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Catheter ablation for atrial fibrillation can be safely performed without invasive hemodynamic monitoring: A multi-center study

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Abstract

Background Arterial invasive monitoring is the most common method in the USA for hemodynamic monitoring during atrial fibrillation (AF) ablation. Although studies have shown favorable comparison between non-invasive and invasive hemodynamic monitoring (IHM) in non-cardiac procedures under general anesthesia, limited data is available for complex cardiac procedures such as AF ablation in the USA. With progressive improvement in AF ablation procedural safety, particularly with routine use of intracardiac echocardiography (ICE) to monitor for pericardial effusion, it is unclear if invasive hemodynamic monitoring provides any advantage over non-invasive methods. Therefore, the purpose of this study is to determine whether noninvasive hemodynamic monitoring is non-inferior to invasive hemodynamic monitoring during AF ablation under general anesthesia in patients without major cardiac structural abnormality.

Methods A multi-center retrospective data of AF ablation from July 2019 to December 2020 was extracted. A total of three hundred and sixty-two patients (362) were included, which were divided into group A (non-invasive hemodynamic monitoring) and group B (invasive hemodynamic monitoring). The primary outcome was to compare procedural safety between the two groups.

Results Out of 362 patients, 184 (51%) received non-invasive and 178 (49%) received invasive hemodynamic monitoring with similar baseline characteristics. There was no significant difference between the two groups in complication rates (groin hematoma, pericardial effusion, cardiac tamponade). Mean procedure time was longer in group B with 3.35% arterial site discomfort. Urgent arterial access was required in only 1 patient in group A.

Conclusion This retrospective multicenter study strongly suggests that catheter ablation for atrial fibrillation under general anesthesia can be safely performed with noninvasive hemodynamic monitoring without requiring arterial access, with potential benefit in procedural duration and cost.

Keywords Atrial fibrillation ablation · Hemodynamics monitoring · Non-invasive monitoring · Radiofrequency ablation

1 Introduction

Atrial fibrillation (AF) is the most common type of cardiac arrhythmia in the adult population worldwide. Catheter ablation (CA) has become a widely used method for rhythm control in AF. The 2017 HRS/EHRA/ECAS/APHRS/SOLAECE consensus statement on AF emphasized the importance of catheter ablation in management of patients who have failed pharmacologic therapy, issuing a class I indication for patients with refractory, paroxysmal AF and class IIa indication for patients with refractory, persistent AF [1]. Additionally, class IIa indications were recommended for catheter ablation as first line therapy for both persistent and paroxysmal AF [1]. With an increasing role

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in management of AF, ablation for AF has become the most common CA indication and has risen in popularity from an estimated annual 2644 procedures 20 years ago to more than 75,000 performed in hundreds of hospitals across the USA every year [2–4]. Recent data from randomized controlled trials such as STOP-AF and EARLY-AF also supports the superiority of AF ablation over medical treatment as first-line therapy, which will likely further expand the indication for this procedure [5, 6].

While AF ablation has been performed both under general anesthesia and conscious sedation, the procedural sedation protocol in the USA has traditionally been predominantly general anesthesia [1, 7]. Since the time of its inception, significant changes have been implemented in CA for AF to improve procedural safety and reduce perioperative complications. Specifically, the advancement of three-dimensional electroanatomic mapping, intracardiac echocardiogram (ICE) monitoring, and ultrasound guidance for vascular access have greatly improved the safety of CA procedures [8]. Overall, these changes have led to a decrease in perforations/cardiac tamponade from 1.7% in 2010 to 1.1% in 2015 and overall procedure complications from 5 to 2.5% during the same period [9]. The mean procedure time has also decreased with routine use of ICE [10]. At the same time, the indication for AF ablation is expanding to sicker patients who might have been previously excluded, such as those with heart failure, cardiomyopathy, advanced age, and significant left atrial enlargement [11–14].

Traditionally, hemodynamic monitoring during AF ablation in the USA has been performed via invasive femoral or radial arterial access due to historically long procedural duration and perceived procedural risks. Non-invasive hemodynamic monitoring has been slow to uptake due to uncertainties about procedural safety with this modality due to lack of published data. However, invasive arterial monitoring has its own pitfalls, namely, procedural lengthening and potential access site complications. We thus performed a study to determine whether non-invasive hemodynamic monitoring is an acceptable and safe alternative to invasive hemodynamic monitoring in patients with structurally normal heart during AF ablation under general anesthesia.

2 Methods

2.1 Study design

We performed a multicenter retrospective cohort study using AF catheter ablation data from four experienced operators in four separate tertiary care hospitals. The following sites were included: University of Missouri-Columbia, Ascension Saint Thomas hospital, Houston Methodist hospital, and Boulder Heart. The sites were selected to provide equitable distribution between invasive and noninvasive hemodynamic monitoring as 2 of the operators routinely utilize noninvasive monitoring. For this study, all consecutive AF ablation procedures were included for analysis. We examined the medical records from a total of 362 patients who underwent catheter ablation for AF between July 2019 and December 2020. Data collection included information regarding the patient's demographics, procedural parameters, the use of invasive hemodynamic monitoring, periprocedural complications, and complications at the standard 30-day postoperative visit. The study was approved by the respective institutional review boards of all sites.

The patients were divided into two groups based on the type of hemodynamic monitoring used for their procedure. Group A included patients who had noninvasive hemodynamic monitoring using standard cuff blood pressure every 3 min or noninvasive continuous hemodynamic monitoring via Edwards ClearSight system (Edward Life Sciences, Irvine, CA). Group B included patients who underwent AF ablation with invasive hemodynamic monitoring through either radial or femoral arterial access. The data was further analyzed after excluding patients with noninvasive continuous hemodynamic monitoring via Edwards ClearSight system (Edward Life Sciences, Irvine, CA) to avoid observational bias.

2.2 Procedure technique

All ablation procedures were performed under general anesthesia with continuous oxygen saturation and electrocardiography monitoring. The decision to use invasive versus non-invasive hemodynamic monitoring was based on each individual operator's protocol. General anesthesia was normally initiated with propofol and maintained with an inhaled anesthetic such as sevoflurane. If necessary, blood pressure was maintained by the anesthesia team using any of intravenous phenylephrine, norepinephrine, epinephrine, vasopressin, dopamine, and/or dobutamine. None of the patients required antihypertensives during the procedure. Higher blood pressures were managed by adjusting the vasopressor dosage. Ultrasound-guided modified Seldinger technique was used to obtain a total of two to four femoral venous access sheaths for each procedure. There was an expected variation in procedural technique and used tools among operators per individual preference (Table 1). Intracardiac echocardiography was utilized in all patients. All patients underwent postoperative venous hemostasis with a figure of eight suture. Post-procedure heparin reversal with protamine was operator dependent.

Table 1 Individual operator preferences

Operator	Number of transseptal punctures	Goal ACT (seconds)	Deflectable sheath use	Number of right femoral venous access	Number of left femoral venous access	Protamine use
Operator 1	1	> 300	No	2	2	No
Operator 2	1	> 350	Yes	3	0	Yes
Operator 3	1	350–400	No	3	0	No
Operator 4	2	> 350	Yes	2	2	Yes

ACT activated clotting time

2.3 Clinical outcomes

The primary clinical outcome of this study was to compare the safety parameters between the invasive and non-invasive groups. Complications assessed included pericardial effusion, access site hematoma/bleeding, and necessity for urgent arterial access. Pericardial effusion was visualized using intra-operative echocardiography, and access site hematoma was identified visually as swelling and/or bleeding from the arterial access site shortly after sheath removal. Complication rates were calculated as frequency and percentages. Secondary outcomes include overall procedure duration, total AF ablation duration, arterial site discomfort post procedure, and at 1 month and intra-operative vasopressor use for hemodynamic support. The total procedure duration was defined as the time between patient arrival in the room for the procedure till transfer to recovery. The total AF ablation duration was defined as time between femoral venous access and sheath removal at the end of procedure.

2.4 Exclusion criteria

Patients with baseline left ventricular ejection fraction < 0.35, severe pulmonary artery hypertension with pulmonary artery pressure > 50 mm Hg, and hypertrophic cardiomyopathy were excluded from the study as these patients were expected to require more intensive hemodynamic monitoring, as determined by the anesthesia team.

2.5 Statistical analysis

Data analysis was performed with the Stata 16 software platform (StataCorp, College Station, TX). Categorical variables were recorded as frequency and percentage (%) and compared with the use of the Pearson χ^2 squared test as well as the Fisher exact test. Continuous (numerical) variables were described as mean ± standard deviation if normally distributed, or median with 25th and 75th percentiles if not. The Student *t* test or the Wilcoxon signed-rank test was used to compare continuous variables depending upon parametric or nonparametric distribution, respectively. Clinical significance was defined as a two-tailed *P* value less than 0.05.

3 Results

Three hundred and sixty-two patients (362) were included in the study (63.04% male, mean 66 [20–85] years). One hundred and eighty-four (184) patients underwent noninvasive hemodynamic monitoring (Group A) and one hundred and seventy-eight (178) underwent invasive hemodynamic monitoring (Group B). Edwards ClearSight system (Edward Life Sciences, Irvine, CA) continuous noninvasive monitoring was utilized in 23 (12.5%) patients in Group A, purely dictated by anesthesiologist choice. Baseline demographic characteristics were similar between the groups except for higher frequency of hypertension and diabetes and lower frequency of persistent AF in the invasive monitoring group (Table 2). The average left ventricular ejection fraction was lower in invasive hemodynamics group. However, no significant difference was observed when comparing for ejection fraction below 0.4 in both groups.

Table 2 Baseline characteristics

	Group A ($n = 184$) (Non-Invasive group)	Group B ($n = 178$) (Invasive group)	*P* value
Age (years)	66.09 ± 9.79	67 ± 9.01	0.36
Male gender	116 (63.04%)	112 (62.92%)	0.98
BMI	31.37 ± 6.82	32.29 ± 6.63	0.19
Hypertension	121 (65.76%)	142 (79.78%)	0.003
DM	32 (17.39%)	55 (30.9%)	0.003
Heart failure	59 (32.07%)	45 (25.28%)	0.15
CAD	51 (27.72%)	28 (21.35%)	0.15
CABG	11 (6.18%)	15 (8.52%)	0.4
CKD	12 (6.52%)	16 (8.99%)	0.38
LVEF	0.56 ± 0.12	0.52 ± 0.1	< 0.001
LVEF ≤ 0.4	19 (10.33%)	23 (12.92%)	0.3
Persistent AF	111 (60.33%)	83 (46.63%)	0.009
Type of arterial access	1 (0.54%)	Radial 170 (95%) Femoral 8 (5%)	

BMI body mass index, *DM* diabetes mellitus, *CAD* coronary artery disease, *CABG* coronary artery bypass graft, *CKD* chronic kidney disease, *LVEF* left ventricular ejection fraction

3.1 Procedural parameters

The total procedure duration (192.22 ± 62.67 vs. 244.43 ± 108.49 min, $p < 0.001$) and AF ablation duration (130.01 ± 57.01 vs. 174.24 ± 88.12 min, $p < 0.001$) were significantly longer in the invasive hemodynamic group (Table 3). Average time for arterial access by the anesthesia team was 18.99 ± 12.06 min in 111 patients. Eight (4.5%) patients in the invasive monitoring group required femoral arterial access for inability to obtain radial arterial access. There was no significant difference between the two groups for requirement of intravenous hemodynamic support ($p = 0.8$).

3.2 Complications

Arterial access site hematoma was observed in 1 patient (0.65%) managed by prolonged compression. Post-procedure arterial site discomfort was present in 6 (3.35%) of patients, persistent at 1 month in 5 (2.85%) patients. Overall, the two groups were comparable for intra-/peri-procedural complications. All groin (femoral venous access site) hematomas were conservatively managed with prolonged manual compression. There was no reported femoral pseudoaneurysm or arteriovenous fistula. One patient in each group developed pericardial tamponade requiring urgent pericardiocentesis. No surgical intervention was required for pericardial tamponade in any group. Pericardial effusion without tamponade was observed in 1 patient in the invasive monitoring group. Urgent arterial access was required in only one patient (pericardial tamponade) in the noninvasive group.

4 Discussion

This multicenter retrospective study demonstrated that non-invasive hemodynamic monitoring for AF ablation under general anesthesia was comparable to standard arterial monitoring without increased risk of intra-operative complications. The overall procedure duration was longer in patients who underwent invasive hemodynamic monitoring. Only one patient in the non-invasive group required urgent arterial access for pericardial tamponade.

Hemodynamic monitoring has become a core component of AF ablation procedures since changes in autonomic drive during general anesthesia can have a significant effect on procedural outcomes. The choice of perioperative hemodynamic monitoring for any general anesthesia procedure is based on patient-specific risk factors as well as procedural risk, with higher risk patients and procedures traditionally necessitating more invasive monitoring techniques [15]. While AF ablation might have previously been perceived as a high-risk procedure (and thus necessitated more invasive monitoring), recent advancements in procedural safety such as intracardiac echocardiography (ICE) and vascular ultrasound guided venous access have significantly reduced the complication rate and called the necessity of invasive monitoring into question.

4.1 The use of ICE during ablation procedures

Intracardiac echocardiography (ICE) during AF ablation allows safe trans-septal access as well as catheter tracking and continuous intra-procedural monitoring of ventricular contractility and pericardial effusion. Aldhoon et al. demonstrated that AF CA procedures performed with ICE showed significantly lower risk of pericardial effusion (0.7% vs. 1.7%) and total complications (3.3% vs 3.9%) when

Table 3 Procedural duration and complications

	Group A ($n = 184$) (non-invasive group)	Group B ($n = 178$) (invasive group)	*P* value
Total procedure duration (minutes)	192.22 ± 62.67	244.43 ± 108.49	< 0.001
Time for radial arterial access (minutes)	N/A	18.99 ± 12.06 ($n = 111$)	
AF ablation duration (minutes)	130.01 ± 57.01	174.24 ± 88.12	< 0.001
Vasopressor use	155 (84.24%)	151 (84.83%)	0.8
Pericardial effusion	1 (0.54%)	2 (1.12%)	0.54
Urgent arterial access	1 (0.54%)	N/A	
Groin hematoma	1 (0.54%)	6 (3.37%)	0.051
Arterial access hematoma	N/A	1 (0.65%)	
Postop arterial site discomfort	N/A	6 (3.35%)	
1-month arterial site discomfort	None	5 (2.84%)	

N/A not applicable

compared to those performed without [16]. The risk of pericardial effusion during CA for AF has decreased over time, as also seen in our study which found a 0.83% incidence across both groups.

4.2 The use of ultrasound-guided femoral venous access

Femoral venous access can be associated with several complications, including hematomas, AV fistulas, and pseudoaneurysms. While venous access sites were traditionally obtained using anatomical landmarks and femoral pulse palpation, ultrasound-guided femoral venous access was introduced to ablation procedures in the 2010s to allow for direct visual access. Vascular ultrasound guidance has been proven to decrease bleeding complications in AF ablation [17–19]. Specifically, Wynn et al. reported a reduction in vascular complication rate from 7.6 to 1.6% with vascular ultrasound guidance [18]. The access site hematoma rate of 1.9% in our study is similar to previous studies, demonstrating the utility of ultrasound guidance across multiple centers.

4.3 The use of non-invasive blood pressure monitoring

Hemodynamic monitoring is required for any procedures requiring sedation to ensure medication safety and patient stability. Several studies have shown that NIBP monitoring is as accurate and reliable for measurement of mean arterial pressure as standard invasive arterial access [20–23]. Importantly, NIBP has also been shown to be reliably effective for monitoring blood pressure in patients with arrhythmias such as AF [24–26]. Direct invasive arterial pressure monitoring has traditionally been employed during AF ablation due to concerns about rapid hemodynamic changes during cardiac manipulation, procedural arrhythmia, and pericardial perforation. While previous studies have focused on the correspondence between mean arterial pressure/cardiac output between NIBP and an established gold standard (arterial access), we compared clinical outcomes of NIBP and invasive hemodynamics monitoring via arterial line placement. Ours is the first study to demonstrate non-inferiority of NIBP to arterial line placement in AF catheter ablation. Our results were unchanged after excluding the 23 patients with Edwards ClearSight system (Edward Life Sciences, Irvine, CA) continuous noninvasive monitoring to restrict our analysis to only patients with standard NIBP monitoring (Supplementary Tables 1, 2). Although there are contrasting studies that argue against NIBP as an accurate reflection of cardiac output in the setting of cardiac surgery [27, 28], that may hold true for more invasive or open cardiac procedures but not for CA for AF, as seen in our study. While it is hypothetically possible that continuous invasive blood pressure monitoring could enable earlier detection of iatrogenic tamponade, we believe that the same intensity of tamponade monitoring is acquired with careful ICE imaging. The overall incidence of pericardial tamponade was quite low in our study consistent with recent AF ablation literature [29, 30]. A larger study might be required to test this hypothesis.

4.4 Procedure time

One compelling aspect of NIBP is the expected decrease in procedure time, since NIBP setup time is significantly shorter than direct or ultrasound-guided arterial line placement. Other studies have concluded that NIBP monitoring with devices like Edwards ClearSight system (Edward Life Sciences, Irvine, CA) could save up to 30 min per patient during percutaneous heart valve intervention procedures [31]. In our study, we confirmed a significantly longer procedure time in the arterial line access group even allowing for the time taken for arterial access. This is likely secondary to the inclusion of multiple operators from different centers with individual procedural speeds and techniques (Table 1). For a single operator, we predict that the omission of invasive monitoring would be expected to lead to a considerable improvement in procedural and lab turnover time, as evidenced by the mean arterial access time of 18.99 ± 12.06 min in our study as well as the inability to obtain radial arterial access in 4.5% patients.

4.5 Cost saving

Prior analysis of the cost of radial arterial lines estimated the average cost of arterial line placement (including device/staffing costs, multiple attempts, and operation room time) to be around $775 [32]. Since placement of NIBP is much faster and requires minimal setup, we expect use of NIBP will significantly reduce monitoring costs. In addition, there are several major complications associated with arterial line placement that can be reduced with NIBP usage such as access site hematomas, bleeding, and infections that can lengthen procedural time/length of stay and increase costs [33]. Although the Edwards ClearSight system (Edward Life Sciences, Irvine, CA) was used in 12.5% patients in the noninvasive monitoring group in our study, this was dictated purely by anesthesiologist preference and did not appear to confer any advantage over cuff NIBP monitoring. With hematomas and bleeding events costing a hospital an estimated $3779 and $6377 per event respectively, usage of NIBP could potentially result in significant cost-saving in large-volume centers [34].

4.6 Limitations

The nonrandomized and retrospective nature of the study subjects it to potential selection bias, particularly since most noninvasive monitoring cases were performed at 2 centers (203 cases for operators 1 and 2 vs. 96 cases for operators 3 and 4). This could present as a confounding variable if operators 1 and 2 had a shorter mean procedural time than operators 3 and 4. However, this was primarily due to operator preference rather than a difference in patient type or demographic parameters. Additionally, the effect of this bias was minimized by the enrollment of consecutive patients. Importantly, post-procedural arterial access site discomfort might not have been adequately reported due to the lack of a dedicated patient questionnaire in retrospective data collection. We were unable to compare net procedure time (total procedure time minus time for arterial access) reliably across the groups due to institutional differences in procedural documentation. Our study is not powered to detect difference in procedural mortality which is quite low in AF ablation. Our investigation was also limited to stable patients undergoing AF catheter ablations; it is uncertain if our results can be expanded to the excluded population or other complex ablation indications such as ventricular tachycardia.

5 Conclusion

This retrospective multicenter study strongly suggests that catheter ablation for atrial fibrillation under general anesthesia can be safely performed with noninvasive hemodynamic monitoring without requiring arterial access, with potential benefit in procedural duration and cost.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s10840-022-01151-x.

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