel-Cox) test.

Results

Baseline Patient Characteristics

Ablation procedures were performed on 418 adult patients (Table 1). In total, 320 patients with index Cryo procedures and 98 patients with index RF were examined in the study. Median patient age was 63 years (IQR: 20–83), and 66% male. Patients with Cryo procedure versus RF were more likely to be larger in median weight (88 kg vs. 82 kg, p = 0.025), and subsequently higher BMI (28.1 kg/m^2 vs. 26.9 kg/m^2; p = 0.018; Table 1). The difference in patient body habitus between the two patient cohorts underscores the need to account for patient's size when comparing radiation use associated with these techniques. There were no additional differences between ablation groups.

Radiation and Clinical Outcomes

Chronologically, conventional RF ablation preceded use of Cryo. In the RF cohort, the first 30 AF cases were performed after installation of a new imaging system. During early use of the imaging system, a conventional EP imaging protocol was followed to establish a baseline for system performance. In this mode, with the grid in place, the observed median weight-adjusted E was 1.02 mSv (Table 2). Once baseline performance characteristics had been established, gridless imaging was explored. Routine use of the grid was discontinued only after it was confirmed that gridless imaging could safely deliver lower radiation doses without negatively impacting procedural outcome. The median weight-adjusted E among the 68 RF Gridless cases was 0.46 mSv. To reiterate, grid use was available at clinician discretion when image quality was deemed unsatisfactory due to excessive scatter degradation.

The initial 12 Cryo cases were performed with the 3D dataset acquired using the rotational angiography capabilities of the imaging system (Cryo 3D). Review of these cases, however, revealed this protocol had a median weight-adjusted E of 3.07 mSv. As this E was substantially higher than observed with the pre-existing RF techniques, and there were no identified clinical advantages, this 3D protocol was discontinued in favour of the use of 3D data acquired prior to the patient entering the EP suite. The weight-adjusted E among the subsequent 308 Cryo patients, without in-lab 3D acquisition, was 0.30 mSv, a 90.2% reduction in radiation exposure.

The trend over time of technology and technique used for patient treatment is depicted in Figure 2. Comparing the remaining groups with the optimal imaging techniques, patients in the Cryo group were exposed to a statistically significant lower radiation dose compared to patients in the RF Gridless group ($p < 0.001$; Figure 1A).

For comparison to previous publications, FTs are also provided. Median FT was 17.3 and 13.2 minutes in the RF Gridless and Cryo imaging groups, respectively ($p < 0.001$; Table 2; Figure 1B). Median procedure times were 127.5, 110, 132.5, and 80 minutes in the RF Grid, Cryo 3D, RF Gridless, and Cryo imaging groups, respectively (Table 2). Procedure time was significantly shorter in the Cryo group than in the RF Gridless group ($p < 0.001$; Figure 1C).

Clinical Outcomes

Acute procedure success was similar between RF Gridless vs. Cryo groups (98% vs. 96%, p = 0.322; Table 2). Although some patients did experience recurrent AF during the follow-up period, after one year of follow-up, 84% of RF Gridless and 82% of Cryo patients were free from procedural failure or the need for a repeat procedure (Figure 3). After full follow-up to 42 months, there was no significant difference in repeat procedure rates between the RF Gridless group vs. Cryo group (27% vs. 26%; log-rank p = 0.688).

Safety

A total of six major procedural adverse events (requiring intervention to resolve) were documented. In the RF Gridless group, two cardiac tamponades occurred while in the Cryo group, two puncture site complications (bleeding/haematoma) and two phrenic nerve injuries were noted, with no difference between groups (p = 0.629).

Table 1 Patient baseline and procedural characteristics.

	Imaging Arm				P-value[a]
	RF Grid	CRYO-3D	RF Gridless	CRYO	
Patient Characteristics					
N	30	12	68	308	
Age (yrs)	57 (50–66)	63 (57–65)	63 (58–68)	63 (55–68)	0.956
Male, n (%)	22 (73%)	12 (100%)	42 (62%)	200 (65%)	0.682
Height (cm)	179 (173–181)	178 (173–181)	176 (153–195)	176 (152–200)	0.337
Weight (kg)	89 (79–98)	97 (88–107)	82 (70–98)	88 (78–100)	0.025
Body Surface Area (m^2)	2.07 (1.97–2.16)	2.15 (2.03–2.26)	2.01 (1.89–2.16)	2.02 (1.9–2.18)	0.353
Body Mass Index (kg/m^2)	28.6 (25.1–30.4)	29.9 (28.2–32.0)	26.9 (23.8–30.3)	28.41 (25.9–31.5)	0.018
Atrial Fibrillation Classification					
Paroxysmal, n (%)	29 (96.7%)	12 (100%)	65 (94.2%)	290 (94.2%)	N/A
Persistent, n (%)	1 (3.3%)	0 (0%)	3 (4.3%)	18 (5.8%)	N/A
Permanent, n (%)	0 (0%)	0 (0%)	1 (1.4%)	0 (0%)	N/A
Procedural Characteristics					
Contrast (ml)	0 (0–0)	55 (37.8–70.0)	0 (0–0)	43 (30–60)	<0.001
Grid use, n (%)	30 (100%)	8 (66.7%)	0 (0%)	10 (3.0%)	0.675
EA Mapping Technology					
Carto 3/Carto XP, n (%)	18 (61%)	N/A	39 (58%)	N/A	N/A
Ensite/Ensite Velocity, n (%)	12 (39%)	N/A	29 (42%)	N/A	N/A
Number of ablations, median (IQR)	21 (17, 24)	9 (9,11)	18 (12, 27)	9 (8,11)	N/A
Total ablation time (mins), median (IQR)	62 (54,68)	45 (43,50)	55 (44,80)	31 (26,39)	N/A

[a]P-values are calculated comparing RF Gridless to Cryo groups.

Discussion

In this study, radiation exposure during AF ablation procedures was compared between cryoballoon to conventional RF catheters at a single site that employs near real-time monitoring of radiation use and clinical practice. Overall, very low radiation levels were observed after implementing several imaging technique optimisation strategies (Figure 4). Even in the two highest radiation exposure groups, conventional RF Grid and Cryo 3D, reported weight-adjusted effective doses 1.02 mSv and 3.07 mSv (Table 1, Figure 1A) are far less than the 15 mSv average patient dose for catheter ablation procedures reported by Heidbuchel et al. (2014) [1]. Atrial fibrillation ablation procedures utilising cryoballoon catheters resulted in significantly lower radiation exposures than those utilising RF catheters. Initially, 3D imaging and grid techniques were employed, but as real-time monitoring detected trends towards significantly greater radiation exposure, these techniques were abandoned and the Cryo without 3D and RF gridless groups continued in follow-up. The trend over time towards significant decline in radiation levels (Figure 2) was also observed in 12-year observational study by Voskoboinik et al. (2017) [9].

This is the first study to our knowledge to report E in cryoballoon procedures. In the statistically compared groups,

Table 2 Procedure outcomes by imaging group.

Metric	Imaging Arm				P-value[a]
	RF Grid	CRYO-3D	RF Gridless	CRYO	
N	30	12	68	308	
Procedure time (mins)	128 (120–154)	110 (100–136)	133 (102–185)	80 (68–94)	<0.001
FT[b] (mins)	19.9 (17.7–26.0)	24.5 (20.6–25.7)	17.3 (12.6–25.2)	13.2 (11.0–17.6)	<0.001
DAP[c] (Gy cm^2) (Raw)	9.02 (4.28–13.36)	23.95 (23.1–35.62)	2.51 (1.69–5.24)	2.26 (1.46–3.41)	0.025
DAP[c] (Gy cm^2) (Adj)	7.31 (5.75–12.89)	21.91 (18.2–26.42)	3.31 (2.29–4.75)	2.13 (1.65–3.08)	<0.001
E[d] (mSv) (Raw)	1.26 (0.6–1.87)	3.35 (3.23–4.99)	0.35 (0.24–0.73)	0.32 (0.2–0.48)	N/A
E[d] (mSv) (Adj)	1.02 (0.81–1.8)	3.07 (2.55–3.7)	0.46 (0.32–0.67)	0.30 (0.23–0.43)	N/A
Acute success (%)	93%	100%	98%	96%	0.322
12-month free from acute failure or repeat procedure	N/A	N/A	84%	82%	N/A
Safety events					
Puncture Site (Bleed/Harmotome/Ooze)	0 (0%)	0 (0%)	0 (0%)	2 (0.6%)	N/A
Tamponade	0 (0%)	0 (0%)	2 (2.9%)	0 (0%)	N/A
Phrenic Nerve Injury	0 (0%)	0 (0%)	0 (0%)	2 (0.6%)	N/A
Total safety event	0 (0%)	0 (0%)	2 (2.9%)	4 (1.3%)	0.629

Abbreviations: [b]FT: fluoroscopy time; [c]DAP: Dose Area Product; [d]E: Effective Dose.
[a]p-values are calculated comparing RF Gridless to Cryo groups.

median weight-adjusted E was 0.30 mSv for Cryo and 0.46 mSv for RF ($p < 0.001$). While AF ablations have traditionally been considered amongst interventional imaging procedures with the highest radiation risk [1], the levels reported in this study are only slightly higher than plain chest radiography (0.1mSv) and similar to mammography (0.4 mSv) [10]. Given that these rates represent a dose comparable to 10 days–7 weeks of natural background radiation [7], this study demonstrates that it is possible for AF ablation procedures to be successfully performed within a low range of exposure.

While E has not been previously reported for cryoballoon procedures, DAP measurements are available in literature for comparison purposes. The reported median DAP rates (2.13 Gy cm^2 for Cryo and 3.31 Gy cm^2 for RF Gridless) are similar to the 2.85 Gy cm^2 recently reported by Reissmann et al. (2017) [11], a study that reduced DAP by using fluoroscopy instead of filming when assessing PV occlusion, lowering the frame rate and pursuing maximal collimation. However, the present results are significantly lower compared to other previously reported ranges of DAP (48.5-77.3 Gy cm^2) within studies that included both catheter types [12,13]. The lower levels observed are likely due to different imaging practices, as the published levels are similar to the RF Grid and Cryo 3D groups in our early patients. Additionally, each of the former studies found RF to be significantly lower DAP than Cryo, whereas the present study measured Cryo to be significantly lower than RF. Further prospective comparison is warranted. The lowest non-zero observed DAP published in the literature for Cryo was 1.56 Gy cm^2 in a group that used ICE, skipped PV angiography prior to cryoballoon inflation, and avoided fluoroscopy wherever possible [4]. For RF, the lowest non-zero observed DAP was 0.17 Gy cm^2 using general anaesthesia, transoesophageal echocardiography, and contact force sensing RF catheters [14]. This investigation corroborates these studies that minor adjustments to imaging technique can deliver safe and effective doses for both cryoballoon and RF procedures.

Many studies use FT as a surrogate measure for radiation and are, therefore, reported more commonly. Our study showed a similar trend in FT to that already described for E and DAP across study groups. Namely, FT was overall lower than other studies and significantly lower in the Cryo group (13.2 mins) vs. RF group (17.3 mins; $p < 0.001$). These FTs differ from the recently reported FIRE AND ICE trial results, which reported longer FT overall and Cryo longer FT than RF (22 vs. 17 mins; $p < 0.001$) [15]. As with variations

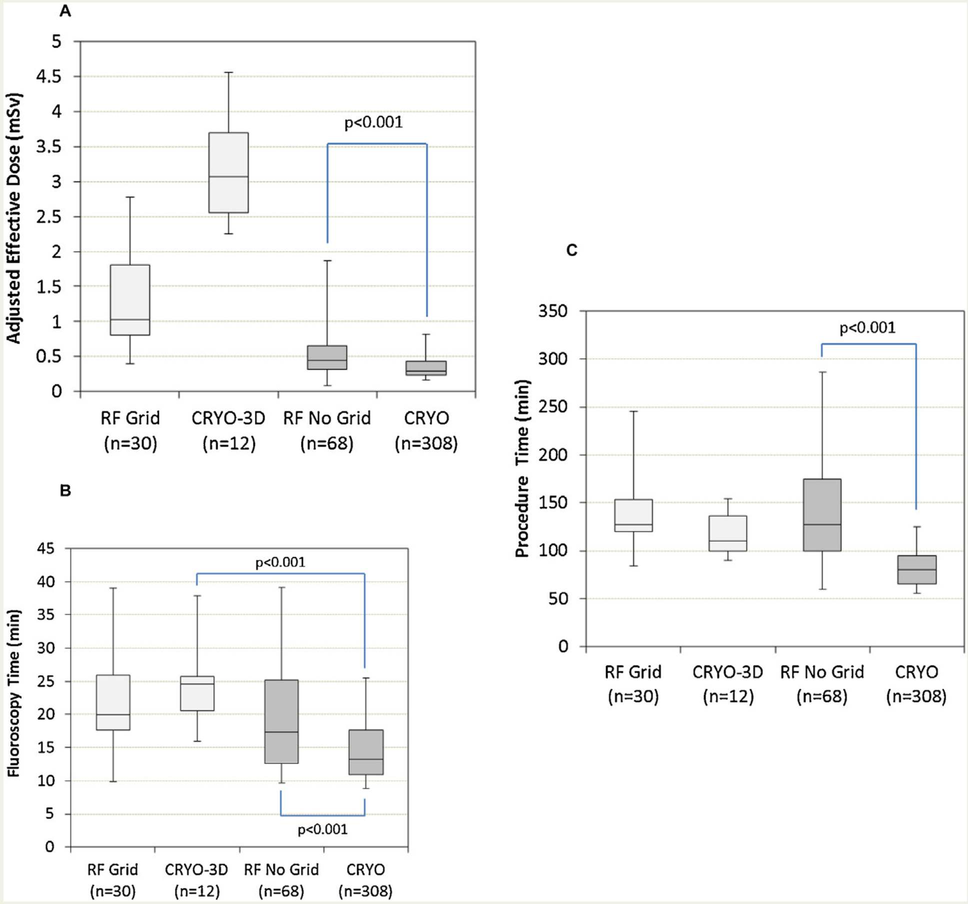

Figure 1 A) Box plot for weight-adjusted effective dose (mSv) by imaging group. B) Box plot for Fluoroscopy Time (mins) by imaging group. C) Box plot for Procedure Time (mins) by imaging group.

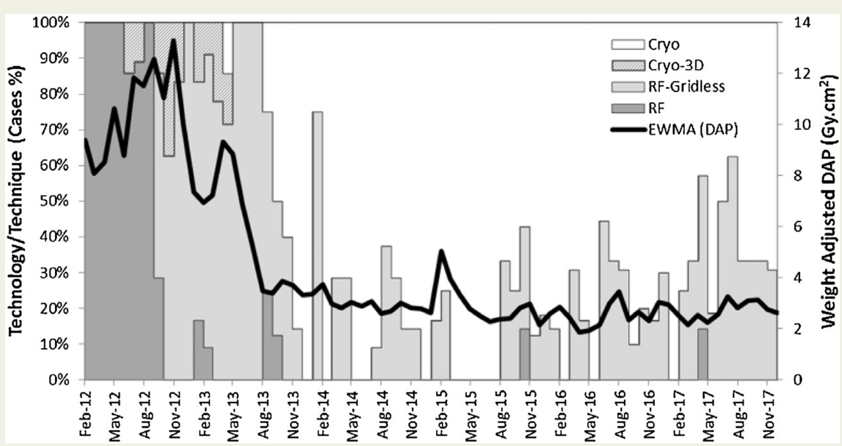

Figure 2 Exponentially weighted moving average (EWMA) chart of DAP including pattern of use of technologies and techniques over time.

observed E and DAP results across multiple studies, this specific difference could be due to varying imaging methodologies, ablation techniques, or operator experience/preference.

Interestingly, the alarming discrepancy observed for E between the Cryo 3D vs. Cryo group and the RF grid vs. RF Gridless group (Figure 1A) was not observed in the FT (Figure 1B). Potentially, the majority of mSv in 3D cases was the result of acquiring the 3D dataset using high dose digital acquisition (which does not contribute to the recorded FT). If FT alone were the sole metric considered when monitoring radiation safety levels, patients may have continued to

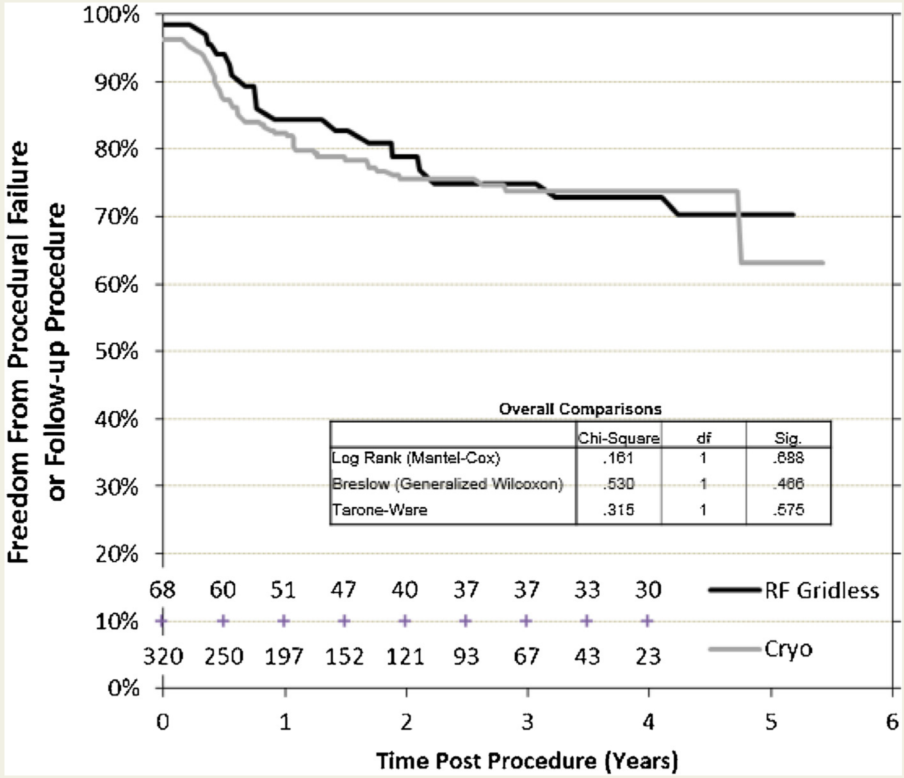

Figure 3 K-M curve for repeat ablations.

Keys to Low Radiation Risk in EP

1. Image at the lowest frame rate (<5 pps) possible
2. Avoid use of high dose digital acquisitions
3. Avoid use of steep angulations (posterior-anterior (PA) if possible)
4. Image with the Anti-Scatter grid removed whenever possible
5. Use a setting with clinically appropriate dose/frame
6. Routinely monitor and evaluate radiation dose and clinical outcomes to avoid exposure creep

Figure 4 Keys to low radiation risk in electrophysiology (EP).

receive undue exposure in the 3D group and Grid group. While the importance of monitoring dose has already been emphasised [1], the discrepancy in this study further illustrates the importance of measuring and reporting radiation dose (DAP and/or E) in addition to FT.

Beyond studies that explore ablation procedures with low fluoroscopy, additional studies have investigated cryoballoon [16,17] procedures and RF [18] procedures with zero fluoroscopy using ICE, augmented reality, navigation systems, etc. While these studies achieved little to no radiation exposure, they may incur increased procedure time and/or increased cost. Consequently, these techniques may not be repeatable or are cost prohibitive in certain geographies. The techniques described in this study are easily reproducible globally and add no cost to the procedure. Importantly, this technique does not sacrifice safety or clinical efficacy; 42-month freedom from repeat procedure of 74% (Cryo) and 73% (RF gridless) would be considered satisfactory outcomes in this patient population.

Study Limitations

There are limitations to this study. As the current study is observational, conclusions regarding causal effects should be minimised. The operator had many years of experience with PVI utilising RF before trialling and adopting cryo technology in 2012. Although biases in technology used for initial AF ablation in this observational cohort is evident, the purpose of the monitoring was to ensure that radiation exposure was not significantly excessive with the adoption of the new cryo technology when compared to historical experience with RF. Additionally, there were some differences in the underlying characteristics between study groups: median weight and BMI were significantly higher in the Cryo group vs. RF Gridless group. This may represent a change in referral patterns as AF ablations become more mainstream and are offered to more patients. There may be an operator preference for a single transseptal catheter to minimise potential risk of tamponade in the heavier patient population. A potential impact of this difference between groups is that increased weight can lead to procedure complexities, resulting in longer procedure and fluoroscopy times, and greater radiation exposure. Since these were not detected in the present study, the difference between groups did not likely influence the results.

Analysis was intentionally limited to index ablation procedures as repeat procedures utilise RF catheters only; therefore, ablation strategies, and potentially patient populations, are possibly different in repeat cases. While the current analysis does not represent all ablation cases, it was deemed more scientifically valid to compare similar ablation strategies and patient populations.

Finally, the optimisation of imaging techniques was achieved through close collaboration between the electrophysiologists, cardiac scientists, radiographers and medical physicist, by implementing processes to monitor near-real time, which allowed corrective interventions to be promptly initiated if required. Similar results at other centres may be dependent on this type of coordination and monitoring.

Conclusions

The current observational study shows that cryoballoon AF ablation procedures can be conducted with low radiation exposure and significantly less exposure than with conventional RF. This study confirms initial findings observed with RF: that removal of the anti-scatter grid is a simple and effective method to reduce radiation exposures and this technique can be safely extended to cryoballoon AF ablation procedures. Further studies would be required to confirm this finding across other operators and imaging systems. Finally, the observation that the magnitude of differences seen in E were substantially more than the differences seen in FT underscores the need to track and report direct measure of radiation use (DAP, E) when comparing the radiation risks associated with different techniques and technologies.

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