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Efficacy and safety of catheter ablation for atrial fibrillation in congenital heart disease – A systematic review and meta-analysis

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ABSTRACT

Background: Prevalence of atrial fibrillation (AF) in patients with congenital heart disease (CHD) is on the rise. Anti-arrhythmic drugs are usually the first line of treatment in CHD, however, it is often ineffective and poorly tolerated. We aimed to perform a systematic review to assess the efficacy and safety of catheter ablation for AF in CHD.
Methods: We performed a comprehensive search on catheter ablation for atrial fibrillation in congenital heart disease up until July 2019 through several electronic databases.
Results: Ablation of AF in patients with CHD had a modest 12 months AF freedom ranging from 32.8% to 63%, which can be increased by subsequent/repeat ablation. The complexity of CHD appears to have a significant effect on a study but not in others. Catheter ablation in ASD and persistent left superior vena cava had a high success rate. Overall, catheter ablation is safe whichever the type of CHD is.
Conclusion: Catheter ablation for AF in CHD had modest efficacy that can be increased by subsequent/repeat ablation and it also has an excellent safety profile. Ablation in complex CHD could also have similar efficacy, however, it is preferably done by experts in a high volume tertiary center.

1. Introduction

Prevalence of atrial fibrillation (AF) in patients with congenital heart disease (CHD) is rising along with the improved survival of children born with CHD [1]. Atrial fibrillation became the most common atrial arrhythmia in adult CHD patients ≥ 50 years old [2]. Increased risk of adverse events associated with AF is troublesome, anti-arrhythmic drugs (AAD) therapy are usually the first-line treatment in CHD. However, AAD is often ineffective and poorly tolerated along with long-term side-effects that are undesirable in young patients to consume it over a lifetime [3,4].

Catheter ablation for AF in CHD is currently recommended, especially after failed attempts of rhythm control [5,6]. The efficacy and safety of catheter ablation for AF in CHD gained interests in recent years, and we aimed to perform a systematic review to assess the latest evidence regarding this matter.

2. Methods

2.1. Search strategy

We performed a comprehensive search on catheter ablation for atrial fibrillation in congenital heart disease with keywords [atrial fibrillation], [congenital heart disease], [catheter ablation], and its synonyms from inception up until July 2019 through PubMed, EuropePMC, EBSCOhost, Cochrane Central Database, ClinicalTrials.

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gov and using the hand-sampling from potential articles cited by other studies. We aimed to use the search keyword unrestricted to other terms in order to obtain the largest number of search results possible. The complexity of CHD is as defined by 32nd Bethesda consensus document. The outcome of interests includes 12 months AF freedom, complications, and predictors of AF recurrence.

2.2. Inclusion and exclusion criteria

The inclusion criteria for this study are all studies that assess catheter ablation for atrial fibrillation in congenital heart disease. Two authors (E.Y and V.C) independently screen for abstracts. Two independent authors (R.P and A.E.T) extracted and critically appraised the studies. We include all related clinical researches/original articles, research letters, and exclude case reports, and review articles.

2.3. Statistical analysis

To perform a meta-analysis, we used RevMan version 5.3. We used the odds ratio and a 95% CI as a pooled measure for dichotomous data. We used Mantel-Haenzsel method for odds ratio with a fixed-effect model for meta-analysis. All P values were two-tailed with a statistical significance set at 0.05 or below.

3. Results

We found a total of 223 results. We screened 139 records after removing duplicates. Thirteen were relevant titles/abstract. After assessing Thirteen full-text for eligibility; we excluded one because of no data on 12 months' follow-up. We included twelve studies in the qualitative synthesis and four studies in the quantitative synthesis (Fig. 1). Nine are cohort studies, and three is case series. There was a total of 393 CHD patients who underwent ablation for AF from thirteen studies. Since the control group for the studies are heterogeneous, and many did not have a control group, we only count the intervention group. The 12 months AF freedom ranges from 32.8% to 100% from 10 studies. The publication date of the studies ranged from 2006 to 2019, in which ablation technique has evolved.

3.1. Patient characteristics

Five studies assessed patients with CHD in general that underwent catheter ablation for AF, four of them divided the CHD into groups according to their complexity as defined in. Three studies assessed exclusively atrial septal defect (ASD)/patent foramen ovale (PFO) patients. Three case-series and 1 cohort study reported catheter ablation in persistent left superior vena cava (PLSVC) (Table 1). The patients were >50 years old and mean/median most of the studies are within the range of 50–60 years' old (mean 54.23 ± 11.58 years' old). Gender was 224 (66.7%). One study described the use of cryoballoon ablation while the others used radiofrequency ablation. The technique of catheter ablation varies according to what the operator deemed fit for the patient due to anatomical variations. 12 months AF freedom was 58.02% from 393 patients and there were 5 major complications and 26 minor complications.

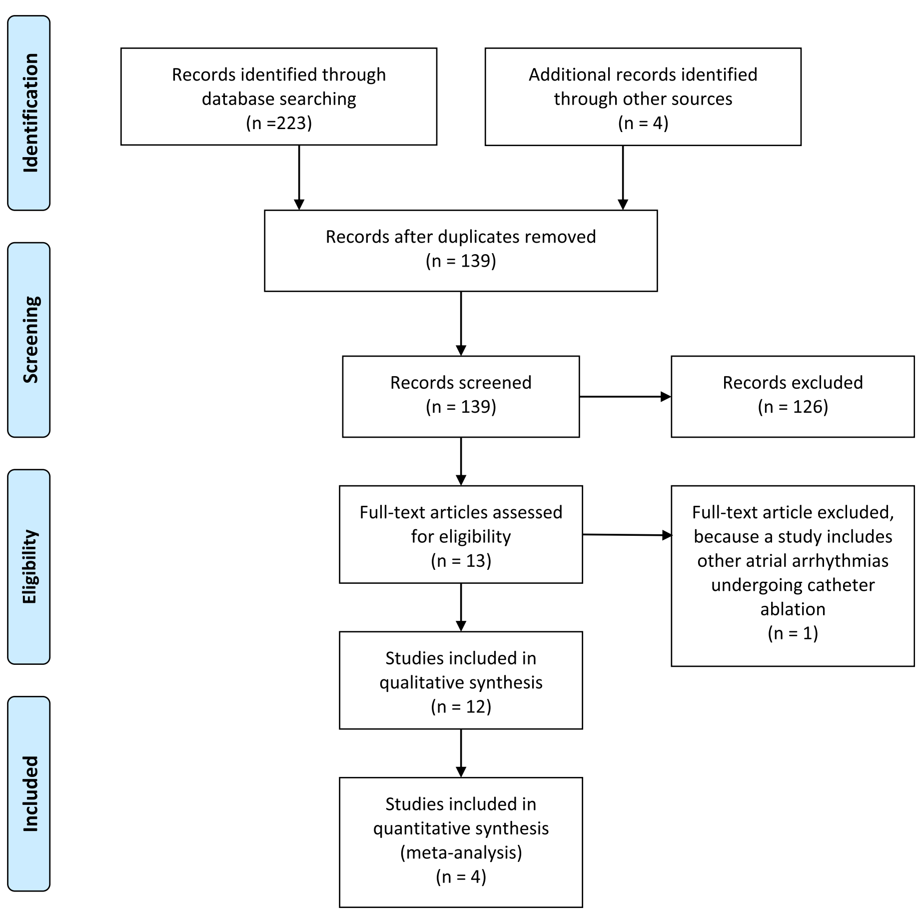

Fig. 1. Study flow diagram.

Table 1
Summary of the included studies.

Author	Study Design	Sample Size without Control (n)	Patients Characteristics	AF (Paroxysmal/ Non-Paroxysmal)	Age (Years)	Gender (Male)	12 Months AF Freedom	Complications	Follow-up (mean)
Liang 2019	Multicenter Retrospective Cohort	84	CHD who were treated with catheter ablation for symptomatic AF CHD Complexity: Simple 51 (60.7%), Moderate 22 (26.2%), Complex 11 (13.1%)	38/46 (45.2%/54.8%)	51.5 ± 12.1	55 (65.5%)	53.1% [Complete] 71.6% [Partial]	0 Major Complications 7 (8.3%) Minor Complications	708.6 ± 807.7 days
Guarguali 2019	Retrospective Cohort	58	CHD undergoing AF ablation CHD Complexity: Simple 25 (43%), Moderate 20 (34%), Complex 13 (13%)	26/32 (45%/55%)	51 (44–63)	33 (57%)	32.8%/40.9%/36.5% (1st/2nd/3rd ablation) Simple-Moderate: 39.3% Severe: 16.6%	0 Major Complications Minor Complications: No Data Available	24 (11–69) months
Abadir 2019	Retrospective Cohort	10	CHD undergoing AF cryoballoon ablation CHD Complexity: Simple 8 (80%), Moderate 2 (20%)	8/2 (80%/20%)	57.9 (48.2 –61.7)	4 (40%)	60%	0 Major Complications Minor Complications: No Data Available	12 months
Sohns 2018	Retrospective Cohort	57	CHD with drug-refractory AF undergoing ablation CHD Complexity: Simple 35 (61.4%), Moderate 10 (17.5%), Complex 12 (21.1%)	21/36 (37%/63%)	51.1 ± 14.8	N/A	63% (Index Ablation) 99% (Subsequent Ablation)	1 (1.8%) Major Complication: Pericardial Tamponade 12 (21.1%) Minor Complications	41 ± 36 months
Philip 2012	Retrospective Cohort	36	CHD undergoing AF ablation (PVAI)	26/10 (72.2%/27.8%)	53 ± 2	24 (66.6%)	42%	6 (17%) 3 Vascular Access Site 1 Embolic Event 2 Pulmonary Stenosis	48 months
Nie 2014	Retrospective Cohort	18	Unrepaired ASD with drug-refractory AF undergoing ablation	13/5 (72.2%/27.8%)	64.06 ± 9.82	11 (61.1%)	55.56% (20 months)	1 (5.6%) Acute HF	20 months
Santangeli 2011	Prospective Cohort	39	Repaired ASD (device closure) with drug-refractory AF undergoing ablation	13/26 (33%/67%)	54 ± 6	28 (72%)	77% (14 ± 4 months)	0 Major Complications Minor Complications: No Data Available	18 months
Lakkireddy 2008	Prospective Cohort	45	Repaired ASD/PFO with AF undergoing ablation	27/18 (60%/40%)	52 ± 11	36 (80%)	67%	N/A	15 ± 4 months
Turagam 2018	Multicenter Retrospective Cohort	28	PLSVC with drug-refractory AF undergoing ablation	17/11 (61%/49%)	61 ± 8	22 (79%)	75%	0 Major Complications 4 (14%) Minor Complications	12 months
Wissner 2010	Case-Series	7	PLSVC with AF undergoing ablation	2/5 (40%/60%)	57 ± 8	3 (42.9%)	86% (20 months)	2 (28.5%) Major Complications (left phrenic nerve injury and cardiac tamponade)	621 (339 –1289) days
Elayi 2006	Case-Series	6	PLSVC with drug-refractory AF undergoing ablation	4/2 (67%/33%)	50 ± 6.4	4 (66.7%)	100%	0 Complications	13 ± 7.4 months
Hsu 2004	Case-Series	5	PLSVC with drug-refractory AF undergoing ablation	4/1 (80%/20%)	46 ± 11	4 (80%)	75%	0 Complications	15 ± 10 months
Total		393		199/194 (50.6%/ 49.4%)	54.23 ± 11.58	224 (66.7%)	1st Ablation = 58.02%	5 Major Complications 26 Minor Complications	25.13 ± 11.16 months

Description: AF = Atrial Fibrillation, ASD = Atrial Septal Defect, CHD=Congenital Heart Disease, PLSVC=Persistent Left Superior Vena Cava, PFO=Patent Foramen Ovale, PVAI=Pulmonary Vein Antrum Isolation.

3.2. Congenital heart diseases in general

There were three studies with samples >50 and published in the year 2018–2019 on ablation for AF in general CHD showed 32.8%–63% 12 months AF freedom and with repeat/multiple procedures reaching 40.9%–99% [7–9]. Guarguali et al. reported up to six ablations, Philip et al. reported up to two ablations, Sohns et al. up to four ablations. Sohns et al. stated that anatomic complexity of CHD (Bethesda 3) is associated with a hazard ratio of 1.98 for AF recurrence, however, Liang et al. and Guarguali et al. showed that then 12 months AF freedom was irrespective of anatomic complexity. Abadir et al. in a small 2019 study involving cryoballoon AF ablation in simple-moderate anatomic complexity of CHD have a 60% 12 months AF freedom. Meta-analysis showed no significant difference (OR 2.61 [95% CI: 0.95, 7.16], $p = 0.06$, I^2: 0%) between simple-moderate complexity compared to severe complexity in terms of 12 months AF freedom. The ablation was exclusively pulmonary vein isolation (PVI) without systematic targeting of extra-pulmonary vein substrate, and there was no repeat procedure [10]. One study by Philip et al., in 2012 showed that AF freedom was 63% [11]. None of the studies reported procedure-related death. Liang et al. Guarguali et al., and Abadir et al. reported no major complications on follow-up. Sohns et al. reported 1 (1.8%) major complication, that is pericardial tamponade [9]. As for the minor complication, Liang et al. reported 7 (8.3%) and Sohns et al. 12 (21.1%) [8]. Liang et al. reported 1 out 51 (1.96%) in simple complexity, 4 out of 22 (18.18%) in moderate, and 2 out of 11 (18.18%) with severe CHD. Sohns et al. reported mild or moderate groin hematoma in 6 (10.5%) patients and others complications (10.5%) in 6 patients. Philip et al. demonstrated complications in 6 out of 36 patients (17%), comprising of 3 vascular access site, 1 embolic event, and 2 pulmonary stenoses.

3.3. Atrial septal defect

Three studies published in the year 2008–2014 investigate the efficacy and safety of ablation in patients with ASD with 12 months AF freedom ranging from 67% to 86% [12–14]. Lakkireddy et al. also included PFO in their samples. Santangeli et al. and Lakkireddy et al. specifically studied ASD that has been repaired while Nie et al. studied unrepaired ASD. Lakkireddy et al. sample consist of 45 patients, in which 22 underwent direct suture repair and 23 with device closure; Santangeli et al. reported ASD with device closure. Lakkireddy et al. reported AF ablation in repaired ASD patient have lower 12 months AF freedom (but not statistically significant) and a similar rate of complication compared to age-gender-AF type matched controls with similar complication rate. Nie et al. showed that unrepaired ASD have a lower 12 months AF freedom (but not statistically significant) and a similar rate of complications compared to age-gender-AF type-left atrial diameter matched controls. Meta-analysis showed no difference in 12 months AF freedom between ASD and matched controls (OR 0.99 [0.48, 2.04], $p = 0.97$, I^2: 15%)

3.4. Persistent left superior vena cava

Three case-series reported AF ablation in PLSCV patients with 12 months AF freedom of 75% and 100% and 20 months AF freedom of 86% [15–17]. One study by Turagam et al. demonstrated a 75% 12 months AF freedom in 28 patients [18]. Wissner et al. reported 2 major complications out of 7 patients. Elayi et al. Hsu et al. and Turagam et al. reported no major complications. Turagam et al. reported 4 (14%) minor complications.

4. Discussion

Ablation of AF in patients with CHD had a modest 12 months AF freedom, which can be increased by subsequent/repeat ablation. The complexity of CHD as defined by 32nd Bethesda consensus document appears to have a significant effect on a study but not in others [19]. Catheter ablation using cryoballoon also appears to be promising. Catheter ablation in ASD type of CHD had high success rate and seemed to be higher compared to CHD in general, although head-to-head comparison could not be made; the studies of ablation for CHD, in general, were published recently, and the outcome was expected to be better. Ablation of AF in PLSVC has a high success rate, the lowest was 75%, and the highest was 100%. Overall, catheter ablation is safe whichever the type of CHD is; with a low number of major complication and an acceptable number of minor complications. Meta-analysis showed no significant difference between simple-moderate complexity compared to severe complexity in terms of 12 months AF freedom, however, a more complex CHD requires a more advanced medical equipment. It seemed that the efficacy might be similar if performed by experts in the tertiary center, although more sample is needed before definite conclusion can be made.

Guarguali et al. demonstrated that female gender, anatomic complexity, persistent AF, and left atrial dimension were associated with risk of AF recurrence [7]. Nie et al. also showed that left atrial diameter is associated with AF recurrence [12]. Lakkireddy et al. also showed that 12 months AF recurrence is more frequent in non-paroxysmal AF group compared to paroxysmal group [13].

Congenital heart disease can lead to development of atrial tachycardia/AF through mechanisms such as volume overload and subsequent left atrial enlargement, and also from the scars developed after surgical repair of CHD that allows macro/micro-reentrant pathway [9,20]. Several types of CHD including uni-ventricular physiology and systemic right ventricle; presence of pulmonary hypertension, and prior intracardiac repair were shown to be independently associated with higher atrial tachycardia burden [21]. Hence, the difference in pathophysiology may affect the outcome of AF ablation. The included studies did not report previous surgery as an independent predictor of AF recurrence, however, analysis on level of anatomic complexity and repaired/unrepaired status with sufficient sample may generate a different hypothesis.

The 12 months of AF freedom varies widely from 32.8% to 63% in a single procedure. Sohns et al. probably performed ablation in the early stage of the disease, which explains a very high success rate that is 63% 12 months AF freedom rising to 99% after subsequent ablation [9]. Guarguali et al. performed a higher percentage of moderate-severe CHD complexity which may contribute to lower a 12 months AF freedom and also no dramatic increase in rate of success after repeat ablation unlike that of Sohns et al. study. Percentage of simple complexity in Guarguali et al. study was 43%, lower compared to Liang et al. (60.7%) and Sohns et al. (61.4%). It should be noted that there are studies showing a lower but not statistically significant 12 months AF freedom in complex CHD, this finding might show a significant difference if the number of samples is increased. Guarguali et al. have the largest percentage of moderate-severe complexity sample and statistical power to compare simple, moderate, and severe complexity. Hence, although our meta-analysis showed no significant difference; additional studies and larger sample size may potentially change the results. The 12 months AF recurrence is high in Philip et al. this might be caused by significant left atrial scar as indicated by lack of left atrial remodeling [11]. The 12 months AF freedom (single procedure) in studies with >60% simple complexity CHD samples, the success rate range from

53.1% to 63%, and those with ASD had a 55.6%–77%. Although the single procedure success rate seemed to be low, it should be noted that simple CHD and ASD is comparable to that of non-CHD which is 64.2% [22].

The rate of major complication requiring treatment is low in all types of CHD in the included studies and seemed safe even in complex CHD, although there is no control group of non-CHD patients in most of these studies. In recent studies that reported those with CHD in general, the rate of a major complication is 1 (0.48%; pericardial tamponade) out of a pooled 209 patients. Liang et al. reported 7 (8.3%) procedure-related minor complications; 1 out 51 (1.96%) in simple complexity, 4 out of 22 (18.18%) in moderate, and 2 out of 11 (18.18%) with severe CHD. The rate of minor complication was shown to be higher in moderate-severe complexity compared to simple complexity. Philip et al. demonstrated complications in 6 out of 36 patients (17%), comprising of 3 vascular access site, 1 embolic event, and 2 pulmonary stenoses; despite its magnitude, the rate of complication has no statistical difference to that of non-CHD in the control group. Studies in ASD patients also showed that the rate of complication is similar in control groups. Studies for PLSVC showed that the procedure is safe, on a pooled of 46 patients, there were 2 (4.35%) major complications that are left phrenic nerve injury and cardiac tamponade.

Catheter ablation for AF in CHD is a promising alternative to AAD and with technological advancements might someday be the first option in young patients in order to avoid a lifetime AAD treatment. However, as of now, it may require subsequent/repeat procedure to have a satisfying result. Catheter ablation for AF can be done effectively and safely, even in CHD with severe complexity but may require special techniques and more extensive ablation strategies with novel mapping tools [7,8]. The procedure is complicated, requires more advanced technology, and non-traditional techniques. Example of non-traditional technique was described by Liang et al. it involves use of robotic magnetic navigation system for a D-TGA post Mustard repair; an epicardial access for anomalous right superior pulmonary vein draining into superior vena cava. Hence, AF ablation in complex CHD is preferably done by experts with extensive experience on the field in a high volume tertiary center with a more advanced medical equipment.

The limitation of this systematic review is that the studies were heterogeneous. Many studies did not have controls to compare efficacy to that of AF ablation in non-CHD. Some studies did not report the 12 AF freedom based on the complexity of CHD. There are many studies that perform other types of ablation in addition to PVI, CHD also has vast anatomical variations. The pooled sample size was also small, the studies were lacking, and studies on PLSVC were mostly case-series. Subgroup analysis on radiofrequency and cryoballoon ablation cannot be performed due to lack of studies. Also, most of the studies are retrospective.

5. Conclusion

Catheter ablation for AF in CHD had modest efficacy that can be increased by subsequent/repeat ablation, and it also has an excellent safety profile. Current evidence showed that the efficacy and outcome do not differ much across the anatomic complexity of CHD, however, it is preferably done by experts in a high volume tertiary center.

Authors contribution

Raymond Pranata conceived and designed the study and drafted the manuscript. Emir Yonas and Veresa Chintya acquired the data and drafted the manuscript. Raymond Pranata and Alexander Edo Tondas interpreted the data. Raymond Pranata performed extensive research and critically revise the manuscript. All authors contributed to the writing of manuscript. Raymond Pranata analyzed the data statistically.

Declaration of competing interest

Authors declare no conflict of interests for this article.

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