Long-Term Follow-Up of Cardiac Rhythm in 320 Patients After the Cox-Maze III Procedure for Atrial Fibrillation

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Background. **The Cox-maze III (CM-III) procedure is the gold standard for surgical treatment of atrial fibrillation (AF). Excellent short-term results have been reported, but long-term outcomes are lesser known. The aim was to evaluate current cardiac rhythm in a nationwide cohort of CM-III patients with very long follow-up.**

Methods. **Perioperative characteristics were retrospectively analyzed in 536 "cut-and-sew" CM-III patients operated on from 1994 to 2009 in 4 centers. Of these, 54 patients had died and 20 were unavailable at follow-up. The remaining 462 patients received a survey concerning arrhythmia symptoms, rhythm, and medication; of these, 320 patients (69%), comprising 252 men, with a mean age of 67 years (range, 47 to 87 years), and 83% with stand-alone CM-III, returned a current 12-lead electrocardiogram. Long-term monitoring was evaluated in 40 sinus rhythm patients. Postoperative stroke/transient ischemic attack was evaluated by register analysis.**

Results. **Mean follow-up was 111 ± 44 months (range, 36–223 months). Electrocardiogram analysis showed sinus rhythm in 219 of 320 patients (68%), and regular supraventricular rhythm (sinus, nodal, or atrial pacing) in 262 (82%), with 75% off class I/III antiarrhythmic medication. This group had lower arrhythmia symptom scores and medication use. Rhythm outcome did not differ by gender, age, type of AF, or stand-alone vs concomitant operation. Patients with more than 10 years of follow-up had a lower rate of regular supraventricular rhythm (69% vs 91%, $p = 0.02$). Long-term monitoring showed freedom from AF/atrial flutter in 38 of 40 patients (95%). The incidence of stroke/transient ischemic attack was 0.37% per year (11 patients).**

Conclusions. **In a single-moment electrocardiogram evaluation 9 years after the cut-and-sew CM-III, 82% of patients were in sinus rhythm or other regular supraventricular rhythm. These findings support a long-lasting positive effect of the CM-III procedure, which is relevant when evaluating current nonpharmacologic therapies for AF.**

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The "cut-and-sew" Cox-maze III (CM-III) procedure was introduced in 1991 by James L. Cox and colleagues [1] and is still considered the gold standard for surgical treatment of atrial fibrillation (AF). In the pre-catheter ablation era, this operation was the only curative option for patients with highly symptomatic drug-refractory AF. Early follow-up studies reported a success rate for freedom from AF of 95% [2, 3]. However, because the CM-III is an open heart operation of considerable length and technical difficulty, it was not commonly adopted by many cardiac surgeons. In time, its role diminished further due to the advent of percutaneous catheter ablation and the introduction of easier surgical ablation methods.

In Sweden, the first cut-and-sew CM-III case was performed in 1992, and the procedure was established as a clinical option in 1994. It spread quite rapidly to 4 centers and was initially offered to patients with lone AF as a stand-alone procedure. Subsequently, the CM-III was also used concomitantly with valvular or coronary operations. The first small Swedish cohort studies [4] confirmed the positive effects reported by Cox, and quality of life studies showed excellent results up to 3 years postoperatively [5, 6]. Despite these short-term benefits, long-term results for CM-III have been scarce and often requested by cardiologists and patients to determine its role among nonpharmacologic therapies for AF. Also, long-term outcomes of CM-III are of considerable interest when assessing newer surgical ablation techniques [7].

The Swedish Arrhythmia Surgery Group, consisting of surgeons and electrophysiologists from all cardiac surgical centers [8], was formed in 2010 to facilitate multicenter

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research of surgical treatment of AF. Initially, perioperative data from 536 cut-and-sew CM-III patients were collected retrospectively from all participating centers. A registry-based mortality analysis was performed using a long follow-up time [9]. However, because no consistent prospective clinical follow-up had been conducted in these patients according to contemporary guidelines [10], comparable interval data of rhythm and other outcome variables were not readily available. We therefore aimed to perform a single-moment analysis of current arrhythmia symptoms, cardiac rhythm, AF-related medication, and incidence of stroke in the same cohort of patients.

Patients and Methods

Patients

A total of 536 patients underwent the original cut-and-sew CM-III in 4 Swedish cardiothoracic centers (Sahlgrenska University Hospital, Gothenburg; University Hospital, Uppsala; and Karolinska University Hospital and Huddinge University Hospital, Stockholm) between 1994 and 2009. Preoperative, perioperative, and early postoperative (30 days) data were collected retrospectively from each center through review of patient records and were analyzed in a collaborative national database. The Regional Ethic Committee in Stockholm collectively approved the study for all participating centers.

At follow-up, 54 patients had died, 14 patients were living abroad, and 6 patients had undergone heart transplantation or ventricular assist device insertion down the road after their CM-III (Fig 1). The remaining follow-up cohort of 462 patients all received a survey of current medication and self-assessment of arrhythmia-related symptoms. All patients were asked to obtain a 12-lead electrocardiogram (ECG) from their primary health care provider. After a reminder, 320 patients (69%), 252 men and 68 women, with a mean age of 67 years (range, 47 to 87 years), returned a current 12-lead ECG and constituted the study group for this report.

Preoperative and perioperative patient characteristics are reported in Table 1. In all, 127 patients had paroxysmal AF (40%), and 193 had persistent or permanent AF (60%). Mean AF duration was 8.3 ± 6.4 years. Comorbidities, such as hypertension, diabetes mellitus, and heart failure, were present in 12% to 17% of patients.

Surgical Procedures

The CM-III was performed in 267 of the 320 patients (83%) as a stand-alone procedure with AF as the primary indication for the operation. In addition to severe symptoms of AF, they had adverse effects of antiarrhythmic drugs (AAD) or a history of thromboembolic events. In contrast, 17% underwent CM-III combined with an operation for primarily mitral valve disease or coronary artery bypass grafting (CABG; Table 1). CM-III was performed as a secondary indication in some of these patients, whereas others were referred primarily for CM-III but additional heart disease was revealed in preoperative investigations. All arrhythmia procedures performed were the classic biatrial cut-and-sew CM-III technique with amputation of the left atrial appendage.

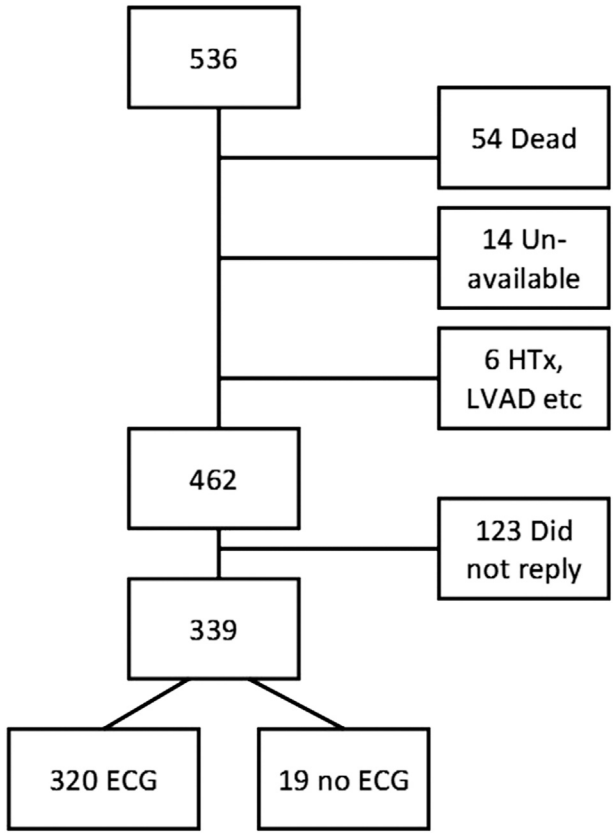

Fig 1. Flow-chart of follow-up in Cox-maze III patients and formation of the study cohort. (ECG = electrocardiogram; HTx = heart transplantation, LVAD = left ventricular assist device.)

Analysis

All collected 12-lead ECG strips were analyzed by a senior electrophysiologist unrelated to the study in other ways. For clinical reasons, a regular supraventricular rhythm, sinus, nodal, or atrial pacing only, was regarded as a successful rhythm outcome. Responding patients were divided into subgroups and classified as having a regular supraventricular rhythm or AF/atrial flutter (unsuccessful outcome). Patients with ventricular (VVI) or dual-chamber (DDD) pacing were also considered unsuccessful because the ECG analysis could not identify underlying AF. The closing date of the follow-up was December 31, 2012.

Long-term ECG monitoring was performed by handheld transtelephonic monitoring (Zenicor-EKG, Stockholm, Sweden) in a randomly selected subsample of 40 patients with sinus rhythm on the 12-lead ECG. Over 2 weeks, the patients registered a 30-second ECG twice a day or if experiencing arrhythmia symptoms. These recordings were subsequently analyzed by a senior electrophysiologist unrelated to the study. The long-term

Table 1. Preoperative and Operative Characteristics of 320 Cox-Maze III Patients Submitting a Current 12-Lead Electrocardiogram

Characteristics	No. (%) or Mean ± SD (Range) (N = 320)
Age at Cox-maze III, y	58 ± 7.4 (33–79)
Sex	
Male	252 (79)
Female	68 (21)
Stand-alone Cox-maze III	267 (83)
Concomitant operation	
MV repair/replacement	22 (7)
AV repair/replacement	0
CABG	18 (6)
Atrial septal defect patch	1 (0.3)
TV repair	3 (1)
Combinations	8 (2.5)
Others	1 (0.3)
Center	
Gothenburg	145 (45)
Uppsala	124 (39)
Stockholm (2 centers)	51 (16)
Operative period	
1994–1999	64 (20)
2000–2004	115 (36)
2005–2009	141 (44)
Previous TIA/stroke	33 (10)
Diabetes mellitus	38 (12)
Hypertension	52 (16)
Heart failure	55 (17)
Ischemic heart disease	41 (13)
Other structural heart disease	35 (11)
LVEF	
<0.30	3 (1)
0.30–0.49	103 (32)
>0.50	190 (59)
Not available	24 (8)
Atrial fibrillation class	
Paroxysmal	127 (40)
Persistent, permanent	193 (60)
Atrial fibrillation duration, y	
All	8.3 ± 6.4 (0.5–36)
Paroxysmal	9.4 ± 6.5 (0.5–30)
Persistent, permanent	7.5 ± 6.2 (0.5–36)

AV = aortic valve; CABG = coronary artery bypass grafting; LVEF = left ventricular ejection fraction; MV = mitral valve; SD = standard deviation; TIA = transient ischemic attack; TV = tricuspid valve.

monitoring was performed from September to December 2014.

A Symptom Checklist-Frequency and Severity Scale based on patient self-assessment of arrhythmia-related symptoms was returned by 320 patients [11]. Comparisons were made for specific arrhythmia-related symptoms (ie, irregular heartbeat, palpitations, tachycardia and chest pain with tachycardia) between patients in regular supraventricular rhythm and patients in AF/atrial flutter/VVI/DDD. Frequency scores were assessed from 1 (never) to 5 (always) and severity scores from 1 (mild) to 3 (severe).

Patient-presented medication lists were reviewed for current intake of class I/III AAD, β-blockers, and oral anticoagulation with warfarin or nonvitamin K oral anticoagulants.

The incidence of stroke or transient ischemic attack (TIA) from the date of the individual operations until December 31, 2012, was assessed by registry analysis. After appropriate consent, the patients' personal identity number was used to retrieve information from the National Inpatient Register administered by the Swedish National Board of Health and Welfare. This register is validated and covers all diagnoses, as defined by the International Classification of Disease-10 Revision, for all patients admitted to Swedish hospitals from 1987 and onwards [12]. This study used codes I60 through I69 for the search.

A comparison was made of baseline characteristics, such as age, gender, type of AF, and AF duration, among survey responders, nonresponders, and the original cohort of CM-III patients.

Statistical Analysis

Continuous data are presented as mean ± standard deviation or median (range) and categoric data as frequency (percentage), unless otherwise noted. Subgroups were compared using the χ^2 or Fisher exact test for categoric variables and the Student *t* test for independent samples or the Mann-Whitney U test for continuous variables. For all analyses, a two-tailed *p* of less than 0.05 was used to determine significance. Statistical analysis was conducted in Statistica software (StatSoft Inc, Tulsa, OK).

Results

For the 320 survey responders who submitted a 12-lead ECG, mean follow-up time was 111 ± 44 months (range, 36 to 223 months). In all, 82% of the patients had a regular supraventricular rhythm, sinus (68%), nodal (8%), or atrial pacing-dependent (6%) rhythm (Table 2). AF or atrial flutter was found in 14%. Of the 51 patients with pacemakers, as assessed by 12-lead ECG, 34 had ventricular or DDD pacing. The remaining 17 patients had a nondependent pacing rhythm and their native rhythms are reported in Table 2.

When rhythm outcomes for subgroups of responders were compared (Table 3), there was no difference between groups by gender, age (≤70 or >70 years) at follow-up, type of AF, or type of procedure (stand-alone or concomitant). A significantly lower rate of regular supraventricular rhythm was found in patients who had more than 10 years of follow-up time compared with those with 10 years or less (69% vs 91%, $p = 0.02$).

Of patients with the highest age at follow-up, there were 37 patients older than 75 years, 78% of whom had regular supraventricular rhythm. Of 44 patients with a follow-up time of more than 14 years, 64% had regular

Table 2. Results of Submitted 12-Lead Electrocardiogram After the Cox-Maze III Procedure

Rhythm	No. (%) (N = 320)
Sinus	219 (68)
Nodal	25 (8)
Atrial fibrillation	37 (12)
Atrial flutter	
Right-sided	1 (0.3)
Left-sided	3 (1)
Ectopic atrial tachycardia	1 (0.3)
Pacing-dependent	
Atrial pacing	18 (6)
Ventricular pacing	5 (1.6)
Dual-chamber pacing	11 (3)

supraventricular rhythm, 18% had AF, and 18% were ventricular pacing-dependent.

Long-term monitoring in sinus rhythm patients confirmed freedom from AF/atrial flutter in 38 of 40 patients (95%). Two patients had short episodes of paroxysmal AF, both having sick sinus syndrome, and receiving dual-chamber pacemakers more than 10 years after the operation.

In comparing specific arrhythmia symptoms and rhythm outcome, mean frequency and severity scores were both lower in patients with regular supraventricular rhythm vs patients with AF/atrial flutter/VVI/DDD pacing (irregular heartbeat frequency: 2.0 vs 2.6, $p < 0.01$ [severity: 1.1 vs 1.5, $p = 0.01$]; palpitations frequency: 1.8 vs 2.2, $p = 0.02$ [severity: 1.0 vs 1.1, $p = 0.37$]; tachycardia frequency: 1.5 vs 1.8, $p < 0.01$ [severity: 0.8 vs 0.9, $p = 0.78$]; chest pain and tachycardia frequency: 1.3 vs 1.7, $p < 0.001$ [severity: 0.6 vs 1.0, $p = 0.09$]).

Analysis of submitted medication lists showed significantly lower use of β-blockers (34.7% vs 72.4%, $p < 0.001$) and warfarin (18.3% vs 56.9%, $p < 0.001$) in patients in regular supraventricular rhythm vs patients in AF/atrial flutter/VVI/DDD pacing. Use of class I/III AAD (6.9% vs 11.5%, $p = 0.23$) and new non-vitamin K oral anticoagulants (1.5% vs 5.2%, $p = 0.09$) was also lower in regular supraventricular rhythm patients but was not statistically significant (Fig 2).

National Inpatient Register analysis revealed 10 strokes and 1 TIA in 2,948 patient-years of follow-up, representing an incidence of 0.37% per year. There were 2 perioperative strokes, and mean time from operation to event was 6.0 ± 4.5 years.

A comparison of baseline data for patients who responded to the survey vs nonresponders showed no difference by gender, type of AF, or AF duration. However, those in the nonresponder group were younger (Table 4).

Comment

In the absence of a guideline-based prospective national follow-up, this multicenter study aimed to give a single-moment view of current patient status after the cut-and-sew CM-III in Sweden with a very long follow-up. The main results showed a high proportion of patients (82%) with a regular supraventricular rhythm more than 9 years after the operation, of whom 69% had sinus rhythm and 75% were off class I/III AAD. There was a low rate of arrhythmia-related symptoms and medication use in this group. The incidence of postoperative stroke/TIA was low.

The original CM-III was based on extensive animal laboratory work and designed to interrupt macroreentry circuits in both atria with surgical blocking lines. The

Table 3. Subgroup Analysis of Rhythm Outcomes After the Cox-Maze III Procedure From Submitted 12-Lead Electrocardiogram

Variable	Total No. (N = 320)	Sinus Rhythm (No.)	1: Regular Supraventricular Rhythm Total No. (%)	2: AF/Flutter Total No. (%)	3: DDD/VVI-Pacing Dependent No. (%)	*p* Value 1 vs 2+3
Sex						
Men	252	177	208 (83)	34 (13)	10 (4)	
Women	68	42	54 (79)	8 (12)	6 (9)	0.44
Age, y						
<70	200	145	167 (84)	28 (14)	5 (2.5)	
≥70	120	74	95 (79)	14 (12)	11 (9)	0.26
AF						
Paroxysmal	127	91	107 (84)	12 (9)	8 (6)	
Pers/perm	193	128	155 (80)	30 (16)	8 (4)	0.37
Operation						
Stand-alone	267	189	223 (84)	30 (11)	14 (5)	
Concomitant	53	30	39 (74)	12 (23)	2 (4)	0.08
Follow-up						
<10 years	191	150	174 (91)	14 (7)	3 (2)	
≥10 years	129	69	88 (68)	28 (22)	13 (10)	<0.001

AF = atrial fibrillation; DDD = dual-chamber pacing; Pers/perm = persistent/permanent; VVI = ventricular pacing.

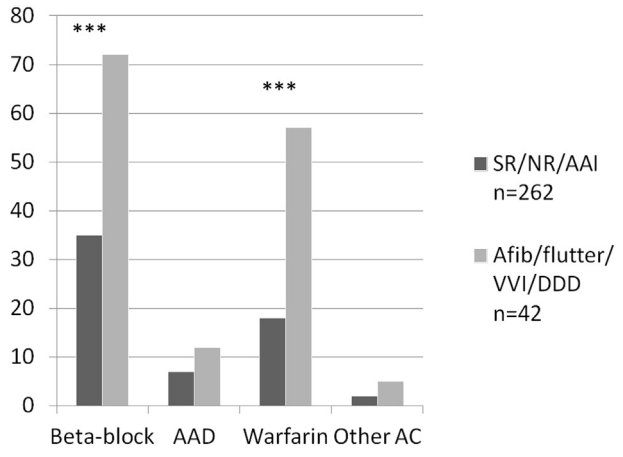

*Fig 2. Current medication use in long-term follow-up after the Cox-maze III procedure. Patients in regular supraventricular rhythm (sinus rhythm [SR], nodal rhythm [NR], atrial pacing [AAI]-pace; black bars) vs patients in atrial fibrillation (Afib), atrial flutter, or ventricular (VVI)/dual-chamber pacing (DDD; gray bars). *** = $p < 0.001$. (AAD = class I/III antiarrhythmic drugs; AC = anticoagulants.)*

primary objective was to eliminate AF and restore sinus rhythm (or electrical atrioventricular synchrony) [1]. In 1993, Cox and associates [2] reported the first results in 65 patients, with a success rate of 98% in cure of AF. A later follow-up of 198 CM-III patients showed 96% freedom from AF after a mean of 5.4 years, with no difference between stand-alone or concomitant procedures [3]. This follow-up, however, was based mainly on mailed questionnaires.

A review of the early results in 100 CM-III patients at Cleveland Clinic reported 90% of patients were in sinus or atrial pacing rhythm after 3 years [13]. Early single-center Swedish studies confirmed these excellent rhythm results, though with quite few operated-on patients [4, 5], but with outcomes based on postoperative clinic visits and ECGs.

Despite the convincing short-term results, CM-III was commonly considered as too invasive and technically demanding to gain widespread acceptance in the cardiologic and cardiac surgical community. With the rapid advance of catheter-based treatment of AF, fewer patients with lone AF were candidates for the operation. In addition, the development of surgical ablation techniques shifted the focus of most surgeons toward concomitant AF procedures.

However, the long-term results of CM-III have been relatively scarce and asked for by many cardiologists, especially as an alternative for lone persistent AF or after unsuccessful multiple catheter-based interventions. Hemels and colleagues [14] reported 5-year results in 29 patients undergoing stand-alone CM-III. Of these, 79% had complete success with freedom from AF and no use of AAD, and 7% were free of AF with use of AAD. Ballaux and coworkers [15] presented follow-up data for 203 CM-III patients, with 90% free from AF in the stand-alone group and 70% in the concomitant group after 4 years, as assessed by Holter monitoring. Mayo Clinic reported results of 97 patients undergoing stand-alone CM-III, with 87% freedom from AF after 5 years and 75% after 10 years, and no difference regarding type of preoperative AF [16].

One previous Swedish single-center article reported 232 consecutive CM-III patients operated on between 1997 and 2009 [17]. Mean follow-up time was 6.5 years, and the results were assessed by reviews of medical records, questionnaires, and ECGs. In total, 80% of the patients were free from AF/atrial flutter without AAD. The corresponding result for the stand-alone patients was 82%. This cohort of patients was also included in the present larger national study, which confirms good and long-lasting results after CM-III in Sweden, with the addition of data from other centers. In the present analysis, 82% of patients were in sinus, nodal, or atrial pacing rhythm more than 9 years postoperatively. In addition to AF/flutter, we considered VVI or DDD pacing dependency as unsuccessful outcomes because underlying AF could not be differentiated in those patients.

The rhythm results are further strengthened by the fact that 83% underwent CM-III as a stand-alone procedure for AF. Long-term ECG monitoring in a random sample of patients in sinus rhythm added confirmation of the 12-lead ECG results. The lower use of β-blockers and warfarin anticoagulation in the regular supraventricular rhythm group indicated a stable rhythm situation. In concordance, when assessing specific arrhythmia

Table 4. Patient Characteristics of Responders vs Nonresponders to Study Survey After the Cox-Maze III Procedure

Variable[a]	1: Responders (n = 320)	2: Nonresponders (n = 123)	3: Entire Cohort (N = 536)	*p* Value 1 vs 2
Age, mean y	58.0 ± 7.4	53.3 ± 9.4	57.0 ± 8.6	<0.001
Sex				
Male	252 (79)	98 (80)	425 (79)	0.82
Female	68 (21)	25 (20)	111 (21)	
Atrial fibrillation				
Paroxysmal	127 (40)	47 (38)	207 (38)	0.70
Persistent/permanent	193 (60)	76 (62)	329 (62)	
Duration, y	8.3 ± 6.4	7.4 ± 6.4	7.8 ± 6.3	0.14

[a] Continuous data are shown as the mean ± standard deviation, or as indicated, and categoric data as number (%).

symptoms, these patients reported a lower frequency and severity of symptoms.

Interestingly, we found no significant difference in rhythm outcomes in regards to gender, age at follow-up, type of procedure, or paroxysmal vs persistent/permanent AF. However, results seemed to taper off beyond 10 years after the CM-III, corresponding to the findings of others [16].

There are likely two important mechanisms behind the excellent success rate after CM-III in various patient groups. First, the lesion pattern includes a box isolation of all 4 pulmonary veins and a compartmentalization of both atria, which in theory should encompass the arrhythmia substrate in all AF patients. Second, the surgically cut lines in the atrial myocardium are per definition transmural and should make reconduction unlikely. As patients grow older, however, the atria may enlarge or develop further fibrosis in relation to advancing structural heart disease, leading to postoperative recurrence and progression of AF.

After years of different ablation techniques and lesion sets being tried in concomitant AF operations, evidence supports a biatrial lesion set mimicking the CM-III incisional pattern as the optimal treatment [10, 18, 19]. At present, most surgeons perform biatrial procedures with linear surgical ablation with radiofrequency or cryoablation. This CM-IV procedure is technically easier and allows a more frequent use in concomitant cases with increasing comorbidities. The CM-IV procedure can also be safely and efficiently performed in stand-alone cases, even with minimally invasive techniques [7, 20]. In summary, although the classic cut-and-sew CM-III could be regarded as an historic operation, it is clearly the foundation of the CM-IV and other surgical AF procedures. In our view, it is reasonable to consider the long-term results of CM-III of benchmark importance when assessing patient outcomes after all AF interventions, whether surgical or catheter-based.

Removal of the left atrial appendage is a fundamental part of CM-III as a preventive measure against stroke. For this study, a questionnaire-based analysis of postoperative stroke was not considered as sufficient. Instead, we analyzed the National Inpatient Register for hospitalizations for stroke or TIA in the study cohort, which revealed a low incidence of 0.37% per year, in accordance with other studies [21]. A previous mortality analysis based on National Cause-of-Death Registry data showed no ischemic stroke-related death in the same cohort of patients [9]. Further studies are needed to determine the long-term benefits of AF operations and left atrial appendage exclusion on stroke prevention.

Study Limitations

This study is based on patient responses to a request to provide a current ECG. Of all available patients, 31% did not respond, and we do not know the rhythm results for these patients. In theory, they could all be in AF and not responding because they are displeased with the procedure. This is unlikely, however, because analysis of important preoperative characteristics showed close similarity between responders and nonresponders (Table 4). We also consider a response rate of almost 70% satisfactory for such a long follow-up after an operation.

We recognize that assessing follow-up results of surgical AF procedures simply by a single 12-lead ECG is not according to contemporary guidelines [10]. This method is a snapshot of reality and will likely underestimate the true incidence of recurrent AF after the CM-III [22]. However, guidelines dictate prospective follow-up, and this study was retrospective with single-moment evaluation in a large group of patients up to 18 years after the operation. Given this study design, we could not report the main results as freedom from AF. For logistical reasons, long-term monitoring was not possible in all responding patients, but long-term monitoring in a sample of sinus rhythm patients showed freedom from AF/flutter in 95%. The technique used has been reported as more effective than Holter-ECG [23].

Conclusions

A single-moment ECG assessment more than 9 years after the CM-III showed 82% of patients in sinus, nodal, or atrial pacing rhythm. Long-term monitoring, low medication use, and a low grade of arrhythmia-related symptoms indicated a stable rhythm situation. Despite the uncertainty concerning survey nonresponders, these results support a long-lasting positive effect of CM-III on cardiac rhythm. This is relevant baseline information when evaluating present nonpharmacologic therapies for AF.

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