Early and Long-Term Mortality in 536 Patients After the Cox-Maze III Procedure: A National Registry-Based Study

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Background. **The cut-and-sew Cox-maze III procedure is the gold standard for surgical treatment of atrial fibrillation. The aim was to study early and long-term mortality based on registry analyses in Swedish Cox-maze III patients.**

Methods. **Preoperative and early postoperative data were analyzed in 536 patients (male/female (425/111), mean age 57 ± 8.6 years), operated from 1994 to 2009 in 4 centers; 422 (79%) underwent stand-alone Cox-maze III. Atrial fibrillation was paroxysmal in 38% and non-paroxysmal in 62%, mean duration was 7.8 ± 6.3 years. Patients were followed for survival or death in a validated national Cause-of-Death registry. Risk factors associated with observed survival were identified in univariable and multivariable analyses in a standard Cox proportional hazards model.**

Results. **Four early deaths (0.7%) occurred due to technical complications. At follow-up, 41 of 536 (7.6%) patients had died. Cause of death was cardiovascular in 19 of 536 (3.5%). No ischemic stroke-related death was registered. Univariable risk factors for all-cause mortality included hypertension (hazard ratio [HR] 2.8, confidence interval [CI] 1.5 to 5.3), heart failure (HR 2.4, CI 1.3 to 4.3), concomitant surgery (HR 2.2, CI 1.1 to 4.1), and postoperative complications (HR 2.5, CI 1.3 to 4.8). Gender, non-paroxysmal atrial fibrillation and long arrhythmia duration did not confer increased risk of death. Multivariable risk factors were hypertension (HR 2.9, CI 1.5 to 5.5) and postoperative complications (HR 2.4, CI 1.2 to 4.6). Survival for cardiovascular death at 5, 10, and 15 years was 98%, 96%, and 93%, respectively.**

Conclusions. **Registry-based follow-up showed low early and long-term cardiovascular mortality and no stroke-related mortality. This is important baseline information when evaluating current surgical and nonsurgical treatment of atrial fibrillation.**

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Atrial fibrillation (AF) is the most common arrhythmia in clinical practice and associated with increased mortality and morbidity. Surgical treatment of AF was introduced by James L. Cox and colleagues in the late 1980s with the maze procedure, preceded by extensive electrophysiological studies in both animals and humans. After modifications of the operative technique, the cut-and-sew Cox-maze III procedure (CS-CMIII) was presented in 1991 [1] and excellent midterm results were reported in 1993 [2]. Since then, the CS-CMIII has been the gold standard for surgical treatment of AF, a foundation and benchmark for the further development of surgical ablation of AF that is most common in cardiac surgical practice today.

The CS-CMIII was first performed in Sweden in June of 1992 and put into clinical practice in 1994 to 1997 at 4 different cardiothoracic centers. Originally, the operation was offered to patients with severely symptomatic and medically refractory AF without other structural heart disease (stand-alone CS-CMIII). Subsequently, patients undergoing other cardiac surgery and concomitant CS-CMIII were included. The number of CS-CMIII in Sweden has declined in recent years, mainly due to the advance of percutaneous catheter ablation. Moreover, as the CS-CMIII is considered technically complex, it has been replaced by surgical ablation using different energy sources in concomitant cases.

Long-term results of the CS-CMIII have been presented by Prasad and colleagues [3], and from other international centers [4–6], showing a success rate in terms of freedom from AF of over 90%. Similar results have been reported in smaller prospective series from

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Sweden [7–9], but the long-term fate of these patients for maintained sinus rhythm, stroke, and other morbidity remains unknown. In addition, there is a lack of mortality follow-up data in this group of patients.

The Swedish Cause-of-Death Registry has been used since 1952 and is administered by the Swedish National Board of Health and Welfare [10]. In a national collaboration between arrhythmia surgeons (The Swedish Arrhythmia Surgery Group) and statisticians at the Swedish National Board of Health and Welfare, 536 patients were identified who were operated with the CS-CMIII between 1994 and 2009. The aim of the current study was to investigate the early and long-term mortality, based on registry analysis, for causes and risk factors of death in this comparatively large cohort of Swedish CS-CMIII patients.

Material and Methods

Patients

A total of 536 patients, undergoing the original CS-CMIII between 1994 and 2009, were identified in 4 different Swedish cardiothoracic centers (Sahlgrenska University Hospital, Gothenburg, University Hospital, Uppsala, Karolinska University Hospital, and Huddinge University Hospital, Stockholm) through review of hospital and patient records. Preoperative, perioperative, and early postoperative (30 days) data were collected retrospectively and analyzed in a collaborative national data base. In all, there were 425 men and 111 women, with a mean age of 57 ± 8.6 years. Analyzing preoperative rhythm, 38% had paroxysmal AF while 62% were classified as having non-paroxysmal AF (ie, persistent, long-term persistent, or permanent AF) [11]. Mean duration of AF in the whole cohort was 7.8 ± 6.3 years (0.2 to 36 years). Preoperative comorbidities such as hypertension, diabetes, and heart failure (based on recorded preoperative diagnosis in patient charts) were present in 12% to 15% of patients (Table 1). Over 70% of patients had a normal left ventricular function preoperatively. The study was collectively approved for all participating centers by the Regional Ethics Committee in Stockholm without requirement of individual consent.

Surgical Procedures

In all, 79% of the patients underwent the CS-CMIII as a stand-alone procedure with AF as the primary indication for surgery. In addition to severe symptoms of AF, they had either side effects of antiarrhythmic drugs, presence of thromboembolic events, or poor quality of life due to their arrhythmia. In contrast, 21% of the patients underwent the CS-CMIII concomitantly with surgery for structural heart disease, primarily mitral valve disease, coronary artery bypass grafting, or atrial septal defect (Table 1). Some of these patients had the arrhythmia procedure performed as a secondary indication while others were primarily referred for CS-CMIII surgery, and in which additional heart disease, such as mitral insufficiency or coronary disease, was discovered in preoperative investigations.

Table 1. Preoperative Characteristics

Characteristic		n 536	(%)
Age at surgery (years)			
	<50	96	(18)
	51 60	231	(43)
	61 70	185	(35)
	>71	24	(4)
	Mean ± SD	57 ± 8.6	
	Range	27 79	
M + F		425 + 111	(79 + 21)
Stand alone CS CMIII		422	(79)
Concomitant surgery	MV rep/MVR	48	(9)
	AVR/AV rep	2	(0.3)
	CABG	37	(7)
	ASD patch	3	(0.5)
	TV rep	4	(0.7)
	Combinations	17	(3)
	Others	3	(0.5)
Center	A	232	(43)
	B	200	(37)
	C	63	(12)
	D	41	(8)
Operative period	1994 1999	141	(26)
	2000 2004	184	(34)
	2005 2009	211	(39)
Previous TIA/stroke		46	(8.5)
Diabetes mellitus		63	(12)
Hypertension		82	(15)
Heart failure		83	(15)
Other structural heart disease		58	(11)
LVEF	<30%	11	(2)
	30% 49%	90	(17)
	>50%	390	(73)
	NA	45	(8)
AF class AHA/ACC	Paroxysmal	207	(38)
	Non paroxysmal	329	(62)
AF duration, mean ± SD (years)		7.8 ± 6.3	

AF = atrial fibrillation; AHA/ACC = American Heart Association/American College of Cardiology; ASD = atrial septal defect; AVR = aortic valve replacement; AV rep = aortic valve repair; CABG = coronary artery bypass grafting; CS-CMIII = Cox-maze III procedure; LVEF = left ventricular ejection fraction; MV rep = mitral valve repair; MVR = mitral valve replacement; TIA = transient ischemic attack; TV = tricuspid valve.

Two cardiac surgical centers performed 80% of the procedures, and the peak number of CS-CMIII in Sweden occurred between 1998 and 2005. There were different routines concerning postoperative anticoagulation for the participating centers. In general, most stand-alone patients were discharged on aspirin or no therapy. Patients undergoing concomitant procedures received warfarin in valve cases and aspirin in coronary cases. In addition, patients with early recurrent atrial arrhythmias were treated with warfarin. The use of beta blockers postoperatively in stand-alone patients varied between centers,

but in general antiarrhythmic drugs were used only in cases with early relapses of AF or atrial flutter.

Registry Analyses

A unique national registration number (personal number) is allocated to every Swedish citizen. All deaths in Sweden are reported to the National Board of Health and Welfare. For each deceased patient, a cause-of-death form has to be filled out and submitted by the responsible physician. In this form, the primary underlying cause of death is required, but in many instances contributing causes of death are stated as well. Such data have been used in the Swedish Cause-of-Death Registry since 1952. All CS-CMIII patients were followed up with respect to survival and cause-of-death by computerized linkage to 2 national registers based on the national registration number, the Swedish Cause-of-Death Registry, and a continuously updated population registry. By combining these registers, all patients could be assigned a date of death or identified as being alive on December 31, 2010, which was the closing date for this study. The mean length of follow-up in the study group was 78.4 months (median 73.4 months).

Causes of death were classified according to the International Statistical Classification of Diseases (ICD)-10 system [12]. Cardiovascular deaths were defined on the primary cause corresponding to codes I00–I99. Pulmonary deaths were defined on codes J00–J99. Causes due to cerebrovascular incidents were classified as I60 through 69, as either primary or contributing causes.

Statistical Methods

The observed survival was calculated by the actuarial (life-table) method. Risk factors associated with observed survival were identified in univariable and multivariable analyses based on the standard Cox proportional hazards model. The hazard ratio (HR) ($\exp(\beta_i)$) and corresponding 95% confidence intervals (CI) were used as a measure of the risk of death in different groups. The following variables were entered into the Cox analyses of observed survival: Age, gender, diabetes, hypertension, prior neurologic event, ischemic heart disease, organic heart disease, congestive heart failure, preoperative type and duration of AF, concomitant surgical procedure, and presence of significant postoperative complications. The latter included reoperation for bleeding, mediastinitis, stroke, renal failure, significant infection (pneumonia, septicemia), pericardial drainage, and need for permanent pacemaker due to third degree atrioventricular block. The factors that gave significant information concerning observed survival in the univariable Cox analyses were considered in the multivariable analyses. The SAS 6.12 statistical program for pc (SAS Institute, Cary, NC) was used for the data processing and statistical analyses.

Additionally, Kaplan-Meier product-limit estimates were generated to provide survival estimates at postoperative points in time. The Kaplan-Meier estimates for total mortality and cardiac death status were compared for equality using the Gehan-Wilcoxon tests. A Kaplan-Meier analysis was also performed on the whole population. Data were managed and analyzed using Statistica Version 10.0 (Statsoft Inc, Tulsa, OK).

Results

In all, 41 of 536 (7.6%) patients had died at registry follow-up after undergoing the CS-CMIII. Mean follow-up was 78.4 months (range 0.03 to 200.6 months). There were 4 early deaths (0.7%) due to coronary stenosis with right ventricular failure postoperative day (POD) 1, coronary occlusion and right ventricular failure POD 2, massive bleeding from postoperative left ventricular rupture POD 2, and coronary occlusion and left ventricular failure POD 4, respectively. Two of these patients underwent stand-alone CS-CMIII and 2 had concomitant surgery. In addition, 1 patient died 69 days postoperatively after a prolonged intensive care stay due to cytomegalovirus pneumonitis and subsequent multiorgan failure. Of all deaths, underlying cause was classified as cardiovascular in 19 patients (3.5%), of whom 9 underwent stand-alone procedures (9 of 422, 2.1%) and 10 had concomitant surgery (10 of 114, 8.8%; Table 2). There was no recorded ischemic stroke-related death, either as underlying or contributing cause, although 1 patient died from a subarachnoidal hemorrhage. Ninety patients (17%) had recorded significant postoperative complications.

Univariable analyses identified higher age (61 to 70 years) (HR 3.9, CI 1.3 to 11.5), hypertension (HR 2.8, CI 1.5 to 5.3), heart failure (HR 2.4, CI 1.3 to 4.3), prior neurologic events (HR 2.4, CI 1.1 to 5.5), other organic heart disease (HR 2.1, CI 1.0 to 4.4), concomitant surgery (HR 2.2, CI 1.1 to 4.1), and presence of significant postoperative complications (HR 2.5, CI 1.3 to 4.8) to be risk factors for all-cause mortality (Table 3). Most of these variables, including concomitant surgery and significant postoperative complications, were also found to be risk factors for cardiovascular mortality (Table 3). There was no gender

Table 2. Principal Causes of Death as Stated in the Swedish Cause-of-Death Registry for 41 Patients After the Cut-and-Sew Cox-Maze III Procedure

Causes of Death	No.	(%)
Cancer	13	(31)
Motor neuron disease	1	(3)
Lung disease	3	(8)
Gastrointestinal	2	(5)
Accident	2	(5)
Unknown cause	1	(3)
Cardiovascular	19	(43)
Cardiomyopathy	3	
Congestive heart failure	3	
Arrhythmia	4	
Myocardial infarction	3	
Valvular disease	3	
Atherosclerotic heart disease	1	
Subarachnoid bleeding	1	
Abdominal aortic aneurysm	1	

Table 3. Univariable Analyses of All-Cause and Cardiovascular Mortality

		Total	No. Deaths All Cause	Univariate All Cause Death			Univariate Cardiovascular Death		
Variable				HR	CI	*p*	HR	CI	*p*
Age (years)	<50	96	4	1.0					
	51 60	231	14	1.7	0.6 5.2	NS			
	61 70	185	18	3.9	1.3 11.5	0.015			
	>71	24	5	8.4	2.2 31.4	0.002			
Sex	M	425	30						
	F	111	11	1.4	0.7 2.8	0.33			
Diabetes	Y	63	4	1,0	0.4 2.9	0.94	1.1	0.2 4.3	0.93
	N	473	37						
HT	Y	82	14	2.8	1.5 5.3	0.0018	4.0	1.6 4.9	0.003
	N	454	27						
Prior NE	Y	46	7	2.4	1.1 5.5	0.03	1.3	0.3 5.8	0.69
	N	490	34						
IHD	Y	63	6	1.5	0.6 3.6	0.35	2.3	0.8 6.8	0.14
	N	473	35						
Other org heart disease	Y	58	9	2.1	1.0 4.4	0.05	4.4	1.7 11.2	0.002
	N	478	32						
CHF	Y	83	10	2.4	1.3 4.3	0.019	4.0	1.5 10.1	0.004
	N	453	31						
Type AF	Px	207	15						
	Non px	329	26	1.5	0.8 2.8	0.22	2.3	0.8 6.4	0.12
AF duration >10 yrs	year	166	9	0.6	0.3 1.2	0.13	0.96	0.4 2.5	0.93
	N	370	32						
Type operation	stand alone	422	27						
	Con comitant	114	14	2.2	1.1 4.1	0.02	3.6	1.5 9.0	0.005
Complication	Y	90	13	2.5	1.3 4.8	0.007	3.0	1.2 7.7	0.02
	N	446	28						

AF = atrial fibrillation; CHF = congestive heart failure; CI = confidence interval; HR = hazard ratio; HT = hypertension; IHD = ischemic heart disease; NE = neurologic event; Px = paroxysmal.

difference for the risk of death. Non-paroxysmal AF and arrhythmia duration of greater than 10 years did not confer an increased risk of death. Multivariable analyses showed independent risk factors for all-cause mortality to be higher age (HR 3.0, CI 1.6 to 5.9), hypertension (HR 2.9, CI 1.5 to 5.5), and postoperative complications (HR 2.4, CI 1.2 to 4.6) (Table 4). Kaplan-Meier analysis showed survival at 5, 10, and 15 years for all-cause mortality to be 95%, 90%, and 80%, and for cardiovascular death to be 98%, 96% and 93%, respectively (Figs 1 and 2).

Comment

The main purpose of this national collaborative follow-up study was to analyze early and late mortality in Swedish patients after the cut-and-sew Cox-maze III procedure. The unique features of the study include the largest mortality follow-up of CS-CMIII patients ever reported and the use of a validated national Cause-of-Death registry, with a follow-up period of over 16 years. The principal findings were a very low operative mortality rate, a low long-term cardiovascular mortality rate in stand-alone patients, and no recorded stroke-related mortality.

Table 4. Multivariable Analysis of All-Cause Mortality

		Total	# Deaths All Causes	HR	CI	*p*
Age	61 70	185	18	3.0	1.6 5.9	0.0011
	>71	24	5	5.4	2.0 14.8	0.0012
Hypertension	yes	82	14	2.9	1.5 5.5	0.016
Complications	yes	90	13	2.4	1.2 4.6	0.011

This study reflects an 18-year-long practice in 4 different centers, with approximately 12 to 15 surgeons involved in these operations. All centers were early adopters with at least 15 years of experience. In total, however, 2 of the centers performed 80% of the procedures. Almost 80% of the patients underwent the procedure as a stand-alone operation for debilitating and medically refractory AF, which is reflected in the relatively young mean age and low percentage of patients with comorbidities or poor left ventricular function. This is basically the type of patient for whom the operation was designed, a group which in the pre-catheter ablation era had few alternative curative options for their arrhythmia. From a peak of 50 to 60 CS-CMIII procedures per year in Sweden, the number has been reduced in recent years, mainly due to the progress of percutaneous

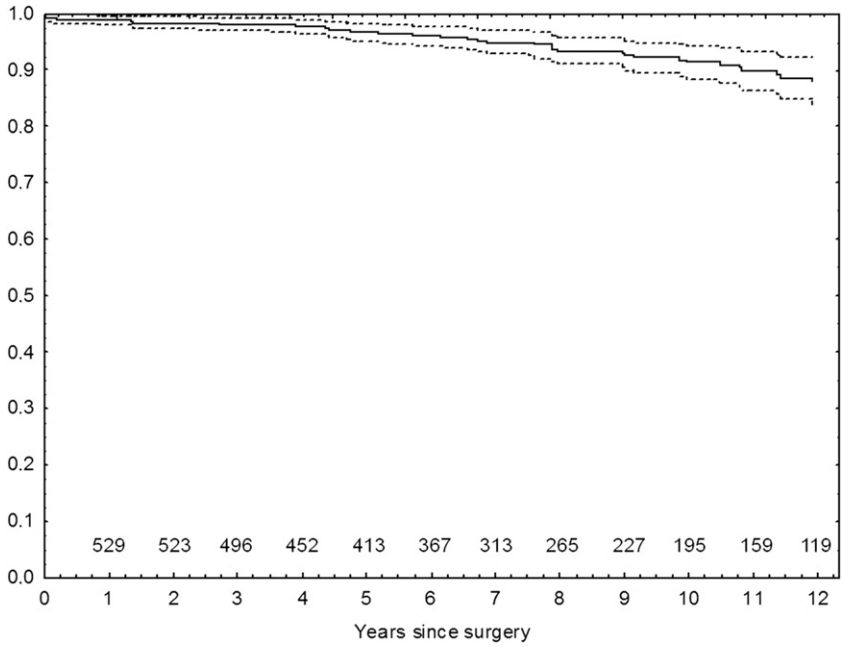

Fig 1. Kaplan Meier analysis of all cause mortality after the Cox maze III procedure, 1994 to 2009. The dashed lines represent 95% confidence interval.

catheter ablation for patients with paroxysmal or persistent AF. As referrals for AF surgery now are most common for patients with structural heart disease requiring surgery, the complexity of the CS-CMIII sets limits, and it has regularly been replaced by surgical ablation using different energy sources [13], in spite of lower success rates as compared with CS-CMIII. This, however, has led to an increase in the overall number of patients undergoing surgical treatment of AF.

The 30-day operative mortality in this series was very low, 0.7%, in comparison with the SWEDEHEART Cardiac Surgery Registry data for all Swedish cardiac operations 2010 of 2.5% [14]. These results are also comparable with other reported series for low-risk CABG or mitral valve repair [15, 16]. A recent study of over 200 Cox-maze III patients with lone AF revealed an operative mortality of 1.4% [17]. All 4 of the early deaths in the current follow-up were associated with technical complications, most often compromising coronary flow with resulting acute heart failure. This could be described as one of the pitfalls of the CS-CMIII as cutting and suturing of the left atrial wall in the deep corner close to the left pulmonary veins and left atrial appendage may jeopardize the circumflex artery. This is also an area

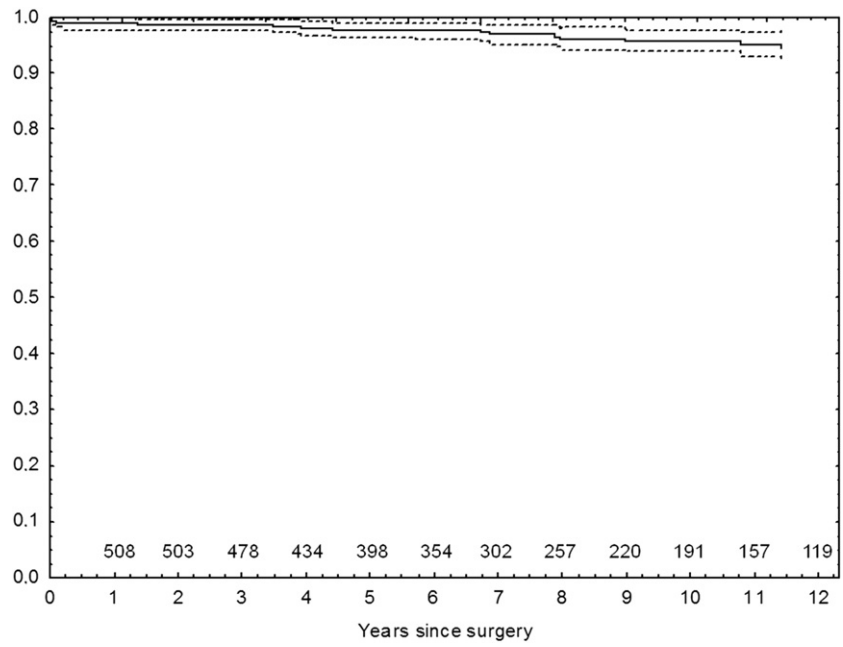

Fig 2. Kaplan Meier analysis of cardiovascular mortality after the Cox maze III procedure, 1994 to 2009. The dashed lines represent 95% confidence interval.

where surgical ablation with non-cutting techniques may prove a safer and faster option.

Although other complications occurred, it did not reflect in operative mortality. This is important information as the CS-CMIII was developed for operative treatment of a cardiac condition not carrying the same immediate threat to the patient as, for example, coronary disease. Thus, although highly invasive, the CS-CMIII by necessity had to be a low-risk operation to be a reasonable option both for patients and referring cardiologists. The presence of postoperative complications in this study, however, was a significant risk factor for long-term mortality both in univariable and multivariable analyses.

Long-term mortality in the whole cohort was 7.6% but 3.5% for cardiovascular causes, during a mean follow-up of 6.5 years. In general, this was a young group of patients with few comorbidities and a low overall death risk. A very recent multicenter study of 1,273 relatively healthy patients undergoing catheter ablation for AF, of similar mean age and gender mix, reported 23 deaths (1.8%) after a mean follow-up of 3.1 (1.0 to 9.6) years [18]. This was deemed equal to an age- and gender-matched general population. In the present study, there were in total 9 of 422 cardiovascular deaths (2.1%) in patients undergoing stand-alone CS-CMIII after a follow-up of over 6 years. Accordingly, univariable analyses showed an increased risk of death for patients with preoperative heart failure and organic heart disease, and patients undergoing concomitant surgery, reflecting subgroups with more progressive heart disease at the time of surgery. It is likely that patients with preoperative congestive heart failure due to structural heart disease will have a worse prognosis regardless of future rhythm status. Naturally, higher age was an independent risk factor for mortality. In the present study, however, preoperative type and duration of AF were not associated with an increased risk of death.

Hypertension was a significant risk factor for death in both the univariable and multivariable analyses. This could reflect a future risk of atherosclerotic and cardiovascular disease but did not seem to be associated with death from cerebrovascular causes. There was only 1 death due to cerebral events reported in the registry and it was not related to ischemic stroke. In general, approximately 20% to 30% of strokes are fatal within the first year [19], and stroke related to AF causes more severe neurologic symptoms and is more frequently fatal than stroke without AF [20]. From the current study, however, it is unknown what the incidence of nonfatal postoperative stroke was among these patients. The reported incidence of stroke in association with CS-CMIII surgery has been very low both short-term and long-term [17, 21], and the absence of stroke-related death in the current study points in the same direction. In addition, as all patients underwent complete CS-CMIII, the left atrial appendage was either excluded or removed, possibly reducing the future risk of thromboembolic stroke [22].

There are several limitations to this study. First, the numbers of overall and cardiovascular deaths were low, reducing the statistical weight of the analysis. Second, although the Swedish Cause-of-Death registry is validated, the stated causes of death may not in complete detail describe what actually happened to the patient. Third, there was no way through the Cause-of-Death registry to relate deaths to certain morbidity occurring beyond the early postoperative period. Detecting no stroke-related death does not mean an absence of postoperative stroke. Given the methodology of the study, it could not answer important questions such as how restoration of sinus rhythm affects long-term outcome after the CS-CMIII procedure. Also, knowledge of postoperative medication including anticoagulant therapy was not possible to attain. Further evaluation of morbidity from registry analyses, as well as individual patient follow-up, are planned in this large cohort and may provide answers to some of these issues.

In conclusion, registry-based follow-up of mortality in 536 cut-and-sew Cox-maze III patients revealed a very low operative mortality, a low long-term mortality from cardiovascular causes in stand-alone patients, and the absence of recorded ischemic stroke-related mortality.

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