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ORIGINAL ARTICLE — NEW METHODS

Minimally invasive hybrid ablation procedure for the treatment of persistent atrial fibrillation: one year results

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Abstract

Background: The concept of a hybrid approach, combining the most effective techniques of surgical and endocardial catheter ablation has resulted in the creation of the convergent ablation procedure. This novel, pericardioscopic, hybrid approach can be an effective option for highly symptomatic patients with persistent atrial fibrillation (PSAF) and longstanding persistent atrial fibrillation (LSPAF) for whom standalone surgical or endocardial ablation procedures offer sometimes unsatisfactory outcomes.

Aim: To assess the safety, efficacy and effectiveness of a hybrid epicardial and endocardial radiofrequency ablation for the treatment of PSAF and LSPAF.

Methods: Single-centre, prospective, non-randomised clinical study. Between August 2009 and December 2011, 27 patients with PSAF (n = 5) and LSPAF (n = 22) underwent hybrid ablation (HABL). Mean age was 52.52 ± 11.27 years, and the mean EHRA class was 2.5; 14 (51.8%) patients had a history of electrical cardioversion (n = 6) or catheter ablation (n = 8). Five patients had left ventricular ejection fraction (LVEF) of less than 35%. Mean AF duration for all patients was 3.46 ± 2.5 years. All patients were on antiarrhythmic drugs (AAD) and oral anticoagulation. Patients were scheduled for three, six and 12 month follow-up with seven day Holters, REVEAL® XT and ECHO measurements.

Results: The HABL procedure was feasible in all patients. At six months post procedure, 72.2% (13/18) of patients were in SR, and 66.5% (12/18) were off class I/III AADs. Four patients were in AF and one patient developed right atrial flutter. At one year post procedure, 80% (8/10) of patients were in SR and off class I/III AADs. At two year post procedure, 100% (6/6) of patients were in SR and off class I/III AADs. Rapid change in left ventricular function was noted in patients with low LVEF (≤ 35%) prior to the procedure. Patients with LVEF +40% had less apparent improvement.

Conclusions: Hybrid, epicardial and endocardial, radiofrequency ablation is feasible and safe, effectively restoring sinus rhythm in the vast majority of patients with PSAF and LSPAF.

Key words: atrial fibrillation, ablation, hybrid surgery

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INTRODUCTION

Atrial fibrillation (AF) remains the commonest cardiac arrhythmia, affecting nearly 2% of the general population. It has been shown that AF is associated with increased risk of cerebrovascular thromboembolic events, increased frequency of cardiac-related hospitalisations, and significantly reduced quality of life. Even more importantly, its occurrence doubles the mortality rate and notably increases the cost of caring for

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patients either suffering from AF or from its non-fatal comorbidities [1–3]. Despite recent advances, medical therapy alone is often sub-optimal and limited by serious toxicities. This has resulted in the introduction of interventional treatment methods. Endocardial catheter ablation is highly effective for paroxysmal AF and remains a class IIa/A indication if optimal medical therapy has failed [4, 5]. However, its success declines in persistent and long-standing persistent types of atrial arrhythmias. Although current guidelines state it may be considered (IIb/C), few studies have documented acceptable long-term outcomes. Published data suggests a high rate of AF recurrence within 12 months of the procedure, implying the necessity for repeated interventions [6], which may not prove successful. On the other hand, surgical ablation, as proposed by J. Cox, results in sinus rhythm restoration in the majority of treated patients [7]. Irrespective of modifications, the Cox-Maze procedure remains technically challenging and complex, limiting its adoption in everyday clinical practice. Rapid advancements in minimally invasive endoscopic and robotic cardiac surgery [8, 9], allow for the recreation of this 'maze pattern' through a minimal surgical incision [10].

The concept of a hybrid approach, combining the most effective techniques of surgical and endocardial catheter ablation, has resulted in the creation of the convergent ablation procedure. This novel, pericardioscopic, hybrid approach can be an effective option for highly symptomatic patients with persistent atrial fibrillation (PSAF) and longstanding persistent atrial fibrillation (LSPAF) for whom standalone surgical or endocardial ablation procedures offer sometimes unsatisfactory outcomes.

The aim of this study was to assess the safety, efficacy and effectiveness of hybrid, epicardial and endocardial, radiofrequency (RF) ablation for the treatment of PSAF and LSPAF.

METHODS

The study protocol was approved by our institutional review board prior to initiating patient enrollment.

Study protocol

The study was designed as a single-centre, prospective, non-randomised clinical study. Consecutive patients with drug-refractory AF were screened for eligibility by a Heart Team consisting of at least one cardiac surgeon and one electrophysiologist. Adult patients over the age of 18 with a left atrium less than 60 mm, willing to comply with the required follow-up, and providing their informed consent, were included in the study. Patients having paroxysmal AF, any previous cardiac surgery or who had not failed previous class I/III antiarrhythmic drugs (AADs) pharmacological therapy were excluded from study participation. Patients who met the inclusion/exclusion criteria and provided informed consent were enrolled in the study. Prior to final qualification for enrollment, all patients had a 24 h Holter to document AF, and contrast-enhanced computed tomography (CT) to visualise the anatomy of the pulmonary veins, left atrium and its relation to the oesophagus. Patients remaining on oral vitamin K antagonists (VKA) were asked to replace it with low molecular weight heparin (LMWH enoxaparine, 1 mg/kg twice a day) 6–7 days prior to the planned procedure. Transoesophageal echocardiographic examination was performed in all patients on the day of admission to rule out possible thrombi and any other possible underlying heart diseases. All patients aged 60 years or over underwent coronary angiography; patients under 60 were subject to a calcium score analysis at CT examination.

The study evaluated the safety and effectiveness of the hybrid ablation procedure (HABL). The primary efficacy endpoint of the study was defined as the percentage of patients who underwent a complete hybrid procedure according to the study protocol and were in sinus rhythm (SR) defined as free from atrial arrhythmia measured by lack of atrial tachyarrhythmia > 30 s in a 7 day ECG Holter monitor at 12 months post procedure. Additional endpoints included freedom from AADs and VKA. The safety endpoint of the study was defined as the occurrence of major adverse cardiac events such as death, myocardial infarction (MI), stroke, or major bleeding throughout the 12-month period.

Study population

From August 2009 to December 2011, a total of 27 AF patients (five persistent and 22 long-standing persistent) qualified for study participation and underwent the hybrid ablation. All patients were on optimal medical therapy including class I and/or III AAD and oral anticoagulation with VKA. The enrolled patients had a mean age of 52.5 ± 11.3 years and 78% (21/27) were male. Mean AF duration was 3.46 ± 2.5 years (range 6 months to 15 years) and a mean European Heart Rhythm Association (EHRA) class of 2.5 (12 patients were in EHRA III or more). In 51.8% (14/27) of patients, AF treatments — restoration of sinus rhythm (SR) was attempted either by electrical cardioversion (n = 6) or endocardial catheter ablation (n = 8) prior to HABL. Of the eight patients who had previous catheter ablation, 75.0% (6/8) had repeated (i.e. two or more) catheter ablations; 18.5% (5/27) of patients were diagnosed with tachyarrhythmic cardiomyopathy with a left ventricular ejection fraction (LVEF) equal to or less than 35%; 14.8% (4/27) of patients had a history of coronary artery disease and had been treated with bare metal and drug-eluting stents more than a year prior to the HABL. Hypertensive heart disease was present in 66.7% (18/27) of patients and diabetes mellitus in 18.5% (5/27) of patients; 14.8% (4/27) of patients had suffered from amiodarone-induced hyperthyroidism. Patient baseline characteristics are set out in Table 1.

Table 1. Patient characteristics

Male	77.7% (21/27)
Mean age [years]	52.5
Mean BMI [%]; ave (SD)	29.5 (3.8)
Mean LVEF [%]; ave (SD)	45 (8.6)
Mean LA diameter [mm]:	45.5 (4.7)
40–45	44.5% (12/27)
> 45	48.2% (13/27)
Prior failed catheter ablation	29.63%
AF type:	
Persistent	18,5 % (5/27)
Longstanding persistent	81.48% (22/27)
AF duration [years]; average (SD)	3.5 (2.5)
$CHADS_2$ score:	
0	25.9% (7/27)
1	37.04% (10/27)
≥ 2	37.04% (10/27)

BMI — body mass index; LVEF — left ventricular ejection fraction; LA — left atrium; AF — atrial fibrillation

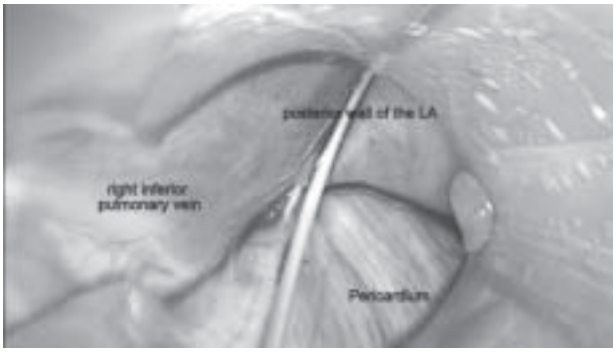

Figure 1. Endoscopic view of the oblique sinus. Colour version of the figure on this issue cover

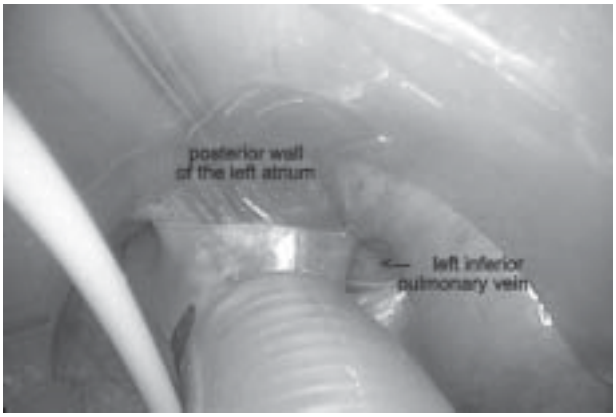

Figure 2. The coagulation device utilises a vacuum to create consistent contact between the 3 cm unipolar radiofrequency electrode and epicardial tissue. Colour version of the figure on this issue cover

Convergent and staged approach

The initial six procedures were performed in the electrophysiological (EP) cath lab, as a single procedure, with epicardial ablation via a minimal surgical access preceding the endocardial ablation via a percutaneous access. Patients were then extubated on the table, and transferred to the Intensive Care Unit (CSICU), and discharged home 7–8 days post procedure.

After the initial six procedures, due to reimbursement issues, the convergent procedure was performed in stages with the epicardial ablation procedure completed first and the percutaneous ablation procedure performed when the patient was readmitted 15–20 days later. Initially, the epicardial ablation procedure was performed in the operating theatre (OR) equipped with a portable C-arm, and later in the hybrid suite. Patients were extubated in the OR, transferred to the CSICU or to the floor on post-operative day 1, and discharged home on the 3rd–5th post operative day.

Epicardial ablation — surgical procedure

Surgical and percutaneous procedures followed standard practice [16]. Patients were anaesthetised using the TIVA technique together with short acting muscle relaxants. Two independent temperature probes (Medtronic, USA) were inserted into the oesophagus. A midline abdominal small 2–3 cm incision was made 1–2 cm below the xyphoid, through which a 10 mm laparoscopic port was inserted. Once the peritoneum was accessed, CO_2 insufflation was initiated and two 5 mm working ports were inserted in the left and right subcostal area. The central tendon of the diaphragm was identified and incised as an inverted T (3–4 cm) with a harmonic scalpel (Ethicon, USA). The pericardium was subsequently entered and the laparoscopic ports removed. A cannula designed for pericardioscopic access (nContact Surgical, Morrisville, NC, USA) was then placed inside the pericardial sac. The cannula, with an endoscope inside it, was pushed forward into the oblique sinus to visualise the posterior wall of the left atrium (LA) and pulmonary veins (PVs) (Fig. 1). An irrigated, unipolar RF ablation device (VisiTrax™ nContact Surgical, Morrisville, NC, USA) was passed through the cannula. The Coagulation Device utilises a vacuum to create consistent contact between the 3 cm unipolar RF electrode and epicardial tissue (Fig. 2). The vacuum additionally pulls saline through the device to cool the surface not intended for ablation, thereby directing energy only into epicardial tissue pulled into engagement with the ablation electrode. The RF generator utilises an algorithm based on impedance that regulates power to prevent tissue overheating and subsequent vapourisation. Linear lesions (90 s each, 30 W power) were created, as depicted in Figure 3. All applications on the posterior wall of the LA were performed under fluoroscopic guidance to visualise the rela-

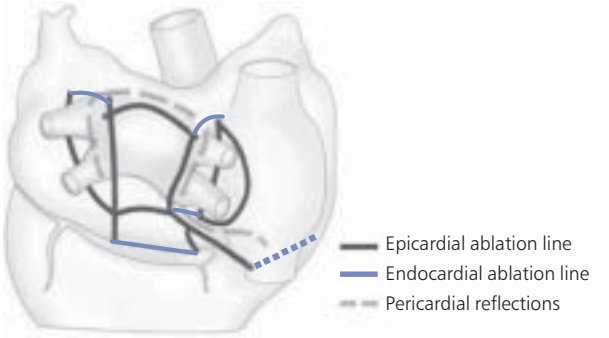

Figure 3. Hybrid endocardial and epicardial procedure lesion pattern

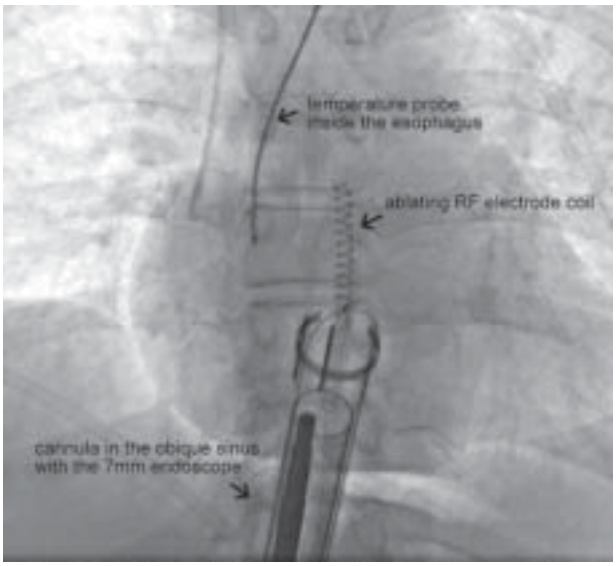

Figure 4. Relation of the oesophagus to the ablating electrode is monitored, and position of the temperature probe is adjusted accordingly

tion between the ablating electrode and the oesophagus (Fig. 4). Temperature probes were positioned to match the position of the ablating electrode. 50 mL of 30°C 0.9% saline was injected into the pericardium prior to RF energy application to submerge the ablating electrode and reduce temperature spread. When all lesions had been created, a small drain was placed behind the LA and passed through one of the 5 mm endoscopic ports. The midline fascia was closed with interrupted permanent sutures. Skin and port incisions were closed using absorbable sutures.

Endocardial ablation — percutaneous procedure

Endocardial ablation procedures were performed using the Seldinger technique to introduce two sheaths via peripheral veins. A 10-polar 6 F electrode, which served as the reference, was introduced into the coronary sinus via the right internal jugular vein. Subsequently, a Brockenbrough needle and a Mullins-type transseptal sheath were both positioned in the upper right atrium and a transseptal puncture was performed under the guidance of intracardiac pressures recorded from the tip of the needle. Immediately after the puncture, a single bolus of 10,000 U heparin was administered, and a 8 F NaviStar irrigated-tip ablation electrode (Biosense Webster, Diamond Bar, CA, USA) was introduced into the LA. With the use of electro-anatomical mapping system (CARTO, Biosense Webster), an isopotential map of the LA was created to identify areas showing electrical activity within the PV ostia and in the region of the LA isthmus. Electrical silence was indicated if the amplitudes of bipolar atrial electrograms were < 0.05 mV. Once identified and marked on the map, areas with persistent conductivity were subsequently ablated using RF applications limiting the power to 40 W and the application time to 60 s. Finally, the electrical isolation of the veins was verified by stimulating the pulmonary ostia with a cycle length of 500 ms.

Postoperative management

All patients were prescribed the same postoperative pharmacological protocol: intravenous infusion of amiodarone (Cordarone, 600 mg/50 mL 2 mL/h) together with IV heparin (25,000 IU/50 mL 2 mL/h; ACT ≥ 180 s) were initiated 1 h post surgery and continued for 48 h thereafter. Potassium was supplemented to maintain levels close to 4.5–4.7. Treatment with warfarin commenced on postoperative day two until the international normalised ratio (INR) was > 2.5 in all patients who underwent the single procedure convergent approach (n = 6). Patients who underwent the staged procedure were discharged on LMWH (Clexane, 1 mg/kg twice daily) and continued that therapy until readmission for the endocardial ablation portion of the procedure. For the first three months, patients were prescribed the same AADs as prior to HABL. Changes in AADs regime were made thereafter, with a reduction or discontinuation of AAD therapy, as medically indicated. Aspirin (75 mg) was substituted for warfarin at six months post procedure if maintenance of SR was confirmed, unless there were other indications for systemic anticoagulation such as $CHADS_2 \geq 2$ [11, 12].

Follow-up

All patients were seen in an outpatient clinic at three, six and 12 months post procedure (patients with implanted REVEAL® XT were seen every three months post procedure). Twenty-four h Holter monitoring was performed at three months, and seven day Holter monitoring at the six and 12 month post procedure visits. Echocardiography (transthoracic) was performed six and 12 months postoperatively. The last three patients in this study had ECG Loop Monitors (Reveal XT) implanted at the time of the epicardial ablation procedure.

Table 2. Early and long term results of the hybrid procedure

	3 month FU Blanking period	6 month FU	12 month FU	24 month FU
Patients who completed FU	19	18	10	6
Patients in SR [%]	12/19 (63.2%)	13/18 (72.2%)	8 (80%)	6 (100%)
Patients in AF [%]	7/19 (36.8%)	4/18 (22.2%)	2 (20%)	–
Patients in AFL [%]	–	1 (5.5%)	–	–
Freedom from AADs [%]	13/19 (68.0%)	11/15 (66.5%)	9 (90%)	6 (100%)
Freedom from VKA [%]	3 (15%)	3/15 (33.3%)	3 (30%)	3 (50%)

FU — follow-up; SR — sinus rhythm; AF — atrial fibrillation; AFL — atrial flutter; AAD — antiarrhythmic drugs; VKA — vitamin K antagonists

Table 3. Echocardiographic findings in patients who underwent the hybrid procedure

	Baseline	3 months	6 months	12 months	P
Left ventricular ejection fraction [%]	45.40 ± 8.6	50.94 ± 5.84	49.53 ± 5.33	55.40 ± 4.48	< 0.05
Left atrium [mm]	45.5 ± 4.7	43.71 ± 5.0	42.20 ± 4.35	39.30 ± 5.48	< 0.05

As of 31 December 2011, 19 patients have completed their three month follow-up, 18 patients have completed six month follow-up, and ten patients and six patients have completed one and two year follow-up respectively.

Statistical analysis

Continuous variables were expressed as mean ± 1 SD. Continuous parameters were compared with the Student t test. A p value ≤ 0.05 indicate statistical significance. The authors had full access to and take full responsibility for the integrity of the data. All authors have read and agreed to the manuscript as written.

RESULTS

Procedural data analysis

In all patients in the study, a defined epicardial endocardial lesion pattern (Fig. 3) was created. Any deviations to the lesion pattern were made to accommodate anatomical challenges or anatomical anomalies. During endocardial ablation, a cavotricuspid isthmus lesion was created in all patients.

Mean duration of the epicardial ablation procedure was 140.6 ± 25 min. Mean number of RF applications was 21.2 ± 6.2. Conversion from AF to SR during the procedure was noted in 33% (9/27) of the patients. The remaining 67% (18/27) of patients underwent successful electrical cardioversion (1 × 200 J) in the OR. All the patients were extubated in the OR and left OR in SR.

Mean duration of the endocardial ablation was 178.75 ± ± 46.50 min. Mean number of RF applications was 38.85 ± ± 21.2 with a mean RF ablation time of 20.73 ± 13.92 min. Mean fluoroscopy time was 13.68 ± 6.47 min with a mean exposure of 333.27 ± 271.16 mGy.

Efficacy outcome analysis

At three months post procedure, 63.2% (12/19) were in SR and 36.8% (7/19) were in AF. Successful electrical cardioversion was attempted in two patients; 68% of patients (13/19) were off AADs and 15% (3/19) were off VKAs. Three month follow-up was considered a blank period. At six months post procedure, 72.2% (13/18) of patients were in SR and 66.5% (12/18) of patients were off class I/III AADs. Four patients were in AF and one patient developed right atrial flutter. The patient was readmitted and successfully ablated using CARTO 3D system. At one year post procedure, 80% (8/10) of patients were in SR and off class I/III AADs. At two year post procedure, 100% (6/6) of patients were in SR and off class I/III AADs. Table 2 summarises patient outcomes at the three, six, 12 and 24 month post procedure time points.

Echocardiographic findings

Transthoracic echocardiography was performed six and 12 months post HABL. Statistically significant improvements in both LA size and LVEF were noted one year post procedure. A greater change in left ventricular function was noted in patients with a baseline LVEF ≤ 35% than in patients with a baseline LVEF greater than 40%. In the two patients who remained in AF at one year post procedure, a slight but noticeable impairment of LVEF was seen. Table 3 details the transthoracic echocardiographic findings at baseline, three, six and 12 months post HABL for all patients who have completed the one year follow-up time point.

Safety outcomes

Three major adverse events were reported for the study.

One patient had cardiac tamponade requiring emergency treatment 12 h after the endocardial procedure. Percutaneous pericardiocentesis was attempted but failed. Surgical intervention followed: a 2 cm incision was made just below the xyphoid and peritoneal cavity was entered and a 28 F drain was introduced to the pericardium through a previously made fenestration of the diaphragm. The patient remained haemodynamically stable thereafter, but was readmitted 30 days later due to significant fatigue and shortness of breath. Transthoracic echocardiography revealed a considerable amount of fluid in the pericardial sac (4–5 cm anterior to the right ventricle). Again, percutaneous pericardiocentesis was unsuccessfully attempted, and a totally endoscopic fenestration of the pericardium through the right pleural space followed. The patient remained stable throughout the hospital stay and was discharged home seven days later. Data obtained from the REVEAL® monitor showed freedom from AF/atrial flutter throughout the short follow-up.

A second patient required a sternotomy due to bleeding from a laceration of the inferior vena cava, following completion of all posterior lesions. Extracorporeal circulation was initiated and the epicardial lesions were completed on the beating heart without aortic cross-clamping, with the same RF device. The ligament of Marshall was cut and coagulated and both right and left atrial appendages were removed. The patient remains in SR throughout the two year follow-up. As the procedure was completed via a sternotomy, this patient was excluded from the final data analysis.

A third patient died 27 days after discharge in unclear circumstances. Cause of death was not determined, as a post mortem was not performed due to the patient's religious beliefs.

DISCUSSION

Feasibility and safety

The purpose of this single centre, prospective, non-randomised clinical study was to assess the safety, efficacy and effectiveness of a hybrid epicardial and endocardial RF ablation of PSAF and LSPAF. Hybrid ablation proved to be safe when performed with great care and meticulous attention to detail. In the present study, there were three major complications: bleeding from a surgical site, atrial perforation by the RF catheter, and death of unknown cause.

Bleeding remains an infrequent complication of all minimally invasive cardiothoracic procedures [13]. Although it is usually not massive and would not represent a major threat during conventional surgery, it becomes a challenging problem that is difficult to control via a limited incision. Median sternotomy is often required to repair a damaged structure. A similar complication is also encountered in every type of percutaneous treatment, but due to the nature of the procedure, may not be immediately noticed. The available data indicates that 1.42% of patients undergoing catheter-based ablation of AF experience bleeding of varying degrees or/and tamponade, and the vast majority of them require immediate surgical intervention [14, 15]. Unsurprisingly, in both patient cohorts, sternotomy greatly affects cosmetics and both patient and referring centre satisfaction. It does not however negatively influence the long term outcome. Conversely, patients in whom median sternotomy was performed due to bleeding often receive a more extensive lesion pattern set and have the LA appendage resected, together with ablation of the ligament of Marshall and ablation of ganglionated plexi, leading to a higher rate of sinus rhythm restoration and maintenance.

It is however the injury to the oesophagus that remains the most devastating complication of both surgical and catheter-based ablation. Although figures differ among centres, the incidence of this fatal complication ranges from 0.01% to 1.2% [1, 6–10, 21] in catheter-based ablation, and reaches 1.5% for patients undergoing surgical ablation [8, 10, 11]. Moreover, recently published endoscopic studies show the development of oesophageal ulcerations in 14–17% of the patients post catheter based AF ablation [16]. The incidence of this complication may be however underreported, as its clinical manifestations are often nonspecific and appear with a 4–6 week delay. This needs to be taken into account, as one of our patients suffered from a sudden onset of high fever and chest pain 25 days post surgical procedure. He was found unconscious by his family the morning of the next day and died shortly thereafter, with symptoms of severe cerebral dysfunction. Although many factors could influence this status, including neglecting VKA therapy, atrio-oesophageal fistula caused by thermal injury is known to have a similar clinical sequence. Laboratory studies and tests following this tragedy proved that the core emitter of the RF energy hidden within the ablating electrode was very well isolated and would not coagulate or affect surrounding tissues, as had been suspected. The only way to cause harm to the adjacent structures is if the electrode is positioned incorrectly. Safety protocols have evolved. Two independent temperature probes are now routinely inserted into the oesophagus. Part of the procedure is performed under brief fluoroscopy to visualise the ablating electrode and its relation to the oesophagus (Fig. 4). The temperature probes are moved accordingly to match the position of the ablating electrode. It is absolutely crucial to verify the device's position in regard to the oesophagus prior to energy application. Since extensive protective measures have been undertaken in all centres performing HABL, no similar complications have been observed.

Convergent vs. dual stage approach

The major drawback of hybrid ablation is the cost of the entire procedure. HABL being a new method, it is not yet recognised by the Polish National Insurance System and therefo-

re does not exist on its reimbursement lists. Both surgical and catheter ablations may be compensated for when performed as separate, rather than convergent, procedures. This means it is necessary to stage the procedure. A minimum of 14 days from discharge to re-admission must exist in order to reimburse both procedures. Although better for hospital financing, such a dual stage procedure seems less satisfactory for the patient, as another hospitalisation and repeated transoesophageal echocardiography prior to endocardial ablation are required. All patients are informed about the nature of the staged procedure, and seem to understand and accept its limitations. However, some patients may remain or return to AF due to incompleteness of the lesion pattern. Conversely, some patients might be reluctant to undergo endocardial ablation because of rhythm restoration and a rapid improvement of quality of life.

Effectiveness of the hybrid approach

Despite pharmaceutical and technical advances, successful treatment of PSAF and LSPAF represents a therapeutic challenge [17, 18]. Current guidelines consider surgical and catheter-based ablation to be equal in terms of therapeutic strategy (IIb), indicating that catheter ablation may be considered an effective treatment option in patients with PSAF or LSPAF [5, 18, 19]. The evidence supporting this recommendation is, however, limited (C). Recently published data shows rather the opposite, with the success rate hardly exceeding 50% [6]. Repeated ablations are often required, exposing the patient to extended radiation and increased risk of periprocedural complications, considerably affecting healthcare expenditure. On the other hand, surgical ablation offers a higher success rate, but its widespread acceptance is slow, mostly due to its invasive nature and the technical expertise required to cope with the endoscopic technique.

Moreover, regardless of previously published statements, ESC limits surgical ablation to patients who have had failed catheter ablation. Given the low level of evidence (IIb/C), such a recommendation remains highly controversial. Growing evidence from hybrid procedures is revealing the benefits of a minimally invasive surgical approach combined with catheter-based ablation as a treatment strategy for symptomatic patients with PSAF or LSPAF. The main advantage of such an approach lies in its comprehensive, bi-atrial lesion pattern which is crucial in stopping sustainable AF circuits and preventing new arrhythmogenic circuits from developing [7, 20–22]. Pulmonary veins are addressed together with complete isolation of the posterior LA and both mitral and tricuspid isthmi, resulting in complex segmentation of the atria. Furthermore, endocardial catheter ablation, difficult and time-consuming, becomes less demanding, as transmural linear epicardial lines effectively block impulse propagation. Although caution must be taken while interpreting the abovementioned results due to the small number of patients, HABL seems successful in sinus rhythm restoration at the first attempt. This optimism is attenuated by the long-term outcome of the first series of patients who underwent HABL using the same approach and ablating devices [23–25]. The initial report by Kiser et al. [24] of 28 patients with PSAF and LSPAF with a mean AF duration of eight years and significantly enlarged LA (5.3 cm) who were subject to a convergent hybrid procedure, revealed 21 (84%) patients in SR at six months, and 19 (76%) patients free from AF and AADs. Importantly, no significant complications occurred throughout the one-year follow up. A larger clinical study, with comprehensive postoperative rhythm evaluation via implantable ECG monitoring, was published in 2011. Out of 65 (92% in PSAF or LSPAF) patients who were subject to a convergent procedure, 82% were in SR and 77% were in SR and free from AADs 12 months post procedure.

Interesting results have recently been published by Krul et al. [26] who combined thoracoscopic pulmonary vein isolation together with ablation of ganglionated plexi and percutaneous complementary ablation in a hybrid surgical-electrophysiological study. This approach resulted in SR restoration in 19 out of 22 (86%) patients. The significant percentage of paroxysmal AF and the high rate of adverse events cast a shadow on these findings. Work done by Bisleri et al. [27] revealed long-term results of a hybrid procedure which combined a surgical, monolateral, thoracoscopic approach with catheter-based ablation. Again, implantable ECG monitoring devices were used in all patients, allowing for detailed analysis of postprocedural success. Out of an initial 21 patients with either persistent (9.5%) or LSPAF (90.5%), a high number of patients (90%) remained free from AF one year after the procedure. Although the technique presented by Bisleri seems less complex, limiting the surgical role to unipolar isolation of the posterior wall of the LA and pulmonary veins ('Box Lesion'), the results are impressive unlike previous experiences with 'Box Lesion' alone [28]. The hybrid approach as presented by Bisleri et al. [27] resembles ours in terms of a 2–3 week intermission between the procedures, which also addressed reimbursement issues.

European guidelines have recently been challenged by Boersma et al. [29] who randomly assigned patients with AF to either surgical or catheter-based therapy. The FAST study is one of the few prospective, randomised, multi-centre clinical trials designed not to fuel the ongoing debate as to the catheter vs. the surgical approach, but rather to reveal the best treatment option for the difficult patient.

One hundred twenty-four patients with antiarrhythmic drug-refractory AF with LA dilatation and hypertension or failed prior catheter ablation (67%) were enrolled into the FAST study. The surgical approach consisted of a minimally invasive, bi-thoracoscopic approach [30] aimed at bipolar circumferential ablation of right and left PVs with additional lesions (trigone lesion). Left atrial appendage was also removed in

98% of patients. On the other hand, the catheter-based approach consisted of a wide-area linear antrum ablation with documented PV isolation using either NavX or CARTO 3D. At six months, freedom from AF and AADs was seen in 44% and 67% of patients in the catheter and surgical groups respectively. This discrepancy increased with time to 36% in SR and free from AADs at 12 months in the catheter-based group and 65% in the surgical arm of the study. Even with AADs, freedom from AF remained significantly higher in the surgical group (78% vs. 42%). These results are consistent with our findings, despite significant differences in patients' characteristics, as 23% of the patients in the FAST trial were diagnosed with paroxysmal AF and 55% presented SR at admission. This rare comparison shows however, that surgical ablation is superior to catheter ablation in achieving freedom from LA arrhythmias after 12 months of follow-up, although the procedural adverse event rate was significantly higher for the surgical group. Most of these were minor and included pneumothorax (six cases!), a rib fracture and one conversion to sternotomy.

It is crucial for minimally invasive techniques to remain truly minimal in all aspects of care. The abovementioned technique was recently introduced to Polish clinical practice and will be subject to further evaluation. A sequel to the FAST trial, the FAST II trial, is now recruiting patients to test whether minimally invasive thoracoscopic ablation as a first time invasive treatment is more effective compared to a percutaneous catheter-based technique in patients with symptomatic paroxysmal AF refractory to AADs. Several other clinical trials are currently being conducted to clarify the importance of either approach for this difficult and demanding patient population.

CONCLUSIONS

This 27 patient, single-centre, prospective, non-randomised clinical study indicates that the minimally invasive hybrid ablation procedure, a collaboration between cardiac surgeons and electrophysiologists, is the key to the procedure's success providing a safe and effective treatment option for PSAF and LSPAF. The procedure efficacy was demonstrated by the restoration and maintenance of SR in a majority of the study patients with PSAF and LSPAF. Moreover, the outcomes from this 27 patient single-centre study indicate that restoration of SR improves left ventricular function and reduces LA dimensions, especially in patients with tachyarrhythmic cardiomyopathy.

The early positive outcomes seen in our study indicate the importance and value of the hybrid approach for the treatment of PSAF and LSPAF. Larger defined randomised studies are needed to confirm the successful outcomes of this 27 patient study.

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Conflict of interest: *none declared*

References

1. Jahangir A, Lee V, Friedman PA et al. Long-term progression and outcomes with aging in patients with lone atrial fibrillation: a 30-year follow-up study. Circulation, 2007; 115: 3050–3056.
2. Chugh SS, Blackshear JL, Shen WK et al. Epidemiology and natural history of atrial fibrillation: clinical implications. J Am Coll Cardiol, 2001; 37: 371–378.
3. Benjamin EJ, Wolf PA, D'Agostino RB et al. Impact of atrial fibrillation on the risk of death: the Framingham Heart Study. Circulation, 1998; 98: 946–952.
4. Noheria A, Kumar A, Wylie JV Jr. et al. Catheter ablation vs antiarrhythmic drug therapy for atrial fibrillation: a systematic review. Arch Internal Med, 2008; 168: 581–586.
5. Camm AJ, Kirchhof P, Lip GY et al. Guidelines for the management of atrial fibrillation: the Task Force for the Management of Atrial Fibrillation of the European Society of Cardiology (ESC). Eur Heart J, 2010; 31: 2369–2429.
6. Oral H, Chugh A, Good E et al. Radiofrequency catheter ablation of chronic atrial fibrillation guided by complex electrograms. Circulation, 2007; 115: 2606–2612.
7. Cox JL, Boineau JP, Schuessler RB et al. Electrophysiologic basis, surgical development, and clinical results of the maze procedure for atrial flutter and atrial fibrillation. Advances Cardiac Surg, 1995; 6: 1–67.
8. Suwalski P, Suwalski G, Wilimski R et al. Minimally invasive off-pump video-assisted endoscopic surgical pulmonary vein isolation using bipolar radiofrequency ablation — preliminary report. Kardiol Pol, 2007; 65: 370–374.
9. Gerosa G, Bianco R, Buja G et al. Totally endoscopic robotic-guided pulmonary veins ablation: an alternative method for the treatment of atrial fibrillation. Eur J Cardio-thoracic Surg, 2004; 26: 450–452.
10. Kiser AC, Wimmer-Greinecker G, Chitwood WR. Totally extracardiac Maze procedure performed on the beating heart. Annals Thoracic Surg, 2007; 84: 1783–1785.
11. Gage BF, Waterman AD, Shannon W et al. Validation of clinical classification schemes for predicting stroke: results from the National Registry of Atrial Fibrillation. JAMA, 2001; 285: 2864–2870.
12. Olesen JB, Lip GY, Hansen ML et al. Validation of risk stratification schemes for predicting stroke and thromboembolism in patients with atrial fibrillation: nationwide cohort study. BMJ, 2011; 342: d124.
13. Salenger R, Lahey SJ, Saltman AE. The completely endoscopic treatment of atrial fibrillation: report on the first 14 patients with early results. Heart Surgery Forum, 2004; 7: E555–E558.
14. Hargrove M, Marshall CB, Jahanjir S et al. Emergency bypass post percutaneous atrial ablation: a case report. Perfusion, 2010; 25: 423–424.
15. Cappato R, Calkins H, Chen SA et al. Prevalence and causes of fatal outcome in catheter ablation of atrial fibrillation. J Am Coll Cardiol, 2009; 53: 1798–1803.
16. Halm U, Gaspar T, Zachaus M et al. Thermal esophageal lesions after radiofrequency catheter ablation of left atrial arrhythmias. Am J Gastroenterol, 2010; 105: 551–556.
17. Ad N, Henry L, Hunt S. The impact of surgical ablation in patients with low ejection fraction, heart failure, and atrial fibrillation. Eur J Cardio-thoracic Surg, 2011; 40: 70–76.

18. Letsas KP, Efremidis M, Charalampous C et al. Current ablation strategies for persistent and long-standing persistent atrial fibrillation. Cardiol Research Practice, 2011; 2011: 376969.
19. Fuster V, Ryden LE, Cannom DS et al. ACC/AHA/ESC 2006 Guidelines for the Management of Patients with Atrial Fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Revise the 2001 Guidelines for the Management of Patients With Atrial Fibrillation): developed in collaboration with the European Heart Rhythm Association and the Heart Rhythm Society. Circulation, 2006; 114: e257–e354.
20. Weimar T, Bailey MS, Watanabe Y et al. The Cox-maze IV procedure for lone atrial fibrillation: a single center experience in 100 consecutive patients. J Interventional Cardiac Electrophysiol, 2011; 31: 47–54.
21. Damiano RJ. Surgical ablation of lone atrial fibrillation on the beating heart: the chaos continues. Europace: European pacing, arrhythmias, and cardiac electrophysiology: journal of the working groups on cardiac pacing, arrhythmias, and cardiac cellular electrophysiology of the European Society of Cardiology, 2010. 12: 297–298.
22. Damiano RJ Jr., Voeller RK. Biatrial lesion sets. J Interventional Cardiac Electrophysiol, 2007; 20: 95–99.
23. Kalarus Z, Zembala M, Kowalski O et al. Minimally invasive, hybrid ablation in a patient with persistent atrial fibrillation — early experience. Kardiol Pol, 2009; 67: 1057––1062.
24. Kiser AC, Landers M, Horton R et al. The convergent procedure: a multidisciplinary atrial fibrillation treatment. Heart Surgery Forum, 2010; 13: E317–E321.
25. Majewski J, Bartus K, Kapelak B et al. Thoracoscopic Ex-Maze III procedure and radiofrequency catheter ablation: a hybrid therapy for permanent atrial fibrillation. A case report. Kardiol Pol, 2009; 67: 1044–1047.
26. Krul SP, Driessen AH, van Boven WJ et al. Thoracoscopic video-assisted pulmonary vein antrum isolation, ganglionated plexus ablation and periprocedural confirmation of ablation lesions. First results of a hybrid surgical-electrophysiological approach for atrial fibrillation. Circulation, Arrhythmia and Electrophysiology, 2011; 4: 262–270.
27. Bisleri G, Curnis A, Botempi L, Muneretto C. Hybrid treatment of lone persistent AF: a safe and effective therapeutic option. Europace: European pacing, arrhythmias, and cardiac electrophysiology: journal of the working groups on cardiac pacing, arrhythmias, and cardiac cellular electrophysiology of the European Society of Cardiology, 2011; 13 (Suppl. 1): i9.
28. Pruitt JC, Lazzara RR, Ebra G. Minimally invasive surgical ablation of atrial fibrillation: the thoracoscopic box lesion approach. J Interventional Cardiac Electrophysiol, 2007; 20: 83–87.
29. Boersma LV, Castella M, van Boven W et al. Atrial Fibrillation Catheter Ablation Versus Surgical Ablation Treatment (FAST): a 2-center randomized clinical trial. Circulation, 2012; 125: 23–30.
30. Edgerton JR, Jackman WM, Mack MJ. Minimally invasive pulmonary vein isolation and partial autonomic denervation for surgical treatment of atrial fibrillation. J Interventional Cardiac Electrophysiol, 2007; 20: 89–93.

Małoinwazyjna hybrydowa ablacja przetrwałego i długotrwającego przetrwałego migotania przedsionków: roczne wyniki obserwacji

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Streszczenie

Wstęp: Wciąż brakuje skutecznego sposobu leczenia objawowych chorych z przetrwałą i długotrwającą przetrwałą formą migotania przedsionków (AF). Połączenie wysiłków kardiochirurga i elektrofizjologa w postaci hybrydowej endo- i epikardialnej ablacji struktur obu przedsionków jest obiecującą opcją dla tych chorych, u których inne formy terapii zawiodły.

Cel: Celem niniejszego badania było określenie bezpieczeństwa, możliwość i efektywności hybrydowego leczenia przetrwałego AF.

Metody: Badanie ma charakter jednoośrodkowy, nierandomizowany. W okresie od 08.2009 do 12.2011 r. zabiegowi hybrydowej ablacji poddano 27 chorych (obecnie, do dnia 05.07.2012 n = 43). Z opisanych w niniejszej pracy 27 pacjentów, 5 miało przetrwałe AF (PAF), a 22 długotrwające przetrwałe AF (LSPAF). Średni wiek wynosił 52,52 ± 11,27 roku, średnia klasa EHRA 2,5. U 6 osób w przeszłości wykonano elektryczną kardiowersję, natomiast 8 przeszło ≥ 1 ablację endokardialną. U 5 chorych stwierdzono upośledzoną funkcję skurczową lewej komory (LVEF < 35%). Średni czas trwania AF wynosił 3,46 ± 2,5 roku. Wszyscy pacjenci stosowali maksymalnie tolerowaną farmakoterapię oraz doustne leki przeciwzakrzepowe. Okres obserwacji po zabiegu zakładał wykonanie 7-dniowego badania EKG metodą Holtera oraz badanie echokardiograficzne w 3., 6. i 12. miesiącu po zabiegu. U części pacjentów implantowano stały rekorder EKG REVEAL® XT.

Wyniki: Procedurę przeprowadzono u wszystkich chorych. Sześć miesięcy po ablacji 72,2% (13/18) pacjentów pozostało na rytmie zatokowym (SR), a u 66,5% (12/18) było możliwe odstąpienie od leczenia antyarytmicznego (leki klas I/III). U 4 osób stwierdzono AF, natomiast u 1 wykryto trzepotanie przedsionków. Rok po zabiegu 80% (8/10) osób pozostało na SR bez stosowania leków klasy I/III (wg danych z dnia publikacji manuskryptu, gdy n = 43: wyniki dotyczące SR w 3., 6. i 12. miesiącu wynosiły odpowiednio: 75,8%, 76,9% i 84%).

Wnioski: Małoinwazyjna, hybrydowa ablacja, łącząca zalety endo- i epikardialnej ablacji prądem o wysokiej częstotliwości jest bezpieczna i skuteczna w przywróceniu SR u większości chorych z objawowym, przetrwałym i długotrwającym przetrwałym AF.

Słowa kluczowe: ablacja, migotanie przedsionków, zabieg hybrydowy

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