

Approaching a Paradigm Shift: Endoscopic Ablation of Lone Atrial Fibrillation on the Beating Heart

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Background. Percutaneous catheter ablation has been the preferred treatment strategy for many patients with symptomatic drug-refractory atrial fibrillation (AF). However, incomplete ablation lines and varying success rates remain a problem in certain subgroups. This article evaluates the feasibility and efficacy of endoscopically performed left atrial ablation in patients with lone AF.

Methods. Epicardial bipolar radiofrequency ablation was performed on the beating heart through a bilateral endoscopic approach in 89 consecutive patients with lone AF. This included isolation of the pulmonary veins using a clamp; isolation of the posterior left atrial wall, including a trigonal line to the aortic noncoronary sinus using a linear ablation device; and resection of the left atrial appendage (LAA). Preoperative, perioperative, and postoperative data were collected prospectively and included questionnaires and 24-hour Holter monitoring at 6 and 12 months and annually thereafter.

Results. Mean follow-up was 12 ± 6 months (range, 4–28 months). No patients were lost to follow-up. Mean duration of AF was 6.4 ± 5.7 years, with 35% paroxysmal AF and 65% persistent or long-standing persistent AF. Mean operation time was 180 ± 43 minutes. There were no deaths, no conversion to sternotomy, and no early or late stroke. Freedom from AF was 88%, 90%, and 90% at 6, 12, and 24 months, respectively. Freedom from AF without antiarrhythmic drugs was 71%, 82%, and 90% at 6, 12, and 24 months, respectively.

Conclusions. Endoscopic radiofrequency ablation on the beating heart reveals high success rates with low procedure-related morbidity. For improvement of future treatment strategies, a randomized trial is advisable to compare this procedure with catheter ablation in certain patient subgroups.

(Ann Thorac Surg 2012;94:1886–93)

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Atrial fibrillation (AF) remains the most common sustained arrhythmia, with an expected increase in our aging population [1]. In addition to the significant morbidity that is secondary to hemodynamic compromise and tachycardia-induced cardiomyopathy, stroke remains the most feared complication, with a 5-fold increased risk [2, 3]. The limitations of pharmacologic therapy, with long-term failure rates as high as 85%, have made catheter ablation a recognized first-line treatment for patients with symptomatic drug-refractory AF [4–7]. However, results have been variable, with single-procedure success rates ranging from 16% to 84% [7]. Moreover, certain patient subgroups have done poorly, particularly patients with persistent or long-standing persistent AF [8–10].

Although the Cox-Maze III procedure, with more than 2 decades of documented follow-up, revealed excellent long-term success rates independent of the type of AF, it is technically challenging and associated with significant morbidity [11, 12]. Alternative energy sources have enabled surgeons to create lines of ablation to replace most

incisions of the original cut-and-sew technique, which shortened and simplified the procedure [13–15]. Given the multiple theories of the pathologic mechanism causing AF, it is not surprising that there is ongoing discussion as to what lesion set should be applied [16–18]. After taking lessons from the catheter-based literature, most attention has been paid to the left atrium (LA). Moreover, advances in the design of ablation devices enabling port access have shifted the surgeon's focus to less invasive procedures [14, 19].

This report evaluates the feasibility and efficacy of endoscopically performed bipolar radiofrequency ablation on the beating heart, which includes an extended left atrial lesion set as well as the resection of the left atrial appendage (LAA). It also discusses the growing recognition of surgical intervention in the treatment of lone AF in certain patient subgroups.

Drs Weimar and Czesla and Ms Vosseler disclose that they have financial relationships with AtriCure; Dr Doll discloses financial relationships with AtriCure, Esteche, and St. Jude.

Accepted for publication July 11, 2012.

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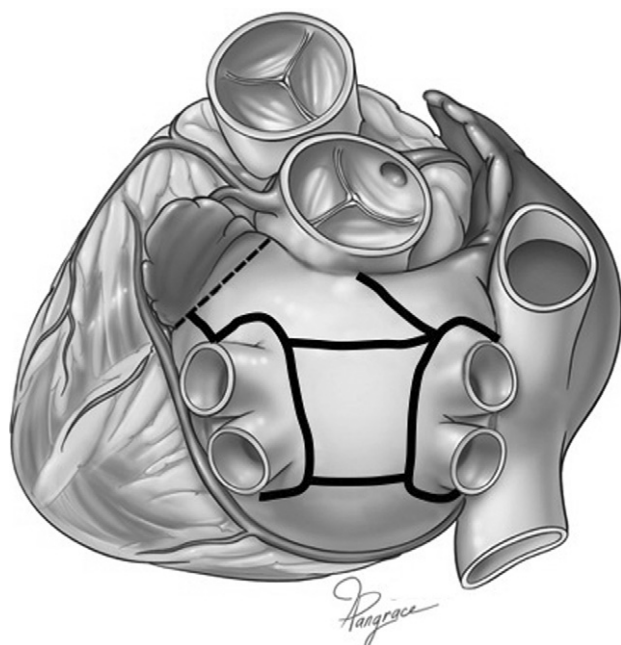


Fig 1. Left atrial lesion set including pulmonary vein isolation, a roof line and bottom line, a trigonal line to the aortic noncoronary sinus, and resection of the left atrial appendage (dashed line).

Patients and Methods

From May 2009 through January 2012, a total of 89 consecutive patients underwent a bilateral thoracoscopically performed epicardial ablation for lone AF on the beating heart at our institution. The study was approved by the institution's ethics committee.

Atrial fibrillation was defined as paroxysmal, persistent, or long-standing persistent according to recent guidelines [7, 20]. Criteria for enrollment in the study included recurrent symptomatic episodes of AF refractory to class I or class III medical therapy or failure of electrical or pharmacologic cardioversion within 6 months before operation. All patients were informed of alternative treatment options, including catheter ablation. Patients older than 60 years of age and younger patients with an existing cardiovascular risk profile underwent coronary angiography or cardiac computed tomography to evaluate Ca^{2+} scores before the surgical procedure. Patients in whom catheter ablation had previously failed underwent thoracic computed tomography to rule out pulmonary vein (PV) stenosis. All procedures were performed by 3 surgeons (N.D., T.W., M.C.) applying the identical lesion set (Fig 1). A bipolar radiofrequency clamp (Isolator Synergy series; AtriCure, Inc, Cincinnati, OH) was used for PV isolation. For the linear lesions to isolate the posterior LA, the 30-mm-long irrigated CoolRail Linear Pen (AtriCure, Inc) was applied in 65 patients (73%), and the second-generation 20-mm-long nonirrigated Isolator Linear Pen (AtriCure, Inc) was used in 24 patients (27%). The LAA was resected using a stapler device (Duet-TRS and Endo-GIA; Covidien, Dublin, Ireland and the ECHELON FLEX ENDOPATH sta-

pler; Ethicon Endo-Surgery GmbH, Norderstedt, Germany). Epicardial mapping as well as detection and ablation of ganglionated plexuses (GPs) were performed with the Isolator Multifunctional Pen (AtriCure, Inc). All devices used alternating current to produce coagulative thermal injury, with the energy either applied between electrodes embedded in the jaws of the clamp or between the electrodes arranged in parallel in the linear devices. Algorithms measuring tissue conductance or impedance were used to determine the time of ablation and to estimate when a transmural lesion had been achieved.

Surgical Technique

Oral anticoagulation therapy was discontinued 3 days before the surgical procedure, and enoxaparin sodium was administered twice a day until the evening before the surgical procedure. Patients were intubated with a double-lumen endotracheal tube, and external defibrillator pads were placed. A transesophageal echocardiogram confirmed the absence of LAA thrombus in all patients. A camera port was placed at the right fifth intercostal space. Two working ports were placed in the fourth and sixth intercostal spaces at the midaxillary line (Fig 2). Using 1-lung ventilation, the pericardium was opened anterior and parallel to the phrenic nerve from the superior vena cava to the diaphragm. An articulating and illuminating dissector (LumiTip Dissector System; AtriCure, Inc) holding a guiding sheath was introduced around the PVs. After the dissector was removed, the sheath remained in place as a guide for the insertion of the ablation clamp. At this point, the patient underwent cardioversion to sinus rhythm if needed to obtain pacing thresholds from the PVs. In the first 31 patients, GPs were detected and ablated. High-frequency stimulation (burst circle length of 100 milliseconds, output 20 V at 2 milliseconds) evoked a vagal response, inducing bradycardia when applied to GPs. The detected areas were ablated



Fig 2. Port placement for thoracoscopic access on the right side of the chest.

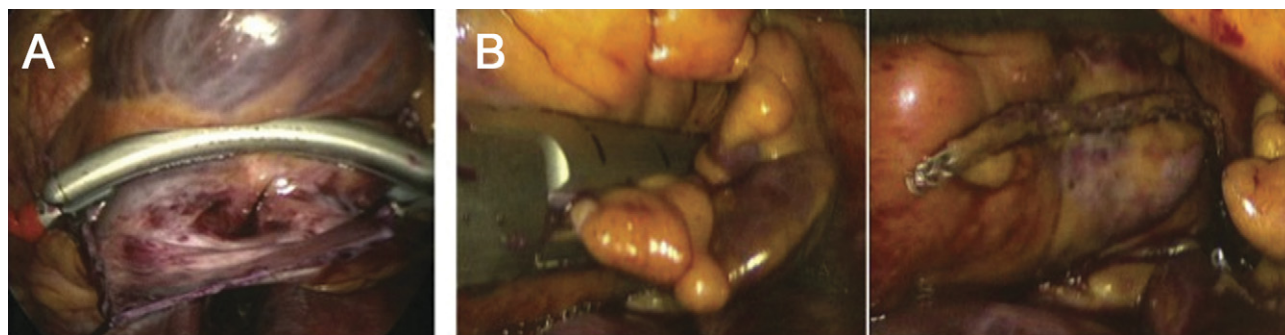


Fig 3. Thoracoscopic view. (A) Isolation of the right pulmonary veins with a bipolar radiofrequency clamp. (B) Resection of the left atrial appendage.

until the vagal response diminished. This policy was abandoned in the later series because there is currently no strong evidence that ablating GPs improves long-term success. After pacing maneuvers were completed, the PVs were isolated by placing the ablation clamp on the surrounding cuff of atrial tissue (Fig 3A). In patients in whom pacing could be performed (89%), ablation was continued until bidirectional block was documented for each PV. However, ablation runs were repeated at least in triplicate.

In addition to PV isolation, the transverse and oblique sinuses were dissected. This allowed for a box lesion set isolating the posterior LA by ablating a roof line and bottom line using the linear ablation device. To substitute for the left atrial isthmus line, a trigonal line was added from the isolated right superior PV to the noncoronary sinus of the aortic annulus, which has a fibrotic connection to the mitral annulus (Fig 1). Isolation was confirmed by demonstrating a conductance delay as shown in Fig 4.

The approach to the left side of the chest was similar to that already described. However, the ports were positioned more posteriorly. The pericardium was opened posterior to the course of the phrenic nerve. The ligament of Marshall was divided. The dissector and the guiding

sheath were used to position the clamp around the left PVs. After isolation, bidirectional block was confirmed for the left PVs.

The LAA was resected by stapling across the base with a stapler device (Fig 3B).

Pacing and sensing were performed from within the box to demonstrate bidirectional block. All linear ablation runs were also repeated at least in triplicate.

Postoperative Care and Follow-Up

Patients underwent continuous telemetric monitoring after operation. If not contraindicated, 900 mg amiodarone was administered intravenously over 12 hours starting at the time of operation. Patients experiencing atrial tachyarrhythmias (ATAs) during the postoperative course were given class I or class III antiarrhythmic agents and underwent electrical cardioversion as needed. Anticoagulation therapy with warfarin was started 1 day postoperatively and continued for at least 3 months. If patients were in sinus rhythm, antiarrhythmic drugs were discontinued after 3 months, and rate control medication was started at that point if appropriate. Warfarin was discontinued at 3 months if patients were free of ATAs, confirmed by 24-hour Holter monitoring, and an echocardiogram ruled out atrial stasis or thrombus.

The clinical demographics and postoperative outcome variables were collected prospectively in a longitudinal database. Follow-up was conducted by office visits at 3, 6, and 12 months, and annually thereafter. At each visit, a history, physical examination, and electrocardiogram were obtained. Twenty-four-hour Holter monitoring was obtained in 87% of patients. Late recurrence was defined as any episode of ATAs—including AF, atrial flutter, or atrial tachycardia—that lasted longer than 30 seconds. Permanent failure was deemed to have occurred in any patient requiring an interventional procedure after a blanking period of 3 months. The procedure was considered to be a success only if patients were both free of AF and not taking antiarrhythmic drugs (class I or class III).

Health-related quality of life was evaluated before operation and 12 months postoperatively using the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) by calculating a score for each domain [21].

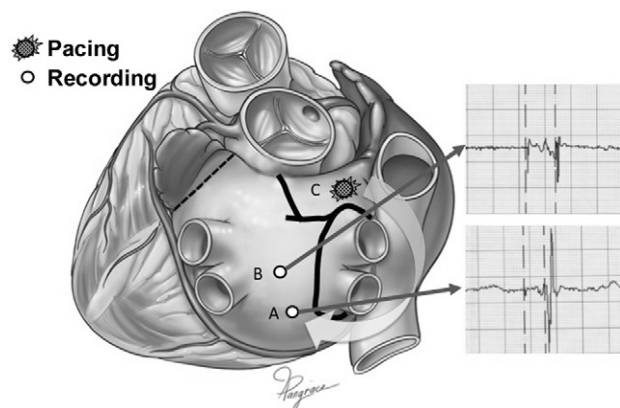


Fig 4. Mapping of the trigonal line: a conductance delay between sensing point A and sensing point B when pacing at point C confirmed isolation.

Table 1. Patient Characteristics

Variables	N = 89
Age (y)	60 ± 11
Male sex	63 (71%)
AF duration (y)	6.4 ± 5.7
Type of AF	
Paroxysmal	31 (35%)
Persistent	21 (24%)
Long-standing persistent	37 (42%)
Previous failed electrical cardioversion	46 (52%)
Previous failed catheter ablation	26 (29%)
Left ventricular ejection fraction (%)	60 ± 10
Body mass index (kg/m ²)	27.3 ± 4.5
Hypertension	52 (58%)
Diabetes mellitus	10 (11%)

Data are expressed as counts or mean ± standard deviation.

AF = atrial fibrillation.

Statistical Analysis

Continuous data were expressed as mean ± standard deviation. Categorical data were expressed as counts and proportions. Subgroup comparisons were performed using the unpaired *t* test for continuous variables and the χ^2 or Fisher's exact test for categorical variables. Preoperative and perioperative variables including age, sex, type and duration of AF, left ventricular ejection fraction, failed catheter ablation, LA diameter, body mass index, and history of arterial hypertension or diabetes mellitus were evaluated in an univariate analysis to identify potential predictors of late recurrence of ATA. Significant covariates on univariate analysis ($p \leq 0.10$) or covariates deemed clinically relevant were entered into a stepwise multivariate Cox proportional hazard regression analysis. SF-36 follow-up scores were compared with baseline scores using a paired *t* test. All data analyses were performed with SPSS for Windows, version 11.0 (SPSS, Chicago, IL).

Results

Patient Demographics

Baseline characteristics of 89 patients are shown in Table 1. The predominant type of AF was persistent or long-standing persistent AF (65%). The mean duration of preoperative AF was 6.4 ± 5.7 years (range, 0–30 years), and catheter ablation had failed a mean of 2.1 ± 1.0 (range, 1–5) in 29% of patients. Nine patients (10%) had a history of thromboembolic events. Preoperative echocardiography excluded significant valve pathologic processes in all patients, whereas the mean LA diameter was enlarged by 4.5 ± 0.8 cm (long axis in parasternal view).

Perioperative Results

Perioperative data are shown in Table 2. There was no operative mortality (≤ 30 days) and no conversion to median sternotomy. The mean operative time was 180 ± 43 minutes (range, 95–355 minutes). In 1 patient (1%),

bleeding occurred at the LAA resection site as a result of manipulation with the stapler device after the lesion set had been completed on the beating heart. One of the left-sided port incisions was slightly extended and the bleeding was managed by a suture under direct vision. Despite stable hemodynamic conditions at all times, this patient had a transient ischemic attack in the early postoperative period. This 1 reoperation for bleeding and 1 pacemaker implantation were the only procedure-related complications (3/89 [3%]).

There were no episodes of mediastinitis and no early stroke (≤ 30 days), defined as radiologic demonstration of a new cerebral lesion associated with a focal neurologic deficit.

One patient (1%) required postoperative pacemaker implantation because of sick sinus syndrome. The device was explanted 2 months postoperatively because of restored chronotropic competence. Early postoperative ATAs were documented in 34 patients (38%). Eighty patients (90%) were discharged in sinus rhythm.

Intention to Treat

Overall, 3 of 92 patients (3%) underwent conversion to right lateral minithoracotomy using femofemoral extracorporeal circulation and received an endocardial biatrial ablation (Cox-Maze IV) using cryoenergy: 1 patient presented with extensive epicardial fat, resulting in questionable success of the epicardial ablation. Two patients had pericardial adhesions from a hemopericardium after warfarin therapy in the past, which could not be managed thoracoscopically. All 3 patients were free of AF at 6 and 12 months but were excluded from the reported study population.

Late Follow-Up

The mean follow-up time was 12 ± 6 months (range, 4–28 months). No patients were lost to follow-up. There was no late mortality or late stroke. Freedom from recurrence

Table 2. Perioperative Data

Variables	N = 89
Operative	
Procedure time (min)	180 ± 43
Conversion to median sternotomy	0 (0%)
Conversion to extracorporeal circulation (for complication management)	1 (1%)
Operative mortality (≤ 30 d)	0 (0%)
Postoperative	
Length of intensive care unit stay (d)	1.5 ± 1.5
Operative morbidity	3 (3%)
Temporary pacemaker dependency	1 (1%)
In-hospital electrical cardioversion	21 (24%)
Length of hospital stay (d)	8.3 ± 4.8
Late mortality	0 (0%)
Early/late stroke	0/0 (0%)

Data are expressed as counts or mean ± standard deviation; late = >30 d.

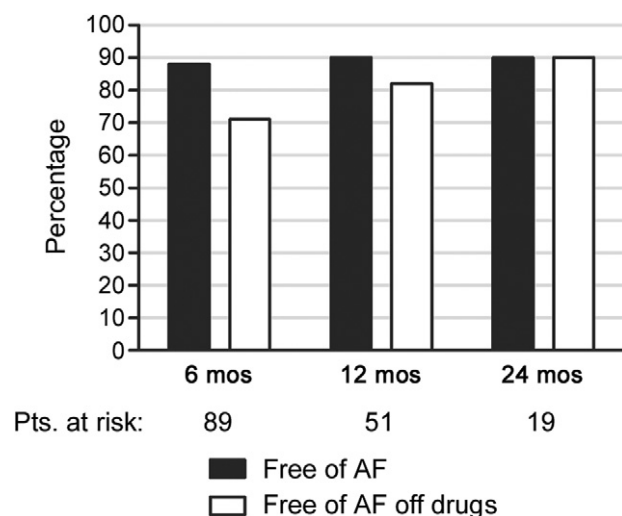


Fig 5. Overall freedom from atrial fibrillation (AF) and freedom from AF without antiarrhythmic agents at follow-up.

of AF was 88%, 90%, and 90% at 6, 12, and 24 months, respectively. Freedom from both AF and the need for class I or class III antiarrhythmic medication was 71%, 82%, and 90% at 6, 12, and 24 months, respectively (Fig 5). There was no significant difference in freedom from AF between patients with paroxysmal AF and those with persistent or long-standing persistent AF at any time (Fig 6). Four patients (5%) underwent a hybrid approach, receiving catheter ablation after recurrent ATA after operation. In 3 of those patients, right atrial flutter could be detected; in 1 patient a gap in the roof line was the cause for recurrent AF. All 4 patients were in stable sinus rhythm after the intervention, but the interventions were deemed failures in our series.

Although duration of AF and type of AF were not predictive for recurrent ATAs, LA diameter and body mass index could be identified as independent predictors for failure after endoscopic ablation (Table 3).

At last follow-up, 71% of patients were free of the need for anticoagulation therapy with warfarin. The quality of life assessed by SF-36 scores revealed a significant improvement compared with baseline (Fig 7A). Patients in need of antiarrhythmic agents after the procedure showed significantly lower physical and mental component summaries (Fig 7B).

Comment

Patients with symptomatic drug-refractory AF remain a treatment dilemma. Although catheter ablation has advanced to first-line treatment, as recommended by the recent consensus statement, reported single-procedure success rates are variable and rather disappointing in patients with persistent AF [7, 9]. A recent study from Haïssaguerre's group [8], reported a single-procedure success rate as low as 29% after 5 years. Many patients in whom catheter ablation has failed therefore remain exposed to thromboembolic risk and symptoms. The ran-

domized FAST (Fluid Accumulation Status trial) comparing catheter ablation with endoscopic ablation recently revealed a significantly higher success rate of 66% versus 37% freedom from AF at 1 year in favor of surgical intervention [22]. However, invasiveness seems to remain 1 of the major concerns of patients and referring electrophysiologists. Endoscopic ablation reduced the rate of adverse events, optimized cosmetic results, and excluded postpump inflammatory response as a possible independent trigger for AF [23]. The present report confirms that an endoscopic approach can be performed with low complication rates and low morbidity without compromising the efficacy that was previously reported for surgical ablation [12, 15, 24]. Up to 2 years after operation, 90% of patients were not only free of recurrent AF but also did not need antiarrhythmic medication, independent of their preexisting type of AF. Moreover, 71% of patients were not receiving anticoagulation therapy. This was reflected in a significant improvement in quality of life, which represents the therapeutic goal that should be achieved. However, current guidelines did not define withdrawal of anticoagulation therapy as an aim for any interventional treatment of AF, and it remains mandatory to thoroughly reassess an individual's risk before discontinuing warfarin [20].

There were no strokes documented in our entire series. An advantage of surgical intervention is the ability to address the LAA, which reduces the thromboembolic risk even if the procedure fails. However, we experienced 1 case of LAA bleeding that could not be managed through port access and required extracorporeal circulation. The cause of a transient ischemic attack in the same patient remains unclear, but a procedure-related reason

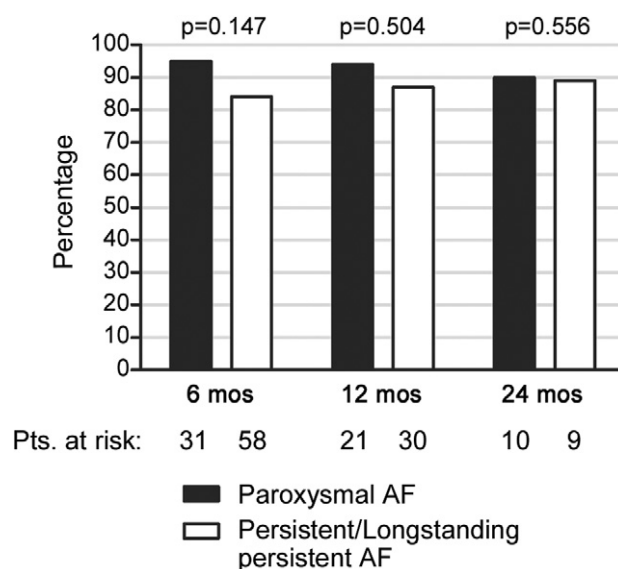


Fig 6. Success rates for different types of atrial fibrillation (AF).

Table 3. Multivariate Cox Proportional Hazard Regression Analysis of Predictors for Failure After Endoscopic Ablation

	Coefficient	Standard Error	p Value	Hazard Ratio	95% CI
LA diameter	0.143	0.047	0.002	1.154	1.053–1.264
Body mass index	0.200	0.081	0.014	1.221	1.042–1.431

CI = confidence interval; LA = left atrium.

could not be excluded. This happened early in the series, and no further bleeding complication occurred after more experience was gained and second-generation stapler devices were introduced. However, the LAA is a fragile structure subject to the risk of tearing and requires careful management.

One patient required pacemaker implantation because of chronotropic incompetence after operation. It is unknown if this patient presented with preexisting sick sinus syndrome. AF can detrimentally affect the sinus node, which was possibly unmasked by restoring sinus rhythm [25]. The sinus node recovery time is known to normalize over time after termination of AF. After no single pacing episode for 8 weeks, the device was explanted 3 months after its implantation.

Twenty-four-hour Holter monitoring as suggested by our follow-up protocol and required by the consensus statement was not available for all patients [7]. Thirteen percent of patients refused 24-hour Holter monitoring because they felt free of any clinical symptoms indicating a possible relapse of AF. However, multiple electrocardiograms documenting these patients' heart rhythms had been obtained at and between the follow-up visits. For future randomized trials comparing this procedure to catheter ablation, the implantation of a reveal device is strongly recommended to improve patient's compliance with follow-up protocols, to avoid an underestimation of recurrent ATAs, and to gain a better understanding of the actual AF burden.

Although 3 patients experienced right atrial flutter that was not necessarily related to a failure of this procedure, the mechanisms for AF recurrence were not well defined in some patients. One possible explanation of failure would be a lack of transmural or the development of reconnections over time for some lesions. Although bipolar radiofrequency clamps have proved to reliably create transmural lesions, the performance of linear devices applied epicardially on a heteromorphic structure such as the LA might remain a problem [14]. Resistive heating is subject to the heat sink effect, and wall

thickness varies extremely in structures such as the lateral ridge or Bachmann's bundle. Ablations were therefore repeated at least in triplicate at the same spot. Although we confirmed bidirectional block for the linear lesions, reconnection might have occurred over time [26]. Continuous follow-up is therefore mandatory for this new approach to detect a possible decline in long-term success rates.

Moreover, there is still conflicting data about whether an extended left atrial lesion set is sufficient to treat the underlying pathologic mechanism of AF. Although a meta-analysis by Barnett et al [27] revealed the superiority of a biatrial lesion set, more recent randomized studies reported comparable success rates and clinical outcomes with biatrial and left atrial lesion sets [28]. Future diagnostic tools to identify the patient subgroup benefiting from a biatrial ablation might further improve results.

The question remains unanswered about whether our failure rate was due to technical difficulties in creating a complete lesion set epicardially or to an inherent atrial pathologic process. Interestingly, in 3 of 4 patients who had recurrent ATAs and therefore underwent an electrophysiologic study, no gaps could be detected in the entire lesion set.

In conclusion, this report confirms that a thoroscopically performed extended left atrial lesion set reduced the invasiveness of the procedure without compromising the efficacy of surgical ablation. These results can be achieved with low morbidity and low complication rates that are comparable to those of catheter ablation. With a freedom from AF without antiarrhythmic agents of 90% at 2 years, independent of the type of AF and no reported stroke in the entire series, this procedure should potentially develop into a superior alternative to catheter ablation and should be considered as an equivalent first-line treatment in patients with persistent or long-standing persistent lone AF. However, to support this statement, a randomized trial is necessary to compare the

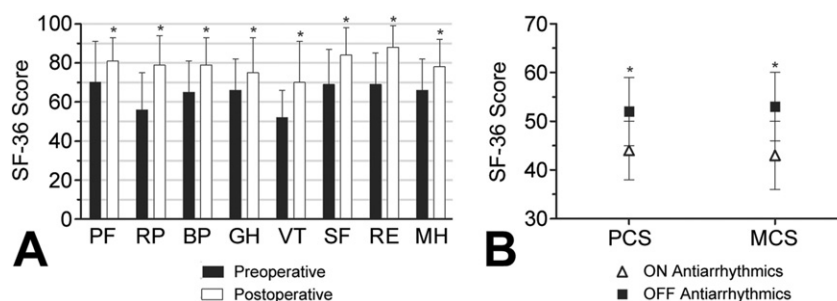


Fig 7. (A) Changes in quality of life at 12 months compared with baseline. * $p \leq 0.001$. (B) Postoperative quality of life with and without antiarrhythmic agents. * $p \leq 0.001$. (BP = body pain; GH = general health; MCS = mental component summary; MH = mental health; PCS = physical component summary; PF = physical functioning; RP = role physical; RE = role emotional; SF = social functioning; VT = vitality.)

2 approaches in this patient subgroup with regard to success rates, safety, and quality of life.

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INVITED COMMENTARY

The report by Weimar and colleagues [1] is a study of 89 patients undergoing minimally invasive surgical atrial fibrillation (AF) ablation and their follow-up over 2 years. The study is a challenge to existing catheter

techniques and medical therapies to examine in a prospective and randomized fashion the success of individual treatment approaches, elimination of medication and its effect on quality of life for medical