Mid-Term Results of the 'Hybrid Maze': A Combination of Bipolar Radiofrequency and Cryoablation for Surgical Treatment of Atrial Fibrillation

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Background and aim of the study: **Although the use of new sources of energy for the ablation of atrial fibrillation (AF) has simplified the procedure, concerns have been expressed with regard to the safety and efficacy of the various devices. Herein are described the results of a technique using a combination of bipolar radiofrequency (RF) and cryoablation.**
Methods: **Between February 2004 and August 2005, the combined procedure was used on 60 patients, 32 of whom (54%) had persistent AF, and 28 (46%) permanent AF. Lesions set similar to the Maze III procedure were used, with the addition of a right atrial isthmus lesion in the area of the coronary sinus and without right atrial appendage amputation and septal lesion.**
Results: **There were no operative complications and no death or major morbidity. The mean duration of the ablation procedure was 30 min (range: 27-36 min) for biatrial procedures, and 16 min (range: 15-19 min) for left atrial procedures. Forty-two patients (70%) were discharged in sinus rhythm. On completion of follow up, 48 patients (80%) were in sinus rhythm. Among 45 patients treated with cryoablation rather than monopolar RF, 89% were in sinus rhythm at the mean follow up of nine months. The predictor for recurrent post-procedural AF was preoperative permanent AF for more than 10 years' duration (p = 0.039), while that for postoperative atypical flutter was use of the monopolar RF ablator rather than the cryoablator (p = 0.001).**
Conclusion: **The use of a bipolar RF device with the cryoprobe is an appealing combination which enables the Maze III lesion set to be completed in a straightforward, safe, and efficient manner.**

The Journal of Heart Valve Disease 2006;15:664-670

Atrial fibrillation (AF) is the most frequent type of cardiac arrhythmia, with more than five million people worldwide suffering from the condition. Many studies have shown AF to be an independent risk factor for morbidity such as stroke, heart failure or death (1-3). The surgical treatment of AF is based on the creation of a set(s) of lesions on the atria, with subsequent development of scar tissue with low electrical conductance. The lines of the scar tissue interrupt the macro-reentrant circuits responsible for AF (4). The Maze procedure, which was introduced during the late 1980s, produces these lesions when the atria are cut and sewn (5). Unfortunately, the procedure has not gained wide popularity among surgeons, due mainly to its complexity. Over the past few years, the use of new sources of energy to produce scar tissue - including radiofrequency (RF) ablation, microwave, cryoablation and ultrasound - has simplified the Maze procedure. However, concerns have been expressed with regard to the safety, lack of transmurality, and high cost of the various devices (6-8). Herein are described the authors' results using a self-developed technique based on the classic lesions set of the Maze III procedure, using a combination of bipolar RF ablation and cryoablation.

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Clinical material and methods

Patient characteristics

Between February 2004 and August 2005, anti-arrhythmia procedures according to the study protocol were performed in 60 patients (34 males, 26 females; mean age 64 years; range: 41 to 82 years) with AF at the authors' institution. A monopolar RF ablator (Medtronic, Inc., Minneapolis, MN, USA) was used in the first 15 patients (group 1), before cryoablation became available at the institution. The subsequent 45 patients (group 2), who received hybrid treatment, constituted the present study population (Table I).

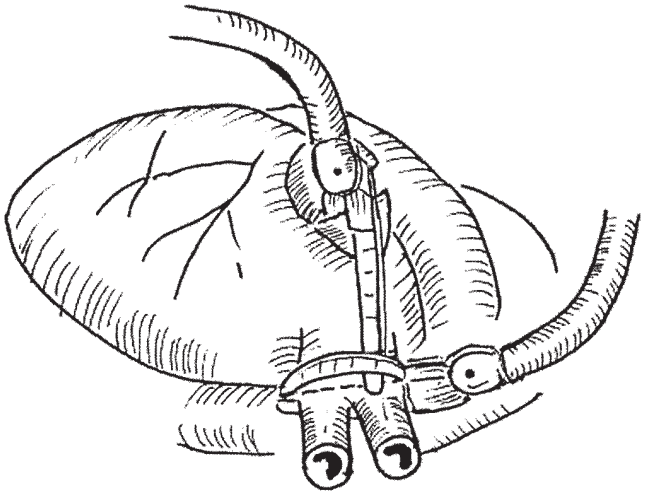

Figure 1: Isolation of the left pulmonary veins and amputation of the left atrial appendage. The ablation line passes from the appendage stump to the left superior pulmonary vein ostium.

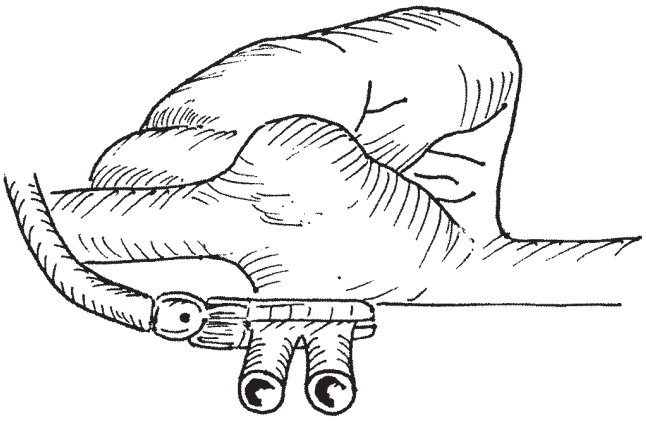

Figure 2: Isolation of the right pulmonary veins.

Thirty two patients (54%) had permanent AF, and 28 (46%) suffered from persistent AF. Sixteen patients had permanent AF of more than five years' duration, and three had a duration of more than 10 years. Fourteen patients had a left atrial (LA) volume >200 ml. Most patients (48; 80%) were in NYHA functional classes I or II. The left ventricular ejection fraction was normal in 38 patients, moderately reduced in 12, and severely reduced in 10. Ten patients had undergone previous cardiac surgery.

Study protocol

Anti-arrhythmia surgery was performed only on those patients with permanent or persistent AF. Cases of paroxysmal AF were left without ablation during the study as, based on findings of previous studies, the effect of surgery had appeared to be equivocal. Two types of anti-arrhythmia surgery were performed: the biatrial Maze III type lesion set; and the left atrial lesion set. Both pragmatic and theoretical considerations led to formulation of the study policy: ablation lines on both atria were performed on patients with permanent AF, or when right-sided procedures (viz., tricuspid surgery or atrial septal defect (ASD) repair) were performed. In cases of persistent AF undergoing mitral valve procedure without tricuspid or ASD surgery, only the left atrial lesion set was performed.

Bipolar RF ablation

Bipolar RF ablation was carried out using the Cardioblate bipolar RF ablator (Medtronic, Inc., Minneapolis, MN, USA), and was considered by the present authors to be capable of providing a proven transmural lesion on the atrial wall. A major advantage of this device was the lack of collateral damage in relation to the very local energy spread between the two jaws of the ablator. Moreover, a very short time (usually 16 s) was needed to produce the lesion. Application of the bipolar RF device around the valve annulus was impossible due to greater wall thickness and location of circumflex coronary artery; hence, cryoablation was used in these areas and in the coronary sinus area.

Cryoablation

A cryoablator (Frigitronics, Cooper Surgical. Inc., Trumbull, CT, USA) working with liquid nitrous oxide was used in areas of the mitral and tricuspid annulus and coronary sinus. Application of the probe for 2 min at -60°C provided the transmural lesion (9). This device is recognized as being safe, producing good results, and having a good long-term follow up. Another positive feature of the device was the availability of multi-use probes, which minimized procedural costs.

Operative technique

Although epicardial pulmonary vein ablation can be carried out on the beating heart, the present authors chose to perform the entire procedure on the arrested heart, as this was found to be easier and safer, and also required minimal additional time as it provided good exposure, an empty relaxed heart, and less tension of the left atrium between the jaws of the bipolar clamp.

Procedure

Initially, isolation of the left pulmonary veins was performed, using electrocautery to divide the Marshall ligament, with manual blunt dissection around the pulmonary veins. A bipolar RF ablator was applied

J Heart Valve Dis
Vol. 15. No. 5
September 2006

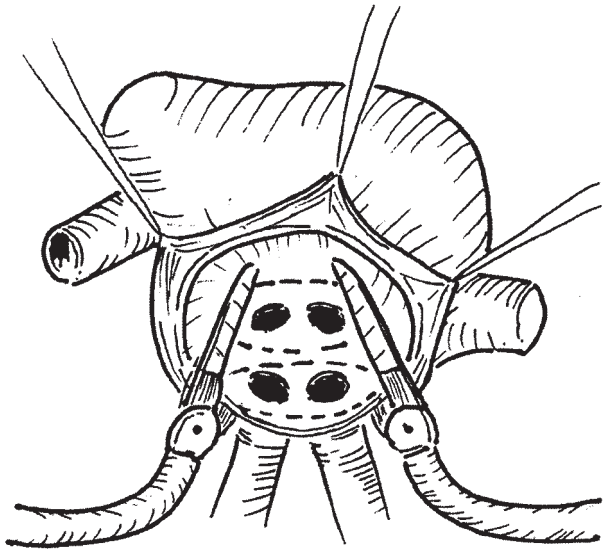

Figure 3: Connection of the previously created ablation lines around the right and left pulmonary veins, creating a 'box' lesion.

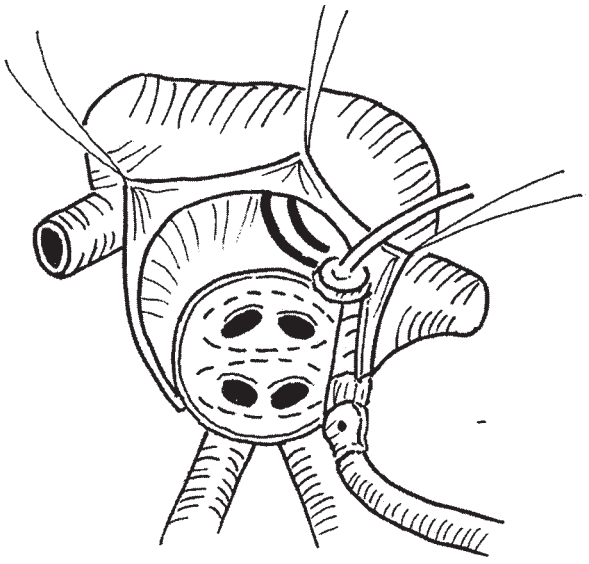

Figure 4: Radiofrequency ablation line from the inferior corner of the left atriotomy to the posterior mitral annulus. Cryolesion on the mitral valve annulus.

epicardially to the left atrial wall at 5-10 mm above the ostium of the left pulmonary veins (Fig. 1). After the amputation of the left atrial appendage, the bipolar ablator was applied epicardially and endocardially through the orifice of the amputated appendage to create a line from the appendage stump to the left superior pulmonary vein ostium, thereby connecting to the ablation line around the left pulmonary vein ostia. The left atrial appendage stump was then closed with two rows of running 5/0 polypropylene sutures (Fig. 1).

After blunt manual dissection around the right pulmonary veins, an epicardial lesion was created on the left atrium around the pulmonary vein ostia, using a bipolar device (Fig. 2). Next, a right atriotomy was performed through the interatrial groove. The atriotomy was extended below the inferior vena cava to facilitate mitral valve exposure. Again, a bipolar device was applied through the atriotomy epicardially and endocardially to connect the previously created ablation lines around the right and left pulmonary veins, thus creating a 'box' lesion around the pulmonary veins (Fig. 3).

An important step in this technique was to create an ablation line from the inferior corner of the left atriotomy almost to the posterior mitral annulus with the bipolar ablator epicardially and endocardially. Normally, the mitral annulus was approached between P2 and P3, and could be reached by extension of the left atriotomy below the inferior vena cava with the bipolar ablator close to the mitral valve. A cryoprobe was used to complete this line, including the mitral valve annulus (Fig. 4). The left-sided lesions were thus completed.

The right-sided lesions were started with a vertical right atriotomy. From the lower corner of the incision, the bipolar RF ablator was applied epicardially and endocardially towards the superior and then the inferior vena cava. A linear cryoprobe was applied from the upper corner of the atriotomy to the tricuspid annulus. A RF ablation line was placed in a downward direction epicardially and endocardially through the small opening in the right atrial appendage. The line ended 1.5 cm before the atriotomy and the ablation line towards the superior vena cava (Fig. 5).

A RF ablation line was then placed downwards, through the opening in the right atrial appendage on the inner right atrial wall, to the tricuspid annulus. The lesion was completed up to the tricuspid valve with a cryoprobe. An important point was that the RF ablation lesions were positioned downwards (towards 9 o'clock) of the tricuspid annulus in order to avoid the right coronary artery (Fig. 6). Finally, a cryoprobe was applied to ablate the right atrial isthmus, an area located between the tricuspid annulus, coronary sinus orifice and inferior vena cava (Fig. 6).

Postoperative care and follow up

All patients were treated in normal fashion after heart valve surgery. In all cases, atrial and ventricular pacing wires were inserted at surgery. Atrial overpacing was used in all patients whenever possible to prevent postoperative AF. Amiodarone was administered in cases of de-novo postoperative AF, but if a patient was still in AF before discharge from hospital an electrical cardioversion was attempted. Anticoagulation was commenced on the day after surgery. Oral anticoagulation was continued postoperatively for at least three months, depending on the type of surgery and

heart rhythm. Electrical cardioversion was performed, if required, three months after surgery. The patients were followed up at one, three, six, and 12 months after surgery by the cardiologists and cardiac surgeons. The follow up procedures included electrocardiogram recordings at one month, Holter studies at three and six months, and echocardiographic assessment at six months. Any major adverse cardiovascular events that occurred were recorded.

Statistical analysis

Discrete variables were compared using Student's *t*-tests, and outcome measures were compared using chi-square analysis. A p-value <0.05 was considered to be statistically significant.

Results

Early results

No intraoperative complications occurred when using this method. In all patients but one, an ablation procedure was used in addition to another open-heart procedure, usually mitral valve repair or replacement (Table I). This single patient, operated on for lone AF, underwent a biatrial procedure. Thirty-six patients underwent the biatrial procedure, and left atrial ablation was performed in 24. The average time for ablation was 30 min (range: 27 to 36 min) for the biatrial procedure, and 16 min (range: 15 to 19 min) for the left atrial lesion set.

The median intensive care unit stay for these patients was 2 days (range: 1 to 5 days), and the median hospital stay 7 days (range: 5 to 17 days). All patients were weaned from ventilation within first 36 h postoperatively. There was no excessive bleeding requiring reexploration. In total, 42 patients (70%) were discharged from hospital in sinus rhythm, with eight undergoing electrical cardioversion before discharge. Six patients (10%) had a pacemaker implanted, and one patient suffered a postoperative transient ischemic attack.

Mid-term results

Forty-eight patients (80%) were in sinus rhythm at the mean follow up of 12 months; seven of these were still receiving amiodarone. Six patients (10%) had atrial flutter, and four atypical flutter. Six patients were still in AF; the mean duration of AF was 72.5 months, the mean left atrial size 5.95 cm, and mean left atrial volume 166.2 ml. Among the latter 12 patients, eight were receiving amiodarone. Thus, 25% (n = 15) of the patient pool were receiving amiodarone at mid-term follow up. Excluding the first 15 patients, who underwent ablation with monopolar RF, 45 patients underwent bipolar RF and cryoablation, and 89% of these were in sinus rhythm at the nine-month follow up. The main predictor for post-procedural recurrent AF was

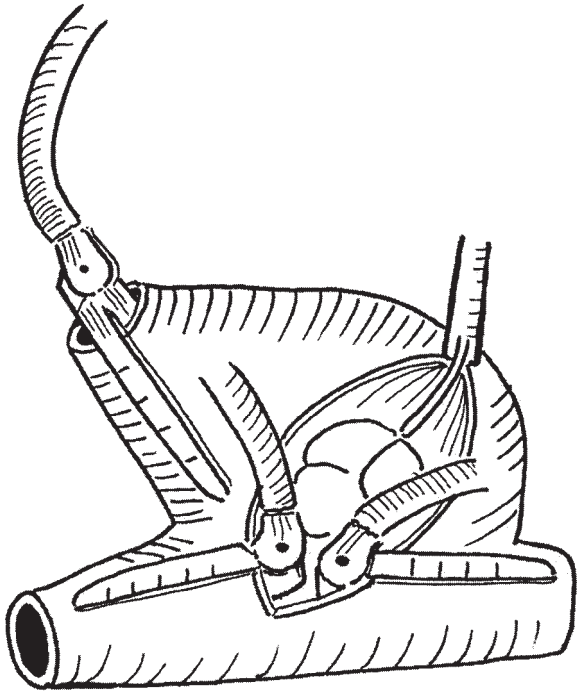

Figure 5: Vertical right atriotomy. A linear cryoprobe is applied from the upper corner of the atriotomy to the tricuspid annulus. The radiofrequency ablation lines are on the right atrial wall.

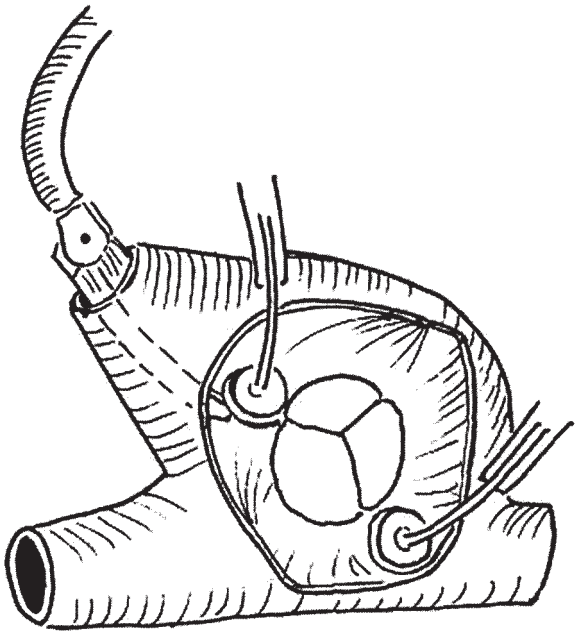

Figure 6: Radiofrequency ablation line downward on the inner atrial wall to the tricuspid annulus. The lesion is completed with a cryoprobe. Cryoablation of the right atrial isthmus line.

Table I: Characteristics of the patients.

Parameter	All patients (n = 60)	Group 1 Monopolar RF (n = 15)	Group 2 Hybrid (n = 45)
Male (n)	34	10	24
Female (n)	26	5	21
Age (years)*	64 (41-82)	63 (42-81)	64 (41-82)
Permanent AF (n)	32/60 (54)	13/15	19/45
>5 years	16/60	5/15	11/45
>10 years	3/60	2/15	1/45
Persistent AF (n)	28/60 (46)	2/15	26/45
Mean duration of AF (months)*	55.8 (1-270)	82.9 (4-270)	45.7(1-204)
NYHA class I/II (n)	48/60 (80)	12/15	36/45
LVEF			
Normal (n)	38	10	28
Moderately impaired (n)+	12	3	9
Severely impaired (n)+	10	2	8
Mean LA diameter (cm)*	5.32 (3.7-7.3)	5.46 (4.0-6.9)	5.26 (3.7-7.3)
LA volume (ml)*	152.6 (88-300)	140.9 (88-206)	156.7 (100-300)
LA volume >200 ml (n)†	14	2	12
Previous cardiac surgery (n)	10	3	7
Procedures (n)			
MVR	23 (38)	8	15
MV repair	17 (28)	3	14
MVR/MV repair + TVR	13 (22)	1	12
AVR + MVR/MV repair	5 (8)	3	2
CABG	1 (2)	0	1
Isolated MAZE	1 (2)	0	1
Successful conversion to NSR (n)			
Permanent AF	22	8	14
Persistent AF	26	2	24
LA ablation	19/21	2/3	17/18
Biatrial ablation	29/39	8/12	21/27

*Values are mean ± SD (range).
+Moderately impaired LVEF 50-30%; severely impaired LVEF 30%>.
†LA volume >6.5 cm diameter.
Values in parentheses are percentages.
AF: Atrial fibrillation; AVR: Aortic valve replacement; CABG: Coronary artery bypass grafting; LA: Left atrial; LVEF: Left ventricular ejection fraction; MV: Mitral valve; MVR: Mitral valve replacement; NSR: Normal sinus rhythm; RF: Radiofrequency; TVR: Tricuspid valve repair.

Table II: Risk factors for postoperative atrial fibrillation (AF) and atrial flutter.

Risk factor	Group 1	Group 2	p-value
Postoperative recurrent AF (n = 6)			
Redo surgery	2/10	4/50	NS
Permanent AF >10 years	3/5	3/55	0.039
LA volume >200 ml	3/15	3/45	NS
Postoperative atrial flutter (n = 6)			
Monopolar RF instead of Cryo	6/15	0/45	0.001

NS: Not significant. Other abbreviations as Table I.

preoperative permanent AF of more than 10 years' duration (p = 0.039). The main predictor for postoperative atypical flutter was the use of monopolar RF ablation instead of cryoablation (p = 0.001) (Table II).

Discussion

Although the classic Maze III procedure provides excellent long-term results of more than 90% freedom from AF (6), the 'cut and sew' technique proved too difficult for wide acceptance by many surgeons. Recently developed methods for the surgical treatment of AF include the use of alternative energy sources and different lesion sets (7-11). However, although these methods have popularized anti-arrhythmia surgery, several concerns have been raised. The first objection, of collateral damage and tissue perforation such as esophageal injury, was raised by Doll et al. (12). Some surgeons have reservations about using this highly user-dependent device in a region where there is a high degree of anatomic variability and tissue thickness as the mitral annulus. The second problem concerned the transmurality of lesions, which is deemed mandatory by some surgeons for acceptable success rates and durable results (7,8). Some have described atypical atrial flutter as a late complication of this procedure (13), and in the present study the use of monopolar RF ablation rather than cryoablation proved to be a predictor of atypical atrial flutter. Despite the small number of patients in group 1, this might suggest that monopolar RF ablation might be less effective than the hybrid approach. An earlier study conducted by the present authors (13) had established the above-mentioned association, and had observed a predominantly left-sided origin of postoperative atrial flutter, which argued against routine ablation of the right atrial isthmus during AF surgery. The third problem was the high cost of disposable equipment, especially in the face of minimal government reimbursement in most countries. Whilst it seems that there is no one perfect device, in terms of safety and transmurality the bipolar RF probe ablator appears superior. It is the 'sure' method, apart from 'cut and sew', that enables a secure transmural lesion to be made, as focused energy delivery between jaws of the ablator avoids collateral damage. Moreover, using the bipolar probe shortens the procedure time. There are, however, several lesions that cannot be performed with the bipolar probe in order to complete a full Maze procedure. One example is the area close to the valve rings where, by using reusable cryoprobes, a complete procedure can be carried out without doubling the cost.

Another issue is to define the patient population that might benefit most from anti-arrhythmia surgery. It has been noted in some studies that those patients with very large, dilated atria may fail an anti-arrhythmia procedure, though this was not the case in the present investigation, perhaps due to the small size of the study population. However, longstanding permanent AF (for more than 10 years) was statistically related to recurrent AF after the ablation procedure. In the present protocol an attempt was made to configure the lesion set of the Maze III procedure with some variations. It is believed that, for more difficult cases of permanent AF, a biatrial lesion set can provide the more complete answer. For persistent AF, and with the valvular procedure limited to the mitral valve, the left atrial lesion set may be adequate, and current reports seem to confirm this suggestion. In any case, following the principle of 'primum non nocere' (first, do no harm), the only atrial incisions performed in the present study were standard left and right atriotomies, as are used in all cases of valvular surgery. In the right atrium, a right atrial isthmus line lesion was added using the cryoprobe, which seems important in order to prevent right atrial flutter (14,15). An interatrial septum lesion was not performed, nor was the right atrial appendage amputated in order to preserve cardiac natriuretic peptide levels. Neither was any postoperative fluid retention observed, as has been described by others (16,17). The salutary effect of surgery has neither been obvious nor confirmed in cases of paroxysmal AF in the literature, though such cases were excluded in the present study.

Currently, the use of a bipolar RF device seems effective in the treatment of AF, and provides transmurality without causing collateral damage. In areas where bipolar ablation is technically difficult, or even hazardous, use of the cryoablator (rather than monopolar RF) may reduce both postoperative atypical atrial flutter and the cost of the procedure. Furthermore , cryoablation at -60°C for 2 min, producing lesions of <4 mm, secures transmurality.

Recently, several new techniques and technologies have been introduced into AF surgery (7,18,19), in both clinical and experimental models, although the safety and reproducibility of these have not yet been confirmed. In the present study, bipolar RF ablation (with cryothermy) was adopted as the primary modality on the basis of its safety and established efficacy in the clinical situation.

Although further clinical studies, in addition to a larger patient pool and a longer detailed follow up, are needed to evaluate the long-term efficacy of this technique, the initial impression is that left atrial lesions alone are sufficient in mitral valve patients, even when they are in permanent AF. Likewise, an investigation of the relevance of left atrial size and volume in the failure of AF surgery would require a longer term study to

be conducted, and to include a larger group of patients.

References

1. Wolf PA, Abbott RD, Kannel WB. Atrial fibrillation as an independent risk factor for stroke: The Framingham Study. Stroke 1991;22:983-988
2. Task Force. Risk factors for stroke and efficacy of antithrombotic therapy in atrial fibrillation: Analysis of pooled data from five randomized controlled trials. Arch Intern Med 1994;154:1449-1457
3. Wolf PA, Abbott RD, Kannel WB. Atrial fibrillation. A major contributor to stroke in the elderly: The Framingham Study. Arch Intern Med 1987;147:1561-1564
4. Cox JL, Schuessler RB, D'Agostino HJ, Jr., Stone CM, Chang BC, Cain ME. The surgical treatment of atrial fibrillation. III. Development of a definite surgical procedure. J Thorac Cardiovasc Surg 1991;101:569-583
5. Cox JL. The surgical treatment of atrial fibrillation. IV. Surgical technique. J Thorac Cardiovasc Surg 1991;101:584-592
6. Schaff HV, Dearani JA, Daly RC, Orszulak TA, Danielson GK. Cox-Maze procedure for atrial fibrillation: Mayo Clinic experience. Semin Thorac Cardiovasc Surg 2000;1:30-37
7. Gillinov AM, Blackstone EH, McCarthy PM. Atrial fibrillation: Current surgical options and their assessment. Ann Thorac Surg 2002;74:2210-2217
8. Cox JL. Intraoperative options for treating atrial fibrillation associated with mitral valve disease. J Thorac Cardiovasc Surg 2003;125:S24-S27
9. Cox JL, Jaquiss RDB, Schuessler RB, Boineau JP. Modification of the Maze procedure for atrial flutter and fibrillation. II. Surgical technique of the maze III procedure. J Thorac Cardiovasc Surg 1995;110:485-495
10. Mokadam NA, McCarthy PM, Gillinov AM, et al. A prospective multicenter trial of atrial fibrillation: Early results. Ann Thorac Surg 2004;78:1665-1670
11. Williams MR, Stewart JR, Bolling SF, et al. Surgical treatment of atrial fibrillation using radiofrequency energy. Ann Thorac Surg 2001;71;1939-1944
12. Doll N, Borger MA, Fabricius A, et al. Esophageal perforation during left atrial radiofrequency ablation: Is the risk too high? J Thorac Cardiovasc Surg 2003;125:836-842
13. Golovchiner G, Mazur A, Kogan A, et al. Atrial flutter after surgical radiofrequency ablation of the left atrium for atrial fibrillation. Ann Thorac Surg 2005;79:108-112
14. Cox JL. Atrial fibrillation II: Rational for surgical treatment. J Thorac Cardiovasc Surg 2003;126:1693-1699
15. Nakagava H, Lazzara R, Khastgir T, et al. Role of the tricuspid annulus and the Eustachian valve/ridge on atrial flutter. Relevance to catheter ablation of the septal isthmus and a new technique for rapid identification of ablation success. Circulation 1996;94:407-424
16. Cox JL, Boineau JP, Schuessler RB, Jaquiss RDB, Lappas DG. Modification of the Maze procedure for atrial flutter and fibrillation. I. Rational and surgical results. J Thorac Cardiovasc Surg 1995;110:473-484
17. Ad N, Tian YY, Verbalis J, Imahara SD, Cox JL. The effect of the maze procedure on the secretion of arginine-vasopressin and aldosterone. J Thorac Cardiovasc Surg 2003;126:1095-1100
18. Benussi S, Nascimbene S, Calori G, et al. Surgical ablation of atrial fibrillation with a novel bipolar radiofrequency device. J Thorac Cardiovasc Surg 2005;130:491-497
19. Gaynor SL, Byrd GD, Diodato MD, et al. Dose responses curves for microwave ablation in cardioplegia-arrested heart. Heart Surgery Forum 2005;8:E331-E336