Catheter ablation for atrial fibrillation in a low-volume center using contemporary technology

Julian Cheong Kiat Tay, Xinzhe James Cai, Jing Lin, Shufen Liang, Ai Ling Him, Sherida Binte Syed Hamid, Kelvin Cheok Keng Wong, Colin Yeo, Vern Hsen Tan

Department of Cardiology, Changi General Hospital (CGH), Singapore
Orchard Heart Specialist Clinic, Mount Elizabeth Medical Centre, Singapore
National Heart Center Singapore (NHCS), Singapore

ABSTRACT

Background: Catheter ablation is increasingly being performed worldwide for atrial fibrillation (AF). However, there are concerns of lower success rates and higher complications of AF ablations performed in low-volume centers. Thus, we sought to evaluate the safety and efficacy of AF catheter ablation in a low-volume center using contemporary technologies.

Methods and results: 71 consecutive patients (50 paroxysmal AF [pAF] vs 21 persistent AF) who underwent first catheter ablation were studied. Primary outcome was AF recurrence rate. Secondary outcomes included periprocedural complications, hospitalization for symptomatic tachy-arrhythmias post-ablation and number of repeat ablations. Mean age of our cohort was 59.1 ± 9.7 years, of which 56 (78.9%) were males. 1-year AF recurrence was 19.5% in pAF and 23.8% in persistent AF (p = 0.694). Ablation in persistent AF group required longer procedural (197.76 ± 48.60 min [pAF] vs 238.67 ± 70.50 min [persistent AF], p = 0.006) and ablation duration (35.08 ± 15.84 min [pAF] vs 52.65 ± 28.46 min [persistent AF], p = 0.001). There were no significant differences in secondary outcomes. Major periprocedural complication rate was 2.8%.

Subset analysis on (i) cryoablation vs radiofrequency, (ii) Ensite vs CARTO navigational system and (iii) circular vs high density mapping catheter did not yield significant differences in primary or secondary outcomes.

Conclusions: The AF ablation complication and recurrence free rates in both paroxysmal and persistent AF at one year were comparable to high-volume centers. Long-term follow up is needed. In addition, first AF catheter ablation in a low-volume center is realistic with comparable efficacy and safety outcomes to high-volume centers using contemporary ablation technologies.

1. Introduction

Atrial fibrillation (AF) is the most common cardiac arrhythmia that is associated with significant morbidity, mortality and socioeconomic burden [1,2]. Catheter ablation has emerged as a viable and effective treatment option for patients with symptomatic AF, especially in those refractory to antiarrhythmic drugs (AADs) and as first-line therapy in the select few with impaired quality of life or heart failure with reduced ejection fraction (HFREF) despite guideline-directed medical therapy [3–8]. AF catheter ablation has a 1-year AF recurrence-free rate of 60–80% in patients with paroxysmal AF (pAF) and a lower rate of 50–60% in patients with longstanding persistent AF. This varies further depending on ablation modality e.g. cryoablation/ radiofrequency ablation, incorporation of technologically-modified equipments such as contact force sensing catheters to even operator or center experience [9–12]. Currently, there is mixed data on procedural outcomes comparing high and low-volume operators or centres [13–14]. In high-volume centers, reported peri-procedural complication rates ranged from 1 to 8% [15–17] while the 1-year AF recurrence-free rates were 76–78% [13,15]. Therefore, the aim of this study is to evaluate the safety and efficacy of AF catheter ablation in our institution, a low-volume center with the use of contemporary ablation technologies.
2. Methods

2.1. Study design and population

This is a prospective, single center observational study in one of Singapore’s public tertiary hospitals, Changi General Hospital (CGH). Consecutive AF patients who underwent their first catheter ablation procedure of pulmonary vein isolation (PVI) with or without adjunctive ablation procedures were recruited from October 2014 to January 2020 since the inception of AF ablation in our institution. Patients with prior PVI were excluded. All AADs except amiodarone were discontinued for at least 5 half-lives prior to ablation. Therapeutic doses of oral anticoagulation therapy with either warfarin (international normalized ratio of 2.0 – 3.0) or direct oral anticoagulant (DOACs) such as rivaroxaban, apixaban and dabigatran were initiated at least 1 month prior to ablation. DOACs were discontinued at least one dose prior to procedure while warfarin was continued throughout. All patients underwent trans-esophageal echocardiography within 24 h prior to procedure to exclude left atrial appendage (LAA) thrombi. This study was approved by the institutional review board.

AF was classified as paroxysmal, persistent or long-standing persistent AF as per the 2014 AHA/ACC/HRS guideline for the management of patients with AF [18].

2.2. Ablation procedures

With written informed consent, the procedure was either performed under conscious sedation (midazolam and fentanyl intravenous infusion) or general anaesthesia (GA) in fasting state based on physicians’ discretion. A deflectable decapolar catheter (6-French, 2 mm inter-electrode distance and 5 mm space between each electrode pair) (Abbott, St Paul, Minnesota, USA or Biosense Webster Inc, California, USA) was placed at coronary sinus. Single trans-septal puncture was performed using trans-septal needle (BRK-1/71cm, Abbott, St. Paul, Minnesota, USA) via a long sheath (SL1 long sheath 8.5F/63 cm, Abbott, St. Paul, Minnesota, USA) under guidance of Intra Cardiac Echocardiography (ICE) and fluoroscopy. After a single trans-septal puncture, intravenous heparin bolus of 100U/ kg was administered followed by infusion to maintain an activated clotting time of 300–400 s. Next, the remaining right-sided short sheath was exchanged with Agilis™ (Abbott, St Paul, Minnesota, USA) steerable long sheath (medium curve, 8.5F/71 cm). Using the retained wire (Super stiff guidewire with finger straightenable 3mm J tip, 0.032”/180cm, Abbott, St. Paul, Minnesota, USA) technique (the SL1 long sheath with dilator was retracted into right atrium while maintaining the wire in left superior pulmonary vein), ablation catheter was inserted via Agilis™ and crossed through the existing trans-septal access into the left atrium (LA). The SL1 long sheath was then advanced into the LA using fluoroscopic guidance. The mapping catheter was then advanced into LA (after removal of dilator and wire) via the SL1 sheath.

All procedures were done by one of the 3 electrophysiology-trained physicians. All of the electrophysiologists underwent training at various established high-volume centres for at least 2 years prior returning to this centre between 2014 and 2016. As our center is a low volume center with an average of 18 AF ablation procedures per year, each procedure was attended to by two electrophysiologists.

Electro-anatomical maps (EAMs) of the LA and PVs were constructed using a non-fluoroscopic 3D navigational system (EnSite Precision™, Abbott, St. Paul, Minnesota, USA or CARTO 3, Biosense Webster Inc, Diamond Bar, California, USA) in all patients. Mapping was performed with either a circular (INQUIRY™ OPTIMA/ AFOCUS or ADVISA™ FL, Abbott, St. Paul, Minnesota, USA; LASSO™, Biosense Webster Inc, Diamond Bar, California, USA) or a multipolar high-density (HD) mapping catheter (PENTARAY™, Biosense Webster Inc, Diamond Bar, California, USA, ADVISOR HD Grid™, Abbott, St. Paul, Minnesota, USA).

In patients who underwent radiofrequency (RF) ablation, all RF lesions were delivered using a contact-force sensing irrigated-tip catheter (TACTICATH, Abbott, St. Paul, Minnesota, USA or THERMOCOOL SMARTTOUCH catheter, Biosense Webster Inc, Diamond Bar, California, USA). Irrigation flow rates were titrated according to RF energy delivered (<17 ml/min for <30 W and 30 ml/min for 31–50 W). For TACTICATH catheter, the contact force targeted before lesion delivery is 10 to 40 g, with a minimum individual lesion duration of 400 g-seconds-force-time integral. A target lesion size index of 5.0 to 5.5 at posterior wall and 5.5 to 6.0 at anterior and septal wall was achieved in all of our patients [19,20]. For SMARTTOUCH catheter, ablation index was used (550 for anterior and roof and 400 for posterior and inferior LA segments [21–23]. No trans-esophageal temperature probe was used. Wide antral circumferential ablation lesions were delivered around each pair of septal and lateral PV until each pair of PVs were isolated electrically from the LA with evidence of bidirectional conduction block. Voltage mapping was performed before PVI during sinus rhythm. For persistent AF, a stepwise approach was used, starting with PV re-isolation. If the patient remained in AF, a combination of the following approaches was used: linear ablation by anatomic approach, continuous complex fractionated atrial electrogram (CFAE) ablation and/or non-PV ectopy ablation. If the AF turned into organized tachycardia, mapping and RF ablation was performed to terminate the tachycardia. Cavo-tricuspid isthmus (CTI) ablation for typical atrial flutter was performed if there was documented typical atrial flutter either clinically or spontaneously induced during the procedure.

In patients who underwent cryoablation, EAMs were performed using the circular mapping catheter (ACHIEVE™, Medtronic, Montreal, Canada) and ablation using cryo-balloon catheter (Arctic Front, Medtronic, Montreal, Canada) according to best practice guideline [24]. The balloon was placed in each PV until it was occluded and the tissue was then subsequently cooled until bidirectional conduction block was achieved.

As the knowledge and technology of AF ablation is constantly evolving, there are several important timelines worth mentioning. ICE was introduced as an option to assist in trans-septal procedure since October 2017. GA was only available from January 2018 onwards once weekly. Cryoablation was introduced in March 2017 followed by HD mapping catheter from April 2019 onwards.

The endpoint for PV ablation for pAF was confirmation of bidirectional block during sinus rhythm on each PV. In the event patient remained in AF after PVI, electrical cardioversion was performed followed by evaluation of bidirectional block on each PV. For patients with persistent AF, if AF persist after PV isolation, the aforementioned stepwise approach was used until the following endpoints were met: AF or organized tachycardia termination and/or bidirectional block of the anatomical line during sinus rhythm. If patient remained in AF, electrical cardioversion was performed followed by evaluation of bidirectional block on anatomical line as well as targeting non-PV ectopy ablation.

2.3. Follow-up

All patients were discharged with and continued on an oral anticoagulant. AADs were also prescribed upon discharge for at least 3 months. Clinical examination, ECG and 24-hour Holter were performed at 3 months follow-up with additional follow-ups subsequently. AADs were either discontinued after 3 months if patients remained in sinus rhythm or continued if there were...
new symptoms or evidence of AF recurrence. For patients with symptomatic recurrent AF, repeat ablation was offered.

2.4. End-points

Primary outcome was AF recurrence and time to first recurrence of (both symptomatic and asymptomatic) atrial tachy-arrhythmia (AF or atypical atrial flutter) documented by any form of monitoring. A standard 3 months blanking period for early AF recurrences was used [25]. An atrial tachy-arrhythmia qualified as an arrhythmia if it lasted for 30 s or longer.

Secondary outcomes included serious periprocedural complications, hospitalization from symptomatic tachy-arrhythmias post-ablation and proportion of patients requiring repeat ablations.

2.5. Statistical analysis

Continuous variables were summarized as the means ± SDs or medians with interquartile ranges. Categorical variables were summarized as proportions. The differences between the groups were examined using the Chi square test for categorical variables or independent One-way ANOVA for continuous variables. A Kaplan-Meier analysis was utilized to assess the time for AF to recur after the ablation. A log-rank test was used to compare AF-free survival between the groups. A multivariate Cox proportional hazards model was used to determine the predictors of an AF recurrence after ablation. All statistical analyses were performed using SPSS Statistics for Windows, Version 25.0 (IBM Corp., Armonk, NY, USA). A p-value < 0.05 was considered statistically significant.

3. Results

3.1. Baseline and procedural characteristics

From October 2014 to January 2020, a total of 93 catheter ablation procedures for atrial arrhythmias (AF or atypical atrial flutter) were performed on 82 patients. 11 patients were excluded, of which 4 were for atypical atrial flutter and 7 were redo AF ablations. The final study population consists of 71 patients undergoing first AF ablation – 50 with pAF and 21 with persistent AF. 1 patient with long-standing persistent AF was included in the persistent AF group for analysis. The baseline demographic and procedural characteristics were analysed and reported in Table 1. Mean age of our cohort is 59.1 ± 9.7 years with higher prevalence of males (78.9%).

Patients with persistent AF were more likely to have concomitant non-ischemic cardiomyopathy [p = 0.009], history of prior direct current cardioversion (DCCV) [p < 0.001], worse New York Heart Association functional class [p = 0.027], more severely impaired LVEF (left ventricular ejection fraction) [p < 0.001], higher left atrial volume index (LAVI) [p < 0.001], more frequent use of amiodarone as an AAD, longer procedural time [p = 0.006], longer ablation time [p = 0.001] and increase in need for additional ablation lines [p = 0.001] when compared against pAF patients. The mean LVEF in the persistent AF group was moderately impaired at 39.05 ± 18.95% – 10 (47.6%) had normal LVEF (≥50%), none with mildly impaired LVEF (40–49%), 2 (9.5%) had moderately impaired LVEF (30–39%) and 9 (42.9%) had severely impaired LVEF (<30%) at baseline. Out of the 11 persistent AF patients with impaired LVEF, 7 had normalisation of LVEF > 50%, 1 with slight improvement but still impaired and 3 with no improvement.

Twenty-six (36.8%) patients had ICE utilised during ablation. There were 5 (23.8%) patients in the persistent AF group who had adjunctive ablation lines in addition to PVI and CTI ablation: 1 CFAE ablation, 2 mitral isthmus line ablation, 1 roof line with lower LA posterior wall ablation and 1 roof line with mitral isthmus line ablation.

3.2. Outcomes

At 1-year follow-up, the AF recurrence rate was 19.5% vs 23.8% for pAF and persistent AF respectively (p = 0.694). After a mean follow-up duration of 24.65 ± 17.76 months, 24 patients (33.8%) developed AF recurrence (Fig. 1). The recurrence rate for persistent AF was higher than that of pAF [30.0% vs 42.9%; p = 0.296], although not statistically significant. The AF-free duration [p = 0.598], repeat hospitalisation post-ablation due to AF [p = 0.296], periprocedural complication rates [p = 0.245] as well as the need for redo ablation [p = 0.252] were comparable between both groups (Table 2). There were no significant differences in the 1-year AF recurrence rates in the first half of our study (October 2014 – May 2017) compared to the second half (June 2017 – January 2020) (28.0% vs 17.1%, p = 0.314).

Only amiodarone use [adjusted HR 3.570; 95% CI 1.480–8.609, p = 0.005] was associated with higher risk of AF recurrence on multivariate analysis.

There were 2 complications (2.8%) that occurred periprocedurally. 1 patient developed a moderate localised pericardial effusion (1.5 cm) adjacent to right atrium and ventricle after transseptal puncture. No pericardiocentesis was performed as patient was hemodynamically stable. The other patient developed left rectus sheath hematoma that was detected on computed tomography angiography post-procedure. Both patients were treated conservatively with gradual re-initiation of anticoagulation and discharged well. There were no in-hospital mortality or cases of stroke, PV stenosis, atrio-esophageal fistula or diaphragmatic paralysis noted in our cohort.

3.3. Ablation technologies and system

Among the 40 patients who underwent PVI only, 10 (25%) underwent cryo-balloon ablation whereas 30 (75%) underwent RF ablation. Patients who underwent RF ablation had higher likelihood of requiring GA [p = 0.017] and longer procedural time [p = 0.003] while patients who underwent cryoballoon ablation had longer fluoroscopic duration [p = 0.020]. Mean AF-free duration was significantly shorter in the cryoballoon 8.70 ± 6.08 months vs 24.13 ± 18.61 months in RF group [p = 0.015] although AF recurrence rate at 1-year were similar [p = 0.395] when compared with RF group (Table 3A).

Within patients who underwent RF (n = 61), 51 utilized the EnSite Precision™ while 10 used the CARTO navigational system. Other than longer ablation duration [p = 0.001] in the CARTO group, AF recurrence rates, procedural/fluoroscopy durations and outcomes were similar between both groups [p > 0.05] (Table 3B).

We also studied the effect of different mapping catheters on outcomes. Circular mapping catheters were utilised in 59, pentaray in 5 and HD mapping catheters in 7 cases. The use of HD grid or pentaray catheters were associated with more GA use [p < 0.001], longer ablation durations [p = 0.033] but shorter fluoroscopy time [p < 0.001] and fluoroscopy dose area product (DAP) [p = 0.028]. Beyond the above, there were no differences noted in AF recurrence rates, mean AF-free duration, periprocedural complications or the need for redo ablations (Table 3C).

3.4. Redo ablation

Of the 24 patients that developed recurrence, 6 (25.0%) had redo AF ablation; distributed equally between both pAF and persistent AF groups. PV reconnection was found in all patients. PV reconnection pattern was analysed in the redo cases with a total of 12 out of...
Baseline demographics and procedural characteristics by type of AF.

### Baseline demographics

| Variables                      | Total (n = 71) | pAF (n = 50) | Persistent AF (n = 21)* | p-value  |
|-------------------------------|---------------|--------------|------------------------|----------|
| Age, y (SD)                   | 59.1 ± 9.7    | 59.8 ± 9.8   | 57.6 ± 9.7             | 0.390    |
| Males (%)                     | 56 (78.9)     | 37 (74.0)    | 19 (90.5)              | 0.121    |
| Race (%)                      |               |              |                        | 0.725    |
| - Chinese                     | 52 (73.2)     | 36 (72.0)    | 16 (76.2)              |          |
| - Malay                       | 16 (22.5)     | 11 (22.0)    | 5 (23.8)               |          |
| - Indian                      | 1 (1.4)       | 1 (2.0)      | 0 (0.0)                |          |
| - Others                      | 2 (2.8)       | 2 (4.0)      | 0 (0.0)                |          |
| DM (%)                        | 14 (19.7)     | 12 (24.0)    | 2 (9.5)                | 0.162    |
| HTN (%)                       | 37 (52.1)     | 26 (52.0)    | 11 (52.4)              | 0.977    |
| IHD (%)                       | 12 (16.9)     | 8 (16.0)     | 4 (19.0)               | 0.754    |
| NICMP (%)                     | 9 (12.7)      | 3 (6.0)      | 6 (28.6)               | 0.009    |
| VHD (%)                       | 0 (0.0)       | 0 (0.0)      | 0 (0.0)                | N/A      |
| CVA (%)                       | 10 (14.1)     | 5 (10.0)     | 5 (23.8)               | 0.127    |
| OSA (%)                       | 11 (15.5)     | 7 (14.0)     | 4 (19.0)               | 0.592    |
| COPD (%)                      | 2 (2.8)       | 1 (2.0)      | 1 (4.8)                | 0.523    |
| Asthma (%)                    | 3 (4.2)       | 3 (6.0)      | 0 (0.0)                | 0.251    |
| Prior DCCV (%)                | 23 (32.4)     | 18 (36.0)    | 13 (62.0)              | < 0.001  |
| CHA2DS2Vasc (SD)              | 1.83 ± 1.38   | 1.76 ± 1.41  | 2.00 ± 1.34            | 0.309    |
| NYHA class (%)                | 18 (25.4)     | 12 (24.0)    | 6 (28.6)               | 0.686    |
| - I                           | 53 (74.6)     | 38 (76.0)    | 15 (71.4)              | 0.027    |
| - II                          | 69 (97.2)     | 50 (100.0)   | 19 (90.5)              |          |
| - III + PVI                   | 2 (2.8)       | 0 (0.0)      | 2 (9.5)                | 0.977    |
| LVEF, % (SD)                  | 50.97 ± 15.30 | 55.98 ± 10.88| 39.05 ± 18.95          | < 0.001  |
| LAVI, mm/m² (SD)              | 35.83 ± 10.48 | 32.99 ± 9.94 | 42.47 ± 8.67           | < 0.001  |
| Anti-arrhythmic (%)           |               |              |                        |          |
| - Amiodarone                  | 22 (31.0)     | 12 (24.0)    | 10 (52.4)              | 0.002    |
| - Sotalol                     | 13 (18.3)     | 12 (24.0)    | 1 (4.8)                | 0.056    |
| - Flecainide                  | 13 (18.3)     | 12 (24.0)    | 1 (4.8)                | 0.056    |
| - Propafenone                 | 1 (1.4)       | 1 (2.0)      | 0 (0.0)                | 0.514    |
| General anaesthesia (%)       | 25 (35.2)     | 16 (32.0)    | 9 (42.9)               | 0.382    |
| Procedure time, min (SD)      | 209.86 ± 58.54| 197.76 ± 48.60| 238.67 ± 70.50         | 0.006    |
| Ablation time, sec (SD)       | 2416.73 ± 1303.80| 2104.90 ± 950.27 | 3159.19 ± 1707.43     | 0.001    |
| Fluoroscopy time, min (SD)    | 27.19 ± 15.53 | 28.15 ± 17.27| 24.92 ± 10.26          | 0.427    |
| Fluoroscopy (DAP), Gycm² (SD) | 38960 ± 37936 | 35659 ± 39179| 46821 ± 34411          | 0.261    |
| Total skin dose, mGy (SD)     | 361.89 ± 510.50| 285.40 ± 373.48| 544.00 ± 721.78       | 0.051    |
| Procedure (%)                 |               |              |                        | 0.001    |
| - PVI                         | 40 (56.3)     | 29 (58.0)    | 11 (52.4)              |          |
| - PVI + CTI                   | 26 (36.6)     | 21 (42.0)    | 5 (23.8)               |          |
| - PVI + CTI + Others#         | 5 (7.0)       | 0 (0.0)      | 5 (23.8)               |          |
| Mapping system (%)            |               |              |                        | 0.855    |
| - CARTO                       | 60 (84.5)     | 42 (84.0)    | 18 (85.7)              |          |
| Modality (%)                  | 11 (15.5)     | 8 (16.0)     | 3 (14.3)               | 0.436    |
| - Radiofrequency              | 61 (85.9)     | 44 (88.0)    | 17 (81.0)              |          |
| - Cryoballoon                 | 10 (14.1)     | 6 (12.0)     | 4 (19.0)               |          |

* Includes 1 patient with long-standing persistent AF.
# The 5 other ablation procedures include 1 complex fractionated atrial electrogram ablation, 2 mitral isthmus line ablation, 1 roof line with lower LA posterior wall ablation and 1 roof line with mitral isthmus line.

Abbreviations: pAF, paroxysmal atrial fibrillation; DM, diabetes mellitus; HTN, hypertension; CAD, coronary artery disease; NICMP, non-ischemic cardiomyopathy; VHD, valvular heart disease; CVA, cerebrovascular accident/ strokes; OSA. Obstructive sleep apnea; COPD, chronic obstructive pulmonary disease; DCCV, direct current cardioversion; EHRA, European Heart Rhythm Association; NYHA, New York Heart Association; LVEF, left ventricular ejection fraction; LAVI, left atrial volume index; DAP, dose area product aka kerma area product; PVI, pulmonary vein isolation; CTI, cavotricuspid isthmus.

### Procedure characteristics

- **Mapping system (%)**
  - NaVx: 60 (84.5)
  - CARTO: 11 (15.5)
- **Modality (%)**
  - Radiofrequency: 61 (85.9)
  - Cryoballoon: 10 (14.1)

24 (50.0%) PVs were observed to have reconnected; 4 in pAF and 8 in persistent AF which was not statistically significant [p = 0.135]. Reconnection along the right superior, right inferior, left superior and left inferior was found in 5, 4, 2 and 1 cases respectively. These were all successfully isolated with redo PVI. 4 out of 6 patients required additional CTI ablation and 2 patients required additional ablation lines of 1 anterior roof line and 1 line across left superior PV to LAA in each patient.

#### 3.5. Centre’s experience

From October 2014 to January 2020, the breakdown of number of catheter ablations, mean procedural time and mean fluoroscopic time by year are shown in Supplementary Figs. 1 and 2.

### 4. Discussion

In our single center observational study evaluating outcomes of all types of AF patients who underwent their first catheter ablation procedure, we demonstrated several notable findings: (i) Safety outcomes of AF catheter ablation in our low-volume center is comparable to that of high-volume centers; (ii) AF recurrence rate was higher albeit not statistically significant in persistent AF compared to pAF group; (iii) the efficacy and safety outcomes of cryoballoon strategy did not differ from radiofrequency ablation.

We reported a 1-year AF recurrence rate of 19.5% in pAF and 23.8% in persistent AF patients as well as total AF recurrence of 30.0% (pAF) vs 42.9% (persistent AF) over a mean follow-up of approximately 2 years using strategies which reflects contempo-
rary results from international centers. Thus far, observational and randomised controlled trials (RCTs) looking at various ablation modalities have reported significant risk of AF recurrences ranging from 11 to 67% at one year [8,18,26–27]. In a recent prospective multicenter registry comprising 40 German high-volume (>1000 catheter ablations/year) and low-volume (<300 catheter ablations/year) centers, Sultan et al noted a total of 1687 out of 3703 patients (45.9%) had AF recurrence after at least 1-year post-ablation for all types of AF with either radiofrequency or cryoballoon [28]. Similarities between our cohort with Sultan et al. were that of male predominance (78.9% vs 66.9%), more pAF (70.4% vs 65.9%) and high prevalence of cardiovascular risk factors/diseases such as hypertension (52.1% vs 61.5%) and ischemic heart disease (16.9% for both) although there were more DM (19.7% vs 7.9%) and prior CVA (14.1% vs 4.8%) in our cohort.

There have been several studies examining the impact of high vs low-volume operators on ablation outcomes. Sairaku et al reported pAF ablations performed by high-volume operators - defined as those who perform ≥50 catheter ablations each year - were the only independent predictor of freedom from AF recurrence (HR 1.73; 95% CI 1.23–2.48, p = 0.002) with 76.4% patients in high-volume group vs 62.8% in the low-volume group free from AF at 1 year [13]. In this study, they did not note any significant differences in baseline characteristics other than a slightly older age group (64 ± 9 years vs 62 ± 11 years) in the low-volume operator compared to high-volume operator group. However, our 1-year freedom from AF recurrence for first ablation of 80.5% in pAF group is in fact higher than the rate in their high-volume group. Other than a slightly younger age profile (59.1 ± 9.7 years) and lower prevalence of hypertension (52.1% vs 54.0%), our cohort had higher prevalence of DM (19.7% vs 10%), prior CVA (14.1% vs 8%), CHA2-Ds2-VASc score (1.83 vs 1) as well as lower mean LVEF (50.97% vs 63%), albeit still within the normal range compared to Sairaku et al. They did not report on prevalence of ischemic heart disease (IHD) and their population was only focused on pAF patients. Similarly, the 1-year freedom from AF recurrence of 76.2% in our persistent AF group matches up to prior studies reporting up to 80% freedom from AF for pAF depending on ablation strategies adopted.

![Fig. 1. Freedom from AF recurrence at 1 year and overall follow-up by type of AF prior to ablation.](image)

**Table 2** Primary and secondary outcomes by type of AF.

| Variables | Total (n = 71) | pAF (n = 50) | Persistent AF (n = 21)* | p-value |
|-----------|---------------|--------------|-------------------------|---------|
| 1-year AF recurrence (%) | 13/62 (21.0%) | 8/41 (19.5) | 5/21 (23.8) | 0.694 |
| Total AF recurrence (%) | 24 (33.8) | 15 (30.0) | 9 (42.9) | 0.296 |
| Recurrence detection modality (%) | | | | 0.213 |
| - ECG | 14 (19.7) | 7 (14.0) | 7 (33.3) | |
| - Holter | 12 (16.9) | 10 (20.0) | 2 (9.5) | |
| - CIED | 2 (2.8) | 1 (2.0) | 1 (4.8) | |
| AF-free duration, m (SD) | 18.01 ± 15.30 | 18.64 ± 16.74 | 16.52 ± 11.34 | 0.598 |
| Mean duration of follow-up, m (SD) | 24.65 ± 17.76 | 26.90 ± 19.76 | 19.29 ± 10.18 | 0.099 |
| AF hospitalisation post-ablation (%) | 9 (12.7) | 5 (10.0) | 4 (19.0) | 0.296 |
| Complication (%) | | | | 0.245 |
| - Pericardial effusion | 1 (1.4) | 1 (2.0) | 0 (0.0) | |
| - Vascular injury | 1 (1.4) | 0 (0.0) | 1 (4.8) | |
| Redo ablation (%) | 6 (8.5) | 3 (6.0) | 3 (14.3) | 0.252 |
| Latest EHRA score (%) | | | | 0.089 |
| - I | 59 (83.1) | 44 (88.0) | 15 (71.4) | |
| - 2–4 | 12 (16.9) | 6 (12.0) | 6 (28.6) | |
| Latest NYHA class (%) | | | | 0.521 |
| - I – II | 69 (97.2) | 49 (98.0) | 20 (95.2) | |
| - III – IV | 2 (2.8) | 1 (2.0) | 1 (4.8) | |

Abbreviations: ECG; 12-lead electrocardiogram; CIED, cardiovascular implantable electronic devices; EHRA, European Heart Rhythm Association; NYHA, New York Heart Association.
Table 3A
Baseline and procedural characteristics, outcomes by ablation modality in PVI ablation only.

| Variables | Ablation modality | | | | p-value |
|-----------|-------------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| AF type (%) | | | | | | |
| - pAF | Total (n = 40) | CRYO (n = 10) | RF (n = 30) | | 0.307 |
| 29 (72.5) | 6 (60.0) | 23 (76.7) |
| - persistent AF | 11 (27.5) | 4 (40.0) | 7 (23.3) |
| 1-year AF recurrence (%) | 7/34 (20.6) | 2/6 (33.3) | 5/28 (17.9) | 0.395 |
| Total AF recurrence (%) | 11 (27.5) | 2 (20.0) | 9 (30.0) | 0.540 |
| General anaesthesia (%) | 12 (30.0) | 0 (0.0) | 12 (40.0) | 0.017 |
| Procedure time, min (SD) | 185.90 ± 40.85 | 153.60 ± 27.40 | 196.67 ± 39.14 | 0.003 |
| Ablation time, sec (SD) | 1993.43 ± 949.78 | 1348.60 ± 450.26 | 2208.37 ± 979.32 | 0.011 |
| Fluoroscopy time, min (SD) | 27.30 ± 14.38 | 36.09 ± 9.24 | 24.37 ± 14.70 | 0.024 |
| Fluoroscopy (DAP), Gycm² (SD) | 35308 ± 30406 | 50718 ± 38643 | 30171 ± 25899 | 0.063 |
| Total skin dose, mGy (SD) | 358.72 ± 559.83 | 710.30 ± 1007.36 | 241.53 ± 222.97 | 0.020 |
| AF-free duration, m (SD) | 20.28 ± 17.66 | 8.70 ± 6.08 | 24.13 ± 18.61 | 0.015 |
| AF hospitalisation post-ablation (%) | 4 (10.0) | 1 (10.0) | 3 (10.0) | 1.000 |
| Complications (%) | | | | | |
| - Pericardial effusion | 0 (0.0) | 1 (2.5) | 0 (0.0) | 0 (0.0) |
| - Vascular injury | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Redo ablation (%) | 2 (5.0) | 0 (0.0) | 2 (6.7) | 0.402 |

Abbreviations: CRYO, cryoablation; RF, radiofrequency; AF, atrial fibrillation; DAP, dose area product aka kerma area product.

Table 3B
Baseline and procedural characteristics, outcomes by navigational system.

| Variables | Navigational system | | | | p-value |
|-----------|---------------------|-----------------|-----------------|-----------------|-----------------|
| AF type (%) | | | | | | |
| - pAF | Total (n = 61) | ESi (n = 51) | CARTO (n = 10) | | 0.869 |
| 44 (72.1) | 37 (72.5) | 7 (70.0) |
| - persistent AF | 17 (27.9) | 14 (27.5) | 3 (30.0) |
| 1-year AF recurrence (%) | 22 (36.1) | 20 (39.2) | 2 (20.0) | 0.247 |
| Total AF recurrence (%) | 25 (41.0) | 21 (41.2) | 4 (40.0) | 0.017 |
| General anaesthesia (%) | 210.80 ± 57.20 | 218.04 ± 59.10 | 224.40 ± 48.67 | 0.751 |
| Ablation time, sec (SD) | 2591.84 ± 1315.85 | 2357.10 ± 1262.23 | 3789.00 ± 887.22 | 0.001 |
| Fluoroscopy time, min (SD) | 25.74 ± 15.91 | 25.17 ± 15.46 | 28.62 ± 18.69 | 0.535 |
| Fluoroscopy (DAP), Gycm² (SD) | 37033 ± 37791 | 33465 ± 30199 | 55229 ± 63360 | 0.096 |
| Total skin dose, mGy (SD) | 304.77 ± 358.17 | 259.02 ± 289.46 | 538.10 ± 563.35 | 0.023 |
| AF-free duration, m (SD) | 19.74 ± 15.83 | 19.55 ± 16.81 | 19.50 ± 10.04 | 0.993 |
| AF hospitalisation post-ablation (%) | 8 (1.6) | 1 (2.0) | 0 (0.0) | 0.817 |
| Complications (%) | | | | | |
| - Pericardial effusion | 1 (1.6) | 1 (2.0) | 0 (0.0) | 0 (0.0) |
| - Vascular injury | 1 (1.6) | 1 (2.0) | 0 (0.0) | 0 (0.0) |
| Redo ablation (%) | 6 (9.8) | 6 (11.8) | 0 (0.0) | 0.253 |

Abbreviations: ESi, Ensite Precision Navigational system; CARTO, CARTO navigational system; AF, atrial fibrillation; DAP, dose area product aka kerma area product.

Table 3C
Baseline and procedural characteristics, outcomes by type of mapping catheter.

| Variables | Mapping catheter | | | | p-value |
|-----------|------------------|-----------------|-----------------|-----------------|-----------------|
| AF type (%) | | | | | | |
| - pAF | Total (n = 71) | Circular (n = 59) | Pentaray (n = 5) | HD Grid (n = 7) | 0.158 |
| 50 (70.4) | 39 (67.2) | 4 (80.0) | 7 (87.5) |
| - persistent AF | 21 (29.6) | 20 (33.9) | 1 (20.0) | 0 (0.0) |
| 1-year AF recurrence (%) | 13/62 (21.0) | 12/53 (22.6) | 0/5 (0.0) | 1/4 (6.5) | 0.483 |
| Total AF recurrence (%) | 24 (33.8) | 23 (39.0) | 0 (0.0) | 1 (14.3) | 0.108 |
| General anaesthesia (%) | 25 (35.2) | 14 (23.7) | 4 (80.0) | 7 (100.0) | <0.001 |
| Procedure time, min (SD) | 209.86 ± 58.54 | 211.25 ± 60.32 | 203.20 ± 46.05 | 202.86 ± 57.27 | 0.908 |
| Fluoroscopy time, min (SD) | 2416.73 ± 1303.80 | 2280.29 ± 1329.54 | 3839.00 ± 825.03 | 2505.86 ± 633.27 | 0.033 |
| Fluoroscopy (DAP), Gycm² (SD) | 38960 ± 37936 | 43980 ± 39122 | 26173 ± 21898 | 5782 ± 2607 | <0.001 |
| Total skin dose, mGy (SD) | 361.89 ± 510.50 | 403.07 ± 545.12 | 300.80 ± 245.51 | 58.43 ± 23.99 | 0.028 |
| AF-free duration, m (SD) | 18.01 ± 15.30 | 19.69 ± 16.08 | 13.80 ± 6.18 | 6.86 ± 3.93 | 0.089 |
| AF hospitalisation post-ablation (%) | 9 (12.7) | 9 (15.3) | 0 (0.0) | 0 (0.0) | 0.351 |
| Complications (%) | | | | | |
| - Pericardial effusion | 1 (1.4) | 1 (1.7) | 0 (0.0) | 0 (0.0) | 0.981 |
| - Vascular injury | 1 (1.4) | 1 (1.7) | 0 (0.0) | 0 (0.0) | 0.981 |
| Redo ablation (%) | 6 (8.5) | 6 (10.2) | 0 (0.0) | 0 (0.0) | 0.514 |

Abbreviations: HD grid, high definition grid; AF, atrial fibrillation; DAP, dose area product aka kerma area product.
and a lower 50% for persistent and long-standing persistent AF [10,29,30]. While there is a greater proportion of persistent AF patients with recurrence compared to those with pAF, this result is not statistically significant and may be explained by our study’s small sample size.

With regards to safety, our complication rate of 2.8% is in line with rates documented by other high and low volume centres worldwide (2.5–7.8%) with cardiac and vascular complications being more common than others [13,17,28,31]. Sairaku et al also demonstrated that low volume operators have higher major complication rates than high volume operators (7.8% vs 1.4%, p = 0.001) even though they only included pAF patients who underwent first PVI ablation with no adjunctive lines allowed [13]. Experiential data from low-volume centers in literature are scarce. Haman et al reported a much lower 6-months freedom from AF of 48% for pAF, 43% for persistent and 44% for long-standing persistent after first ablation with a complication rate of 3.3% in their institution (total number of procedures 303) from 2004 to 2012 [32]. Plausible explanations for our higher AF freedom rate with lower complication rates could be due to adoption of newer technologies such as contact force sensing catheters [33], and possibly use of high density mapping catheter which were not available during the period when their study was performed. Mean age and comorbidities in our cohort were comparable to these centers [13,32].

We also evaluated the impact of newer technologies such as cryoballoon and multipolar HD Grid catheter on procedural outcomes. In a subset of 40 patients who underwent only PVI, 10 underwent cryoballoon ablation with significantly shorter procedural and ablation duration but longer fluoroscopic time than radiofrequency ablation, a finding similar to other trials comparing the 2 modalities [34]. There were no differences in AF recurrence rates, complications and the need for redo ablation (0% vs 6.7%, p = 0.402 for cryoballoon and radiofrequency ablation respectively). The significantly shorter mean AF free duration in the cryoballoon group is explained by the later availability of this modality in our center from May 2017 onwards. In a Russian pilot study comparing cryoballoon ablation outcomes between high and low-volume centers, they did not observe significant differences in arrhythmia-free rates nor complication rates and argued that cryoballoon ablation has a fast and reproducible learning curve in both high- and low-volume centres [14]. This highlights that newer ablation technologies can be adapted safely in low-volume centers without compromising on efficacy.

Furthermore, we had noted stabilisation in mean procedural time and significant improvements in fluoroscopic time from 2017 onwards as number of cases performed yearly increase to above 20. The drastic decline in fluoroscopic duration is likely attributable to a combination of factors including increasing use of GA to reduce risk of catheter instability during PVI as well as increasing experience of our operators.

Most importantly, there has been significant heterogeneity in the definition of what constitutes as low volume operator or center. Cutoffs to define low volume were varied with less than 50–300 procedures/year used to define low-volume center whereas less than 20–50 procedures/year were used to define low volume operator instead [13,28,35,36]. In some of these papers, they highlighted lower success rates and higher complications rates in low-volume centers and raised questions on minimum level of competency for operators and centers to ensure safety and efficacy of ablations performed for AF [37]. In contrast, while the 2011 American College of Cardiology Foundation/American Heart Association/Heart Rhythm Society guidelines stipulate that the procedure be performed in experienced centers defined as those with at least 50 AF catheter ablations per year, they acknowledge that this recommendation was not evidence-based [38]. With emerging evidence of AF catheter ablation utility beyond symptomatic AF refractory to AADs such as demonstrated in the recent CASTLE-AF trial on HFrEF patients [39], patients who may derive benefit from catheter ablation might not receive it if they were seen in low volume centers should these recommendations be enforced.

4.1. Limitations

Being an observational study, our study is not free from inherent bias of such studies. In addition, our single center experience may not be applicable to other low-volume centers worldwide as newer ablation technologies or mapping systems may not be available in these centers. Furthermore, the training received and experience gained by the electrophysiologist is another potential factor contributing to the outcome of the procedure, even though there is a lack of scientific evidence regarding this aspect. Another limiting factor is the small number of subjects with relatively short duration of follow up. There was no control group in our study. However, comparing to existing publication by Deshmukh et al, the complication rate in low volume center (<25 procedures per operator per year) across United States between 2000 and 2010 was around 7% which was higher compared to our center (3%) [36]. Another potential limitation is the detection of recurrent AF post-ablation. Majority of the publications [13,40] use ECG and Holter as means to detect AF recurrence similar to our practice although this may under-diagnose the true recurrence of AF post-procedurally, particularly in those with asymptomatic AF. Although implantable loop recorder is considered gold standard to detect AF recurrence, it is not feasible in clinical practice.

5. Conclusions

The AF ablation complication and recurrence-free rates in both paroxysmal and persistent AF at one year were comparable to high-volume centers. Long-term follow up is needed. Amidst a slew of recent studies highlighting the importance of operator and center experience in ensuring efficacy and safety of AF catheter ablation, our experience suggests that first AF ablation can be safely performed in low-volume centers through adoption of newer technological advances with comparable clinical outcomes to high-volume centers.

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CRediT authorship contribution statement

Julian Cheong Kiat Tay: Investigation, Formal analysis, Data curation, Writing - original draft, Writing - review & editing.
Xinze James Cai: Validation, Writing - review & editing. Jing Lin: Investigation, Data curation. Shufen Liang: Software. Ail Ling Him: Resources, Project administration. Sherida Binte Syed Hamid: Resources, Project administration. Kelvin Cheok Keng Wong: Validation, Supervision, Writing - review & editing. Colin Yeo: Supervision, Validation, Writing - review & editing. Vern Hsen Tan: Conceptualization, Data curation, Writing - review & editing, Supervision, Validation.

Declaration of Competing Interest

The authors report no relationships that could be construed as a conflict of interest.
Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jchaa.2020.100661.

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