The German Cardiosurgery Atrial Fibrillation Registry: 1-Year Follow-up Outcomes

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Abstract

Objectives This study of German Cardiosurgery Atrial Fibrillation (CASE-AF) registry aims to describe the 1-year outcomes of patients undergoing ablative procedures for atrial fibrillation (AF) in a cardiosurgical setting.

Methods Between January 2017 and April 2020, 17 German cardiosurgical units enrolled 1,000 consecutive patients undergoing concomitant or stand-alone ablation for AF. In-hospital and 1-year follow-up data were collected on web-based electronic case report forms. The protocol mandated telephone-based follow-up contact after 1 year.

Results At 1-year follow-up (median, 14.5 months [12.6–18.2 months]), significant improvement ($p < 0.0001$) in baseline modified European Heart Rhythm Association Class I was reported in both concomitant and stand-alone patients. Follow-up examinations were completed in 97.9% of cases, and a sinus rhythm was reported in 60.2 and 63.6% of stand-alone and concomitant patients, respectively. Statistically significant factors determining late recurrence were female gender ($p = 0.013$), preoperative persistent AF ($p < 0.0001$), and presence of cardiac implantable electronic device ($p = 0.011$). All-cause mortality at 1 year was 1% ($n = 1$) in stand-alone patients and 6.7% ($n = 58$) in concomitant patients.

Conclusion Surgical ablation of AF is safe and provides satisfactory results at short-term follow-up, with significant improvement in patient symptoms. Adequate cardiac rhythm monitoring should be prioritized for higher quality data acquisition.

Keywords
- arrhythmia therapy
- minimally invasive surgery
- heart valve surgery

Introduction

Over 30 years of innovation and further advancement after its original description, the Cox-maze IV still offers superlative results with low complication rates when compared with other ablative techniques. The minimally invasive technologies to create transmural atrial lesions during surgical ablation offered today, which have originated from the

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original "cut and sew" strategy pioneered by James Cox in 1987,[1] are testimony to the advancements in ablative surgery. Historically seen, a maze procedure is only complete after occlusion of the left atrial appendage (LAA), and as such, a surgical ablative procedure today must include LAA occlusion.

Nevertheless, the necessity to monitor and reevaluate the current standard of practice remains the highest priority, particularly in patients undergoing surgical ablation either as stand-alone procedures or during concomitant cardiovascular surgery. Data surveying real-world scenarios to provide snapshots in atrial fibrillation (AF) surgery, though still lacking, are perhaps gaining relevance through registries dedicated to monitoring these patients.

The Cardiosurgery Atrial Fibrillation (CASE-AF) registry, governed by the Institute for Heart Attack Research (Institute für Herzinfarktforschung, IHF), has maintained this ongoing registry for nearly 5 years to sample patients undergoing ablative surgery and their outcomes across Germany. It is the largest national cardiosurgical survey with focus on ablative procedures. A preliminary manuscript detailing the structure and in-hospital outcomes of the CASE-AF registry is readily available.[2] We now aim to present the results of the 1-year follow-up analysis of this ongoing registry.

Materials and Methods

The primary objective of the CASE-AF registry is to describe the in-hospital results and 1-year follow-up outcomes of patients undergoing ablation in a cardiosurgical setting during concomitant or stand-alone procedures. Briefly, the CASE-AF registry is a prospective, observational registry, in which only 17 German cardiac surgery centers enrolled 1,000 consecutive patients undergoing stand-alone or concomitant ablative procedures between January 2017 and April 2020. A central data bank supervised by the IHF enabled data upload using an electronic case report form (eCRF). Pre-, intra-, and postoperative data and, later, 1-year outcomes were gathered. Informed consent was obtained from each patient before ablation, and each center attained approval of its local ethics committee.

At 1-year follow-up, data collected included, but were not limited to, AF relapse, arrythmia documentation, hospital readmission, modified European Heart Rhythm Association (mEHRA) class, CHA_2DS_2-VASc score, electric or chemical cardioversion, redo ablation, cardiac implantable electronic device (CIED) implantation, postoperative out-of-hospital complications, rehospitalization, current anticoagulation, antiarrhythmic drugs (AAD), and mortality.

The IHF was responsible for central data monitoring, and initial queries detected in the eCRF prohibited further data entry until corrected. After data-entry completion, further analysis by dedicated IHF statisticians to detect inaccuracies was performed to maintain data quality. Follow-up studies at 1 year were done according to local center practice or through IHF staff. The protocol mandated telephone contact 1 year after discharge.

Definitions

The classification of AF as *paroxysmal*, *persistent*, or *long-standing persistent* was adapted from the 2016 European Society of Cardiology/European Association for Cardio-Thoracic Surgery (ESC/EACTS) Guidelines for the management of AF.[3] The mEHRA was used to define patient severity of symptoms.[4] Patients undergoing surgery for structural/coronary heart disease and AF surgery were defined as *concomitant* patients. The *stand-alone* patient group consisted of patients undergoing strictly surgical ablation for AF.

Early recurrence of AF was defined as any recurrence of AF > 30 seconds during the *blanking period* (<3 months postablation) and was not considered as failure. Any recurrence between 3 and 12 months postablation was defined as *late recurrence of AF*.[5] *One-year procedural success* was defined as patient survival from atrial arrythmia after the blanking period to follow-up, on or off AAD, without a redo ablative procedure or electric synchronized cardioversion, and an mEHRA score < 3.

Statistical Analysis

Data examination and analysis was conducted by statisticians at the IHF in Ludwigshafen/Rhein, Germany. Categorical variables, compared by chi-square test, were presented as absolute numbers and percentages. Continuous variables, compared by Mann–Whitney–Wilcoxon test, were presented as mean and standard deviation or median and interquartile range (IQR).

Predictors of late AF recurrence after concomitant procedures during 1-year follow-up were analyzed using logistic regression. The following baseline characteristics that showed a significant association with late recurrence in univariate comparison were included in the model: gender, age, body mass index $\geq$ 35, persistent AF, thyroid dysfunction, presence of cardiac implantable electronic device (CIED), left ventricular ejection fraction < 35%, left atrial diameter > 60 mm, and mitral valve repair/replacement.

The cumulative incidence of reablation was estimated using the product-limit method and was visualized as Kaplan–Meier curves. All tests were two-tailed, and *p*-values < 0.05 were considered statistically significant. Statistical analyses were performed using SAS version 9.4 (Statistical Analysis Software, Cary, NC).

Results

The in-hospital outcomes of the CASE-AF registry have already been published.[2] The arrythmia-related patient characteristics at admission are recapped in ►**Table 1** and operative data in ►**Table 2**. To briefly summarize, in Germany, the typical patient undergoing concomitant surgical ablation is a 69-year-old male with valvular heart disease and paroxysmal AF, presenting with mild-to-moderate symptoms related to AF (mEHRA IIa–IIb). Epicardial bipolar radiofrequency (RF) energy to isolate the pulmonary veins

Table 1 Baseline arrhythmia related patient clinical characteristics

	Stand-alone ($n = 101$)	Concomitant ($n = 899$)
Comorbidities		
Congestive heart failure, %	21.8	48.4
Hypertension, %	61.4	76.7
Age (y)	61.9 ± 9.6	69 ± 9.0
Diabetes mellitus, %	10.9	20.6
Stroke, %	8.9	8.3
Vascular disease, %	3.0	6.1
Sex (female), %	28.7	29.8
BMI, kg/m^2	29.3 ± 5.4	27.9 ± 5.0
CHA_2DS_2-VASc score	2.0 ± 1.4	3.2 ± 1.6
$\geq$2 %	60.4	86.3
AF classification, %		
Paroxysmal	15.8	55.4
Persistent	55.4	24.9
Long-standing persistent	28.7	19.7
mEHRA classification, %		
I	3.0	18.9
IIa	5.9	34.5
IIb	38.6	29.7
III	46.5	14.9
IV	5.9	1.9
Underlying cardiac disease, %		
Coronary artery disease	26.6	33.1
Valvular heart disease	6.3	62.8
Other	1.6	4.1
Lone atrial fibrillation	65.6	–
Echocardiographic parameters		
LVEF, %	57 ± 9	54 ± 12
LAD, mm	46 ± 9	49 ± 9

Abbreviations: AF, atrial fibrillation; BMI, body mass index; LAD, left atrial diameter; LVEF, left ventricular ejection fraction; mEHRA, modified European Heart Rhythm Association; SD, standard deviation.
Note: Values are given as mean $\pm$ standard deviation unless otherwise specified.

and LAA excision was the treatment method more commonly practiced during concomitant operations. The patient undergoing stand-alone ablation is a 62-year-old male with persistent or long-standing persistent AF (LSPAF), moderate-to-severe symptoms (mEHRA IIa–III) related to AF, with at least two previous catheter ablative procedures. Totally thoracoscopic epicardial bipolar RF bilateral pulmonary vein isolation and completion of a "box-lesion" with clip (AtriCure, AtriClip) closure of the LAA was the most practiced ablative strategy in this patient cohort. At discharge, a sinus rhythm (SR) was achieved in 63.4 and 88.1% of concomitant and stand-alone patients, respectively.

Follow-up evaluations by telephone contact were completed in 97.9% of the total population at a median of 14.5 months (IQR, 12.6–18.2) after the procedure. Arrhythmia diagnosis in the follow-up period was heterogeneous and varied across different centers. Rhythm monitoring and diagnosis was primarily completed by a 12-lead electrocardiogram (ECG) (77.6%), 24-hour Holter ECGs (68.4%), or CIEDs (9.3%). Within the stand-alone cohort, 46 out of 101 (45.5%) patients received an implantable loop recorder.

Stand-alone Follow-up Status

At follow-up, complete datasets were obtained for 100 patients (99.0%) of the initial stand-alone cohort ($n = 101$). Forty-five patients (46.9%) experienced at least an episode of symptomatic atrial arrhythmia within the blanking period. After this period, 34 patients (35.1%) reported symptomatic recurrence; however, 30 of 34 (88.2%) patients had had an episode within the blanking period. Roughly one-third of all patients required at least one synchronized electric cardioversion. Redo catheter ablation was required in 16 patients, mainly due to atrial flutter/tachycardia (►**Fig. 1**).

An SR was reported in 60.2% of patients at follow up; 1-year procedural success was documented in 37 patients (37.4%). Significant improvement in mEHRA symptoms could be demonstrated after stand-alone ablation, as 61.7 and 31.9% of patients reported no (mEHRA I) or mild (mEHRA IIa) symptoms ($p < 0.0001$), respectively (►**Fig. 2**).

Anticoagulation at follow-up was continued in 73 patients, and 66% received direct oral anticoagulation (DOAC). There was a relevant reduction in AAD therapy after ablative surgery, as only 10 patients were on AAD. The most common prescribed agent was a β-blocker (66.3%). ►**Fig. 3** outlines the medical therapy at follow-up.

Major cardiovascular and cerebrovascular events were reported in one case, in which a perioperative stroke resulted in death within the blanking period. There was one case of significant bleeding, two cases of phrenic nerve paralysis, and one reported case of pulmonary vein stenosis.

Concomitant Ablation Follow-up Status

From the initial concomitant ablation group ($n = 899$), complete datasets from 869 (96.7%) patients were collected after 1 year. At follow-up, 63.6% of patients were in SR. One-year procedural success was documented in 58.8%. Within the blanking period, 29.7% of patients reported AF relapse. Redo catheter-based ablative procedures were required in a total of 10 patients, mainly due to atrial flutter/tachycardia (►**Fig. 1**).

After concomitant ablation, 63.1% patients (vs 18.9% at baseline) reported no (mEHRA I) symptoms related to AF patients ($p < 0.0001$) (►**Fig. 2**). At follow-up, 74% of patients with preoperative paroxysmal AF reported an SR after concomitant procedures where an endocardial cryo-energy source was used. Similarly, 70% of patients with preoperative paroxysmal AF that underwent concomitant bipolar RF ablation reported SR at follow-up. Multivariate logistic regression confirmed that statistically significant predictors of late recurrence (>3 months postablation) included history of

Table 2 Operative technical data and ablative strategies

	Stand-alone ($n = 101$)	Concomitant ($n = 899$)
Surgical access, %		
Totally thoracoscopic	69.7	–
Median sternotomy	9.1	74.7
Right anterolateral minithoracotomy	21.7	21.3
Baseline procedure, %		
Coronary artery bypass surgery	–	39.3
Aortic valve replacement/repair	–	29.6
Mitral valve replacement/repair	–	45.7
Tricuspid valve replacement/repair	–	12.1
Other	–	3.4
Stand-alone ablation	97	–
Energy source, %		
Bipolar radiofrequency	94.9	50.2
Epicardial	94.9	57.8
Cryo-energy	7.1	51.0
Endocardial	6.1	50.2
Linear concept, %		
Box isolation	98.5	62.0
Right pulmonary vein isolation	100	97.6
Left pulmonary vein Isolation	98.3	97.6
Left atrial lesion set	58.8	46.5
Right atrial lesion set	10.3	12.8
Left atrial appendage closure (%)		
Amputation	1.2	40.3
Endocardial suture	–	16.4
Stapler excision	24.1	20.3
Clip exclusion	74.7	19.4
Other	–	3.6
Not done	14.9	14.4
Ablation duration, s		
Bipolar radiofrequency		
N	94	369
Median (IQR)	1,169 (860–1402)	144 (93–351)
Cryo-energy		
N	7	408
Median (IQR)	960 (360–1,140)	450 (360–660)
Intraoperative rhythm, %		
Sinus rhythm preablation	32.7	37.6
Sinus rhythm postablation	93.9	90.4

Abbreviation: IQR, interquartile range.

persistent AF ($p < 0.0001$; odds ratio [OR], 2.39; confidence interval [CI], 1.58–3.61), female sex ($p = 0.013$; OR, 1.64; CI, 1.11–2.42), and presence of CIED ($p = 0.011$; OR, 2.19; CI, 1.20–4.01) (►**Table 3**).

Adverse ablation-related complications (pulmonary vein stenosis, atrioesophageal) were not reported in any patient who underwent concomitant ablation. The survival rate at 1 year was 93.5%. In survivors, a stroke was reported in 3.2%.

Discussion

The CASE-AF registry provides insights into the current standards of treatment available for AF in a cardiosurgical cohort across Germany. The registry is currently enrolling, and with over 1,400 patients, it is the largest European surgical registry detailing ablative procedures in a surgical setting. Participating centers function autonomously in terms of ablative technique, energy source, medical therapy, and follow-up strategies. Data organization and analysis is governed independently by the IHF (Ludwigshafen, Germany). For these reasons, the CASE-AF registry provides a fairly accurate portrait into the current surgical treatment for AF in Germany.

Indeed, one of the most optimistic findings of this registry was the significant improvement postablation ($p < 0.0001$) in the clinical status of both groups. The total number of patients reporting no symptoms (62.4%, mEHRA I) correlated strongly to the overall reported freedom of AF at 1 year (61.9%). Several studies have previously confirmed significant improvement in symptoms and quality of life post catheter and/or surgical ablation.[6–10] The overall rate of conversion into SR at 1 year was 60.2 and 63.6% in stand-alone and concomitant patients, respectively. This conversion rate to SR at 1 year validates results in previously published manuscripts.[11–13] However, the absence of AF-related symptoms does not confirm the absence of AF. Given the insufficient postoperative arrhythmia coverage, our results may include patients with asymptomatic undiagnosed AF recurrences. It has been established that symptomatic patients undergoing AF ablation do experience asymptomatic episodes postablation.[14] This emphasizes the importance of implantable continuous cardiac rhythm monitoring devices. Arbelo and colleagues reported similar improvements in symptoms and conversion rates after catheter-based ablative procedures. Patients here were also predominantly followed up by serial and Holter ECGs and this study group similarly highlighted the importance of adequate arrhythmia monitoring postablation.[15]

To recap, the in-hospital outcomes of the CASE-AF registry reported a SR at discharge in 88.1% of stand-alone cases. The majority of cases were nonparoxysmal AF, in which a totally thoracoscopic maze using RF ablation to create a "box" lesion on the posterior LA wall was most commonly practiced. At follow-up, however, only 60.2% of stand-alone patients reported SR. In nonparoxysmal forms of AF, a "box" lesion seems insufficient to quieten the pathophysiological substrate, a substrate associated with neurohormonal

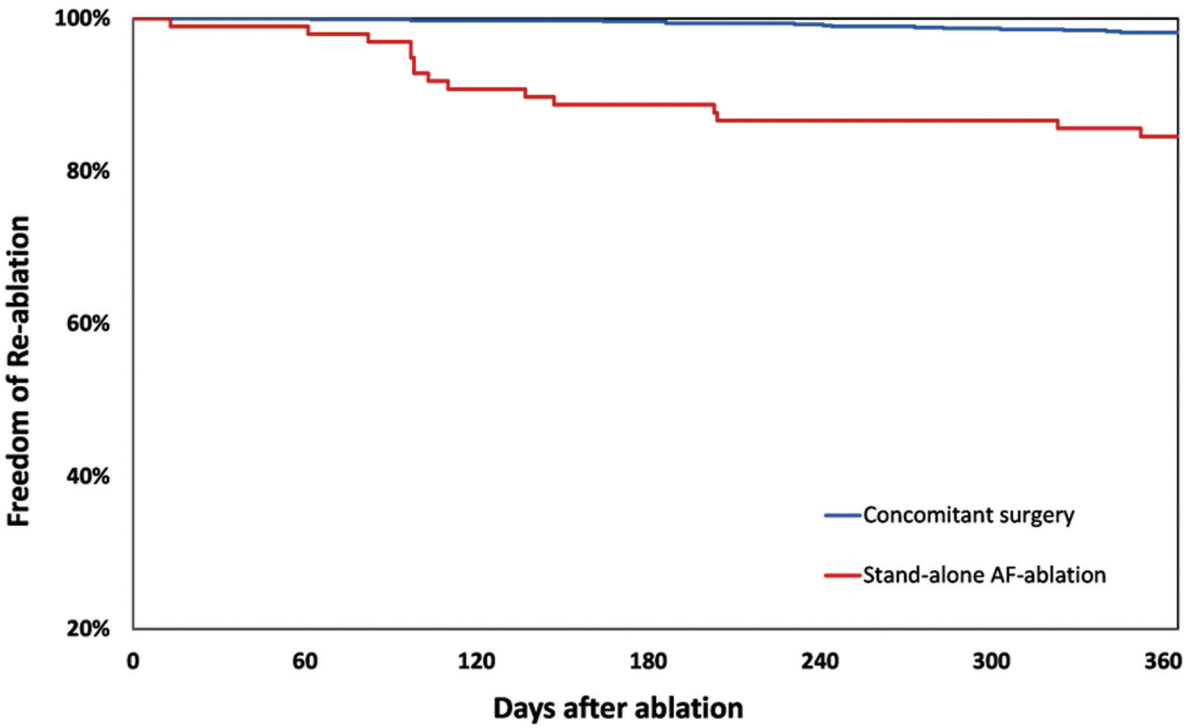

Fig. 1 Kaplan–Meier curve for freedom from reablation in survivors at 1-year follow-up.

remodeling and myocardial fibrosis, resulting in a dilated and diseased LA. Recently, Haldar and colleagues demonstrated, in a randomized control trial, that neither individual catheter-based nor surgical ablation offer satisfactory results to treat LSPAF.[16] A good solution to this dilemma already exists: the Cox-maze IV sufficiently manages nonparoxysmal forms of AF with unparalleled long-term results.[17,18] The invasiveness and complexity of the procedure, however, make it a less attractive approach. In a hybrid one-step approach, complex atrial lesion sets offered simultaneously through a transvenous and a totally thoracoscopic approach offer up to a 3-year arrhythmia-free interval without AAD or the need for redo catheter ablation in more than 80% of nonparoxysmal AF forms.[19,20] Low patient volume and lack of long-term follow-up do limit the feasibility of this approach, and further studies are required, but a multidisciplinary approach does seem reasonable.

In concomitant AF surgical patients, factors predicting AF relapse 3 months after ablation included preoperative AF subtype, gender, and the presence of a CIED. Multivariate analysis found that these factors were significant predictors of late recurrence. In 2005, Gaynor et al. had already discussed that AF duration preablation influences postoperative outcome,[21] and more recently, Pecha et al reported significantly higher success rates post concomitant ablation in patients with preoperative paroxysmal AF.[22] These conclusions coincide with the results presented in this manuscript, namely that, after concomitant ablation, the rate of conversion into SR was up to 71% at 1 year in patients with preoperative paroxysmal AF. This variate comes as no surprise, *contra* gender. The role of gender in postoperative outcomes after AF surgery is still obscure, and several surgical studies have established no direct association between gender and relapse rates at follow-up.[21–23] Conversely, our data are in agreeance with data available from the German Ablation registry. Multivariate analysis of 1-year follow-up data (n= 3,679) from the German Ablation registry revealed female sex and AF subtype to be strong predictors of AF recurrence after catheter ablation.[24]

Reduction of AAD correlated well with the overall conversion rate to SR at 1-year. However, in the postoperative stage after the blanking period, anticoagulation with vitamin K antagonist or DOAC in stand-alone and concomitant patients was still relatively high: 74.5 and 68.0%, respectively. Latest guidelines recommend anticoagulation after AF surgery and appendage closure based on the patient's individual CHA_2DS_2-VASc score,[25] and not postoperative success. This satisfactory guideline adherence to anticoagulation may serve as a fail-safe for subclinical and undiagnosed cases of AF where postablation monitoring is still lacking.

The postoperative mortality at 1 year in the concomitant group (6.7 vs 2.2% at discharge) is strikingly high, but within ranges. A significant associated risk in all-cause mortality during concomitant AF surgery is still uncertain. In a Cochrane

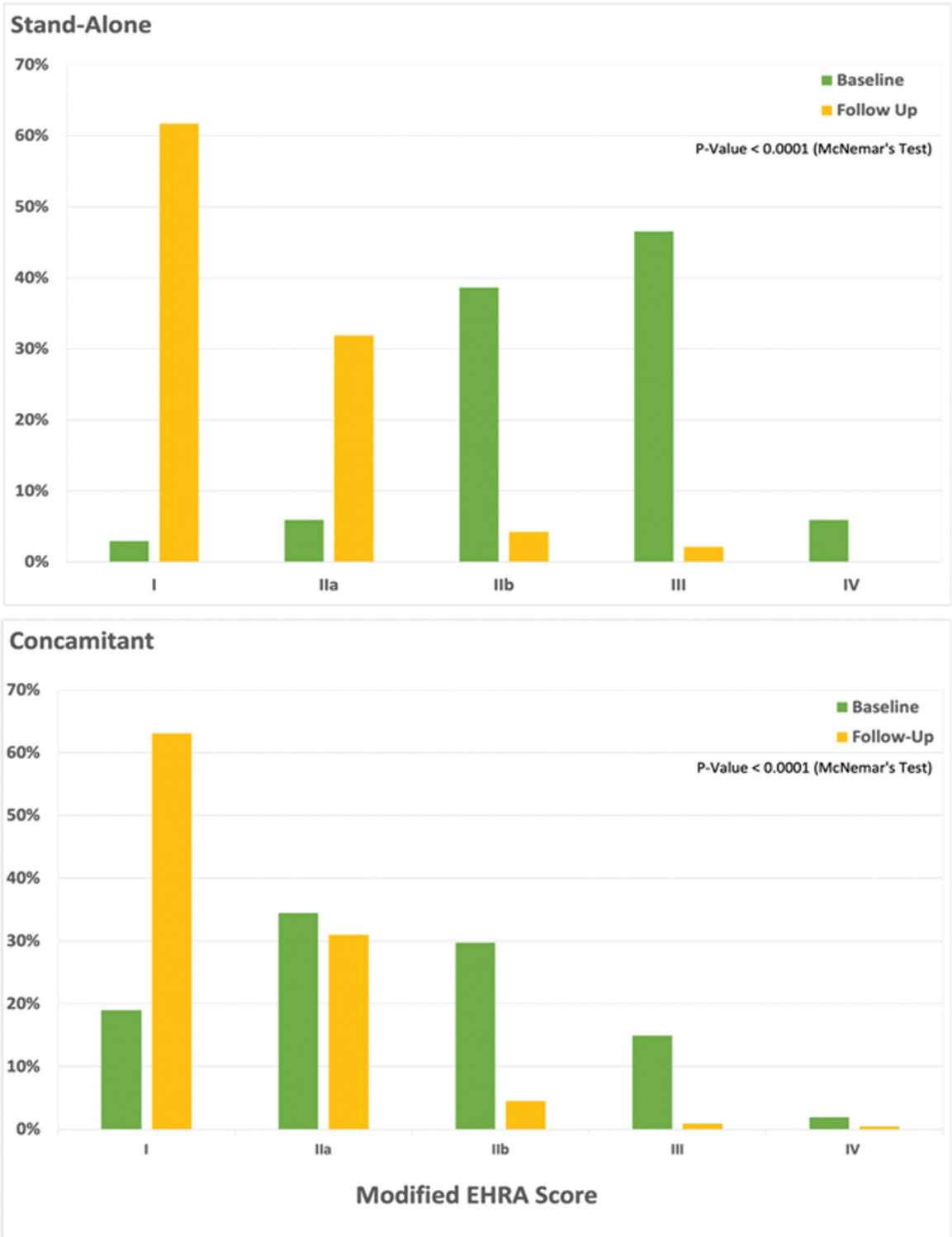

Fig. 2 Modified European Heart Rhythm Association functional class preablation and at follow-up in both patient groups.

database review (22 trials, n= 1,899), the all-cause mortality during concomitant AF surgery when compared with no AF surgery was 7 versus 6.6%.[26] Major adverse cardiac and cerebrovascular events within the concomitant group have not changed overtime and are within previous reported ranges. Within the stand-alone cohort, one patient succumbed as a result of a tear at the base of the LAA after stapling. This complication was managed, but at the cost of a debilitating stroke. This incident has already been published.[27]

Limitations

Arrhythmia monitoring with serial and Holter ECGs provides inaccurate rhythm coverage after ablative procedures and appreciably limits the ability to adequately interpret

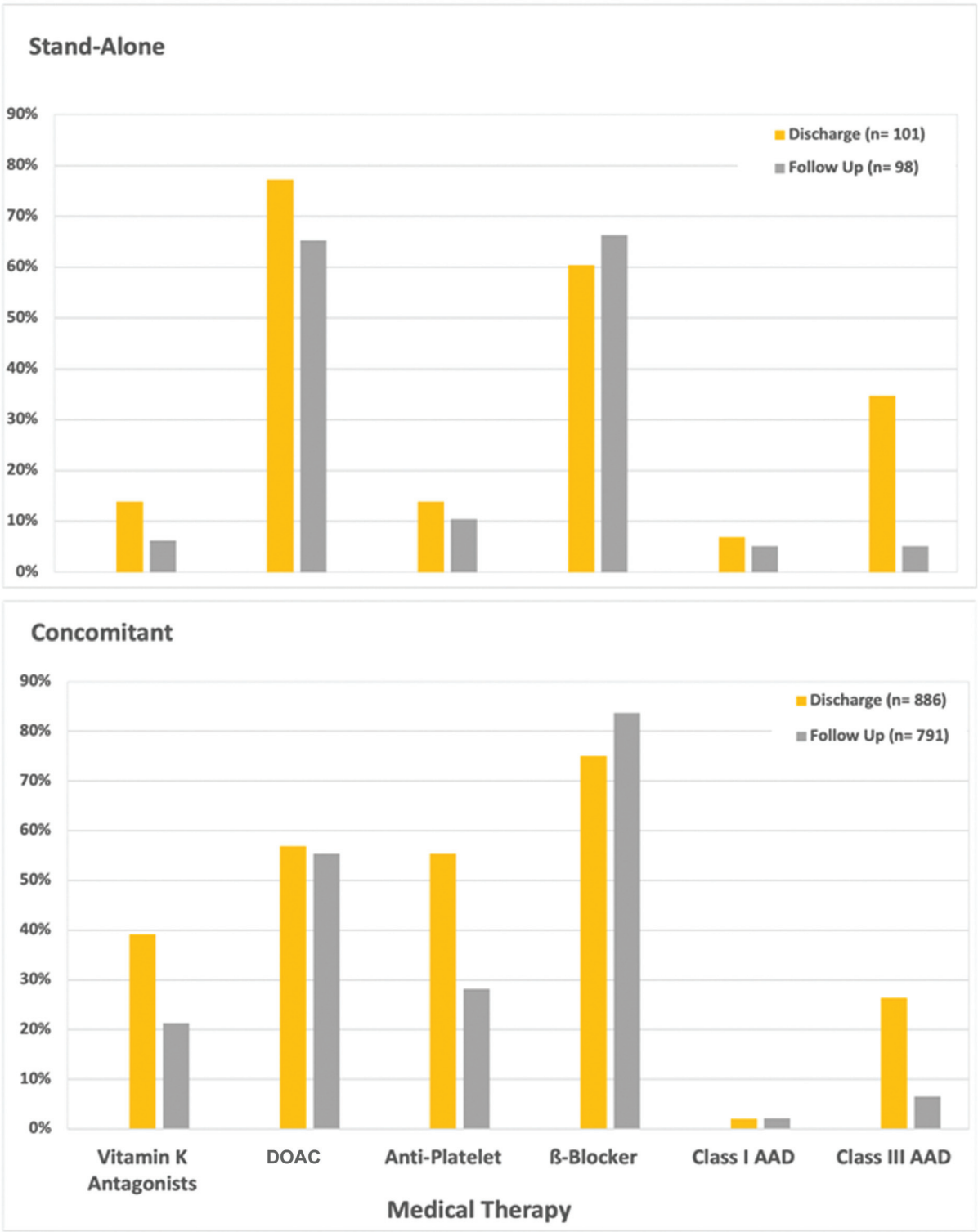

Fig. 3 Medical therapy at discharge and follow-up in both patient groups. DOAC, direct oral anticoagulation; AAD, antiarrhythmic drugs.

outcomes at 1-year follow-up; this may result in success misinterpretation.[28] Moreover, ablative procedures in both cohorts for different AF subgroups were performed in accordance with local center practice or surgeons' preference. The low number of stand-alone procedures did not allow for sufficient analysis to illustrate statistical power. Although patients were included in a continuous prospective manner with data validation performed by an independent body (IHF), the design of a registry, in and of itself, does not exclude sampling bias. It does reflect a real-world scenario and identify management deficiencies, which may eventually lead to alterations in current practice.

Table 3 Multivariate logistic regression model determining patient factors predicting late recurrence (>3 months postablation) after concomitant procedures

	p-Value	OR	95% CI
Female gender	**0.013**	1.644	1.11–2.43
Age (y)	0.54	0.99	0.97–1.01
BMI > 35 kg/m^2	0.28	0.68	0.35–1.35
Persistent AF	<**0.0001**	2.39	1.59–3.61
LA diameter ≤ 60 mm	0.35	1.27	0.77–2.09
LV ejection fraction < 35%	0.32	0.65	0.28–1.50
MVR/r	0.77	0.94	0.63–1.41
CIED	**0.011**	2.19	1.12–4.01

Abbreviations: AF, atrial fibrillation; BMI, body mass index; CI, confidence interval; CIED, cardiac implantable electronic device; LA, left atrium; LV, left ventricle; MVR/r, mitral valve repair/replacement; OR, odds ratio.

Conclusion

At 1-year, the following conclusions could be drawn: Improvement in clinical status of the patient population is significant and overall success at 1-year follow-up is satisfactory. Factors predicting late recurrence of AF included preoperative persistent AF, female gender, and the presence of a CIED. Complication rates are within reported ranges, but mortality is notable. Finally, improvements in postablation monitoring should be prioritized to allow for higher quality data. The German CASE-AF registry is to date the largest registry detailing ablative procedures in a cardiosurgical cohort, and further publications analyzing subgroups are currently underway.

Note

ClinicalTrials.gov Identifier: NCT03091452. https://clinicaltrials.gov/ct2/show/NCT03091452

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Conflict of Interest

None declared.

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