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The long-term efficacy of concomitant maze IV surgery in patients with atrial fibrillation

Camilla Skals Engelsgaard [a,1], Kenneth Bruun Pedersen [a,1], Lars Peter Riber [b,1], Peter Appel Pallesen [b,1], Axel Brandes [a,c,*,1]

[a] Department of Cardiology, Odense University Hospital, Odense, Denmark
[b] Department of Thoracic Surgery, Odense University Hospital, Odense, Denmark
[c] OPEN, Odense Patient Data Explorative Network, Odense University Hospital, Odense, Denmark

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ABSTRACT

Background: Atrial fibrillation (AF) is the most common cardiac arrhythmia, and associated with increased risk of morbidity and mortality. AF surgery is widely used for rhythm control of AF, but previous studies have shown varying results. This study sought to investigate the long-term efficacy of concomitant maze IV (CMIV) surgery in an unselected AF population and identify predictors of late AF recurrence.

Methods: In total 144 consecutive patients, who underwent CMIV between January 2006 and December 2010 were enrolled. By data from electronic medical records, registers, and rhythm prints, late AF recurrences and heart rhythm at latest follow-up were retrospectively registered. All patients still alive were invited to an ambulant follow-up to update rhythm status.

Results: During a median (IQR) follow-up of 7.39 (2.67) years, 114 (79.2%) patients had recurrence. The cumulative incidence of sinus rhythm (SR) without antiarrhythmic drugs (AADs) was 52.3% after 1 year. Long-term results after 2, 5 and 7 years were 47.9%, 32.6% and 25.1%, respectively. At latest follow-up 34.7% were in SR off AADs. No difference in 10-year event-free survival stratified by recurrence were found ($p = 0.678$). Contrary, time to death (5.40 vs. 3.43 years, $p = 0.004$) revealed death as competing risk event. The Fine-Gray model identified preoperative sustained AF (SAF) (SHR 3.54, 95%CI [2.35;5.32], $p < 0.001$), AF duration (1.08, [1.05;1.11], $p < 0.001$), and postoperative atrial tachyarrhythmia (ATA) (2.29, [1.21;4.35], $p = 0.011$) as predictors.

Conclusion: CMIV in the present cohort provided limited long-term success in obtaining SR. SAF, longer AF duration, and postoperative ATA were associated with late AF recurrence.

1. Introduction

Atrial fibrillation (AF) is the most common cardiac arrhythmia, more frequently affecting men and elderly, and associated with increased morbidity and mortality,[1,2], especially due to heart failure or stroke, [1,3]. AF management comprises oral anticoagulation for stroke prevention and rate and/or rhythm control to improve symptoms and preserve left ventricular function. Rhythm control modalities include antiarrhythmic drugs (AADs), cardioversion, catheter ablation, and AF surgery,[1].

Present evidence shows that AADs and ablation procedures, mostly catheter-based pulmonary vein (PV) isolation, reduce rather than eliminate AF,[1,4,5]. Cox-maze surgery aims to create an electrical labyrinth of functional atrial myocardium via biatrial incisions obstructing potential macro re-entry circuits to prevent fibrillatory conduction. The procedure also includes left atrial (LA) appendage exclusion for prevention of thromboembolism,[6]. The lesion sets of maze IV are performed using radiofrequency energy and/or freezing, diminishing complications and technical complexity without reducing efficacy compared to maze III,[7]. Therefore, the use of AF surgery has expanded during recent years,[1]. Several studies have demonstrated that maze III/IV lesions are successful in obtaining sinus rhythm (SR),[8–13] regardless of whether they were performed as a stand-alone or concomitant procedure,[14–16]. However, studies investigating the efficacy of maze IV differ in terms of study design and settings leading to heterogeneous short- and long-term rates of freedom from AF recurrence between 47 and 94%,[8,12,17–20] and 56–91%,[9,18,21–24], respectively. Consequently, predictors of recurrence also are inconsistent.

Therefore, the aim of this retrospective cohort study was to investigate the long-term efficacy of concomitant maze IV (CMIV) surgery in an unselected population of AF patients during a long follow-up and identify possible predictors of late AF recurrence.

* Corresponding author at: Department of Cardiology, Odense University Hospital, J.B. Winsløws Vej 4, Entrance 33, Penthouse/2nd floor, 5000 Odense, Denmark.
E-mail address: axel.brandes@rsyd.dk. (A. Brandes).

[1] This author takes responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

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2. Methods

2.1. Study design

We retrospectively identified consecutive patients, who underwent maze IV surgery between January 2006 and December 2010 at a tertiary Danish university center, from the Western Denmark Heart Registry. Patients were included, if they had AF confirmed by preoperative electrocardiogram (ECG) or long-term monitoring,[1], AF as ablation indication, and survived the first 3 months after CMIV. Patients with catheter-based, surgical stand-alone, or incomplete maze IV procedures were excluded. Incompleteness was defined as lacking or insufficient lesions confer surgical standards,[25].

2.2. Data acquisition

Baseline and follow-up data were obtained from health care registries, electronic medical records, and during ambulant follow-up visits in patients still alive, when the study was performed. Data on prior hospital admissions, treatments and diagnoses were retrieved from the Danish National Patient Registry, and perioperative data from the Western Denmark Heart Registry. Date and cause of death during follow-up were recorded from the Danish National Patient and Cause-of-Death Registry. The Danish National Prescription Database provided data on medications. Echocardiographic parameters were retrospectively measured on preoperative transthoracic echocardiograms (TTEs) by a cardiologist, blinded for other study data. All data were independently adjudicated by two experienced cardiologists.

2.3. Surgical procedure and postoperative management

CMIV was performed after decision by a heart team,[1]. Main procedures included mitral and aortic valve surgery (i.e. repair, replacement) and/or coronary artery bypass grafting (CABG). All patients underwent median sternotomy, following standard cardiopulmonary bypass with bicaval cannulation and cardioplegic arrest. A biatrial maze IV procedure was accomplished with a left and right atriotomy enabling ablation close to the mitral and tricuspid valve. Remaining lesions were performed using a bipolar radiofrequency clamp (AtriCure Inc., USA) and cryoprobe (Frigitronics, CCS200, USA). The right atrial lesion set consisted of a cavo-tricuspid isthmus line connected to the superior vena cava. After cardioplegic arrest, left atrial lesions were performed; a circumferential PV isolation, left- and right-sided PVs separately with a superior and inferior interconnecting line (i.e. box lesion set), a lesion from the left upper PV to the rim of left atrial appendage and from the right lower PV to the mitral annulus. Enclosing lines around the coronary sinus and the tricuspid and mitral annuli were made by cryoablation. Electrical isolation of the box lesion set was documented by assessing exit block via bipolar pacing in all patients. LA appendage was ligated by stapling and excised.

Early postoperative care was similar to other open-heart surgery including continuous rhythm monitoring. Patients received prophylactic AADs. Complications within 30 postoperative days were heart failure (admission to heart failure clinic and initiation/intensification of anticongestive treatment), stroke, major bleeding (Bleeding Academic Research Consortium type 3–5), re-operation, myocardial infarction, renal failure requiring dialysis, and mortality. Furthermore, implantation of pacemaker or implantable cardioverter defibrillator (ICD), was documented.

Routine clinical follow-up visits occurred at 1, 3, 6 and 12 months postoperatively. A 12 lead ECG, TTE, and 48-h Holter monitoring were routinely performed at 1 and 3 months. Between hospital visits, patients were followed with routine ECGs by the referring physician. In case of suspected atrial tachyarrhythmia (ATA), additional Holter monitoring was performed. Cardioversion was recommended during a postoperative 3-months blanking period.

2.4. Long-term follow-up

Follow-up was defined as the time from the end of the blanking period to August 1st, 2016 or death, whichever came first. Long-term rhythm evaluation beyond routine follow-ups was done by available ECGs, Holter monitorings, and/or device interrogations. A12 lead ECG (MAC 5500, GE Healthcare, UK) and 48-h Holter monitoring (Lifecard CF, Spacelabs Healthcare, USA) were performed to update rhythm data in all patients attending the ambulant follow-up visit. Holter recordings were analysed by trained staff using dedicated software (Pathfinder SL, Spacelabs Healthcare, USA). All ECGs and Holter analyses were reviewed by an experienced electrophysiologist blinded for other study data.

2.5. Definition of arrhythmias and events

Preoperative AF duration was defined from the first date of AF documentation to CMIV and AF subtype comprised paroxysmal (PAF) and sustained (i.e. persistent, long-standing persistent, permanent) AF (SAF),[1]. Definitions of remaining baseline characteristics are presented in Online Table 1. Postoperative ATA during the blanking period was defined as monitoring-documented AF, atrial flutter, or atrial tachycardia lasting ≥30 s. The primary efficacy endpoint was freedom from late AF recurrence without AADs. Recurrence of AF was defined as the first monitoring-documented episode of AF, atrial flutter, or atrial tachycardia lasting ≥30 s after the blanking period,[1]. Secondary efficacy endpoints were freedom from recurrence on AADs, need of additional arrhythmia interventions (i.e. catheter ablation, pacemaker/ICD implantation), stroke, all-cause and cardiovascular mortality.

2.6. Ethics

The study was performed in accordance with the Declaration of Helsinki II and approved by the Danish Data Protection Agency (15/49691) and Regional Scientific Ethical Committees for Southern Denmark (S-20150209). All patients alive gave written informed consent before ambulant follow-up.

2.7. Statistical analysis

Descriptive statistics of baseline characteristics were stratified by late recurrence. Taking the possibility of differing individual follow-up times into account, pre-, peri-, and postoperative parameters were evaluated in a univariate Fine-Gray proportional subdistribution hazard analysis allowing for death during follow-up as a competing risk event to identify predictors of recurrence. Subsequently, the effect estimates (i.e. sub-hazard ratios (SHRs)) of the given covariates were adjusted for age and gender,[1]. Hereafter, statistically significant and insignificant covariates deemed clinically relevant were entered into a multivariate Fine-Gray regression by forced entry. Model comparisons were mediated by Akaike Information Criteria (AIC) and Bayesian Information Criteria (BIC) incorporating the trade-off between fit and complexity. Because of missing echocardiographic observations (i.e. LA diameter (LAd), LA volume indexed for body surface area (LAvI)) to some degree, evaluation of model prediction was further based on AIC/BIC relative to Wald's χ^2 test for raw data and multiple imputed. The model with the lowest AIC/BIC relative to highest Wald's index was chosen. Precondition of independence between the event of interest and the competing risk event was ensured by the consecutive study inclusion mediating a homogeneous cardiac risk group, and model assumption of proportional sub-hazards was validated by checking insignificance of time-varying covariates.

For graphically representation, Kaplan-Meier estimates were used to depict the event-free survival, and rates of death and stroke were compared, separately, using Log-rank test. Implementing death as competing risk event, cumulative incidence functions (CIFs) of late AF