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Microwave Ablation of Permanent Atrial Fibrillation during Isolated Bypass Grafting and Isolated Mitral Valve Surgery

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ABSTRACT

Background. This study was designed to compare the rate of restoration to sinus rhythm in patients with permanent atrial fibrillation (pAF) undergoing endocardial microwave ablation during isolated coronary artery bypass grafting (CABG) or isolated mitral valve surgery.

Methods. A total of 42 patients who underwent isolated CABG (age, 70.1 ± 5.8 years) and 68 patients (age, 64.4 ± 8.7 years) who underwent isolated mitral valve surgery were included in the registry. During the operation, all patients received endocardial microwave ablation. Follow-up examinations were performed 1, 3, 6, and 12 months after discharge.

Results. A 1-year follow up was obtained for all patients. In the CABG and the mitral valve surgery groups, sinus rhythm, as determined by a 24-h Holter electrocardiograph, was observed in 72% and 63% of the patients, respectively.

Conclusions. The difference in sinus rhythm restoration in the CABG and mitral valve surgery groups did not reach statistical significance. Microwave ablation in combination with CABG or mitral valve surgery can be performed with comparable and acceptable success rates.

INTRODUCTION

The classic maze procedure is considered to be the gold standard for intraoperative treatment of atrial fibrillation (AF). It was introduced by Cox and initially performed in combination with mitral valve surgery or as a stand-alone procedure [Cox 1991, 1993, 1995]. In recent years, alternative methods to the surgically complex maze operation have been developed. They followed the concept of endocardial delivery of different kinds of energy (radiofrequency, cryoablation, or microwave) to interrupt the arrythmogenic reentry circuit in the left and right atrium. After our initial experiences with radiofrequency as an alternative to the classic maze procedure, we tested microwave as an energy source for intraoperative ablation therapy [Knaut 1999; Spitzer 1999]. We combined endocardial microwave ablation with mitral valve surgery or coronary artery bypass surgery (CABG).

The first pilot study consisted of a series of 137 patients who underwent ablation using the lesion line concept recommended by Zarse et al in 1996. The second pilot study consisted of a series of 112 patients in whom a second lesion concept was used. It was demonstrated that the second lesion line concept resulted in a 10% higher success rate after 6 months. Restoration of stable sinus rhythm was achieved using the first lesion line concept in 55% to 70% of patients with preoperative permanent AF (pAF) [Spitzer 2002; Knaut 2004] and in 78% to 88% of patients treated with the second lesion line concept. There were no procedure-related complications and no increase in mortality due to the additional ablative treatment [Knaut 2005]. These results encouraged us to extend the indication for our microwave ablation technique to all patients with pAF [Knaut 2006]. In this study, we have compared the perioperative results and 1-year follow-up data of microwave ablation therapy in combination with isolated mitral valve surgery or isolated CABG in a prospective order.

MATERIALS AND METHODS

Patients with pAF who underwent isolated CABG or isolated mitral valve surgery (replacement or repair) were consecutively included in our prospective registry study. Patients with the following criteria were excluded: paroxysmal or persistent AF, age younger than 18 years, emergency operation, stroke within the last 6 weeks, known drug abuse, and incompetence and/or other conditions that did not allow the patient to understand the nature, significance, and aim of the registry.

One day before the operation the patients were admitted to the hospital. At this point, antiarrhythmic medication was stopped. Sotalol (2 × 40 mg/day up to 2 × 160 mg/day depending on the hemodynamic situation) was administered exclusively for rhythm stabilization postoperatively. Additionally, the patients received phenprocoumon anticoagulation treatment with a target international normalized ratio of

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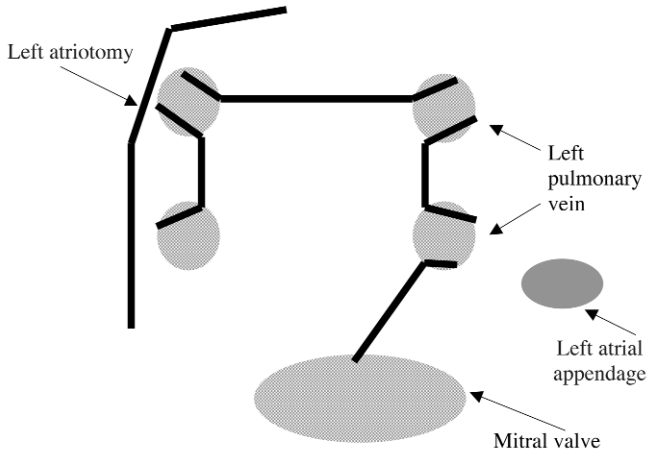

Figure 1. First lesion line concept for endocardial microwave ablation.

2.0 to 3.0 for patients who underwent CABG, mitral valve repair, or biological mitral valve prosthesis and 3.0 to 4.0 for patients who underwent mechanical mitral valve repair. After discharge, anticoagulation therapy and rhythm monitoring were continued by the general physician or cardiologist. During the 1-year follow-up period, 4.5% of patients received amiodarone instead of sotalol (because of various indications). For all patients who demonstrated stable sinus rhythm and good biatrial transport function in echocardiography, antiarrhythmic medication with sotalol was stopped after 3 months. Following the same criteria, the anticoagulation therapy could be terminated for all patients who did not receive a mechanical valve (this was the case in 50% of the patients).

Follow-up investigations took place after 1, 3, 6, and 12 months. After 12 months, a 24-h Holter electrocardiograph (ECG) was recorded and a transthoracic echocardiography was performed looking for atrial contraction (E and A wave in transmitral/transtricuspidal doppler profile).

The benefits and risks of ablation therapy were explained to all patients and they gave informed consent at least 1 day before surgery. The patients also agreed that their data were anonymously included in a registry for scientific evaluation.

Guidant microwave surgical ablation devices (Flex2 and, since 2001, Flex4; Santa Clara, CA, USA), were used to produce linear lesions on the endocardial surface. The microwave energy was delivered to the tissue by an antenna. Details of the method were previously described [Spitzer 1999]. The Flex2 was used with 40 W for 25 seconds and the Flex4 with 65 W for 45 seconds for each ablation step. The ablation lines followed the concept previously described [Zarse 1996].

The procedure starts under visual guidance at the posterior mitral valve annulus including all pulmonary veins. The lines connecting the pulmonary veins ended 1-cm deep in the veins. Then the next lesion line starts at the same depth but at the contralateral site. Sketches of the geometry of both lesions line concepts are shown in Figures 1 and 2.

Statistical Analysis

Continuous data are presented as mean value ± standard deviation, classified data with percentage frequency. The chi-square test was used for group comparison. Probability values less than .05 were interpreted to indicate a statistically significant difference between the groups.

RESULTS

Between December 1998 and December 2003, 102 patients with coronary artery disease had additional pAF. Forty-two of these 102 patients underwent isolated CABG with supplementary microwave ablation. In the same period, of 128 patients with mitral valve pathology and pAF, 68 underwent an isolated mitral valve operation with additional microwave ablation. In all patients, endocardial microwave ablation was performed only in the left atrium. Overall, 110 patients (42 CABG, 68 mitral valve) were included in the registry, and the 1-year follow-up was completed for all patients.

Preoperative data including risk factors are presented in Table 1. CABG patients showed the typical risk-factor profile. Obviously arterial hypertension, diabetes mellitus, hyperlipoproteinemia, and history of myocardial infarction were more frequent in the CABG group. The specific parameters for AF-like history of stroke and duration of preoperative AF were comparable in both groups. Only the diameter of the left atrium was significantly higher in the mitral valve group.

The CABG patients received a mean of 2.9 ± 1.3 distal anastomoses. The mean operation time was 3.02 ± 0.44 hours. The repair of the mitral valve was possible in 21 patients. The remaining patients required mitral valve replacement (39 mechanical and 8 biological prostheses). Mean operation time was 2.41 ± 0.4 hours in this group. We observed no device-related complications in all 110 patients.

No patient of the CABG group died perioperatively (30 days). One patient of the mitral valve group died on the

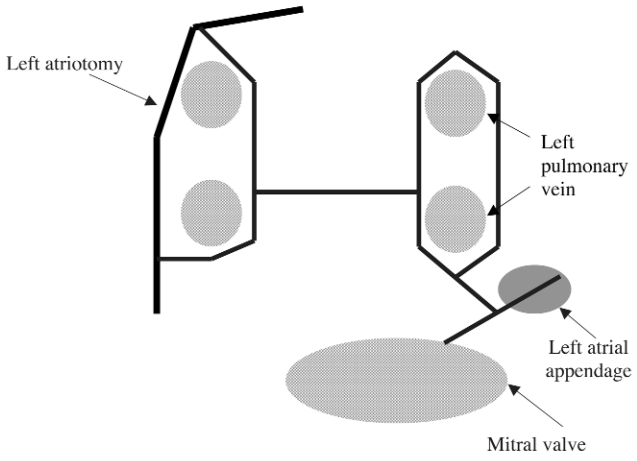

Figure 2. Second lesion line concept for endocardial microwave ablation.

Table 1. Preoperative Data and Risk Factors*

	CABG (n = 42)	MV (n = 68)	*P*
Age, y	70.1 ± 5.8	64.4 ± 8.7	ns
Female sex, %	28.6	29.4	ns
Diabetes mellitus, %	52.4	22	<.01
Arterial hypertension, %	95.2	57.4	<.01
HLP, %	85.7	41.2	<.01
Smoking, %	19	16.2	ns
MI, %	42.8	4.4	<.01
Stroke, %	11.9	8.8	ns
Duration pAF, y	6.9 ± 6.3 (range, 0.3-20.9)	6.5 ± 8.4 (range, 0.3-57.2)	ns
LVEF, %	56.8 ± 11.7 (range, 32-72)	54.2 ± 11.3 (range, 30-75)	ns
LA, mm	47.4 ± 7.1 (range, 30-65)	55.9 ± 9.2 (range, 41-102)	<.05

*CABG indicates coronary artery bypass grafting; MV, mitral valve surgery; HLP, hyperlipoproteinemia; MI, history of myocardial infarction; pAF, permanent atrial fibrillation; LVEF, left ventricular ejection fraction; LA, left atrial diameter in parasternal view in transthoracic echocardiography.

third postoperative day because of right ventricular heart failure. This means a 30-day mortality rate of 1.5%. During the 1-year follow-up period, 3 patients (7.1%) of the CABG group died because of multiple cerebral infarction, kidney failure, and acute heart failure. The mortality rate during the 1-year follow-up period of the mitral valve patients was 5.9% (4 patients). The reasons for the death of the 4 patients were sudden cardiac death, ventricular fibrillation, cardiogenic shock, and multiple embolisms from mitral valve endocarditis.

The follow-up data from 30 days to 360 days are presented in Tables 2 and 3. Success rates for durable restored sinus rhythm did not differ between the 2 groups ($P > .05$). Typical or atypical atrial flutter was observed in a few patients (Tables 2 and 3). The rate of pacemaker implantation was slightly higher in the mitral valve group, although this was not statistically significant.

DISCUSSION

We were able to demonstrate that it is possible to achieve comparable success rates in restoration of stable sinus rhythm using endocardial left atrial microwave ablation after a long-lasting history of pAF. This was achieved either in combination with isolated CABG or isolated mitral valve surgery. Success rates during the follow-up were between 69% and 78% in the CABG group and 63% and 72% the mitral valve group. The additional surgical outlay for CABG patients (bicaval cannulation, opening of the left atrium, additional cross-clamp time), which is needed to create the endocardial ablation line, did not cause a higher mortality rate or additional complications.

Recurrence of AF was observed in some patients in both groups. Our definition of success is documentation of stable sinus rhythm after 1 year. The detection of intermittent episodes of AF and sinus rhythm after 12 months is considered a therapeutic failure. Comparable results to ours were achieved with other endocardial ablation methods like radiofrequency ablation [Mohr 2002]. Nevertheless, the initial success rate of 80% dropped to 60% after 1 year [Doll 2003].

The success rates that we have reached in our study are lower than rates obtained with the classic maze procedure [Cox 1995]. But taking into account the additional structural heart disease and the higher age of our patients, this is not really surprising. The patients operated on by Cox were younger, most of them had only intermittent AF, and the majority underwent operations for AF without any concomitant heart disease. Because of these circumstances, these patients have a better prognosis per se to regain sinus rhythm. Our success rate of at least 63% is considerably higher than the rate of spontaneous restoration of sinus rhythm after comparable operations without ablation therapy, which have been reported between 7% and 33% [Handa 1999; Melo 1999; Gaita 2000; Deneke 2002; Spitzer 2002; Schuetz 2003; Raine 2004; Knaut 2005]. It is important to note that in our study no patient was excluded because of the duration of his or her preoperative AF history and/or left atrial size, which are known to influence the success rate.

Also, the 1-year mortality rates (6% and 7%, respectively) in the 2 groups are comparable to the results of other groups. Lemke et al reported a mortality rate of 12% 1 year after radiofrequency ablation, and Manasse et al reported a mortality rate of 6.3% after cryoablation [Lemke 2003; Manasse 2003]. Studies with larger cohorts of patients with pAF receiving isolated CABG without ablative treatment report a 1-year mortality rate between 8% and 19% [Eagle 1999], which strengthens the hypothesis that microwave ablation combined with CABG does not cause an increase in mortality. How much the patients will benefit from the additional treatment has to be analyzed in a further study with a larger number of patients. Based on a risk analysis of 46,984 patients, Quader [2004] advocates a concomitant ablation procedure in patients with AF undergoing CABG surgery revascularization, resulting in an improved survival

Table 2. Follow-up Data for Patients Who Underwent Coronary Artery Bypass Grafting

	30 d (n = 42)	90 d (n = 41)	180 d (n = 40)	360 d (n = 39)
Death, n	0	1	2	3
Sinus rhythm, %	69	78	74	72
Atrial fibrillation, %	29	20	23	28
Atrial flutter				
Typical, %	2	2	3	0
Atypical, %	0	0	0	0
VVI pacemaker, n	0	0	1	1
DDD pacemaker, n	2	3	2	1

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Table 3. Follow-up Data for Patients Who Underwent Mitral Valve Surgery

	30 d (n = 67)	90 d (n = 65)	180 d (n = 64)	360 d (n = 64)
Death, n	1	3	4	4
Sinus rhythm, %	69	66	72	63
Atrial fibrillation, %	28	27	28	35
Atrial flutter				
Typical, %	3	5	0	2
Atypical, %	0	2	0	0
VVI pacemaker, n	4	4	4	4
DDD pacemaker, n	4	4	5	5

rate. Raine gives the same recommendations for mitral valve patients [Raine 2004].

The incidence of postoperative DDD pacemaker implantation was 8.8% for patients after mitral valve operations and 7.1% for patients after CABG. Most of the patients were preoperatively bradyarrhythmic and showed a sinus bradycardia and/or chronotropic incompetence after ablation therapy. Our results are consistent with those reported by others, where the incidence of postablational pacemaker implantation was between 4% and 14% [Sie 2001; Doll 2003; Raine 2004; Gillinov 2004]. An additional 6 patients (5 from the mitral valve group and 1 from the CABG group) received a VVI pacemaker in other institutions during the follow-up period. The decision to implant a single-chamber pacemaker was guided by the presence of AF, although an ablation was done, not taking into account that a double-chamber pacemaker with antitachycardic function could be helpful to regain durable sinus rhythm.

Patients with recurrence of AF required an electrical cardioversion postoperatively. Initially, electrical cardioversion was performed in the early postoperative period to regain sinus rhythm as quick as possible. However, since we have noticed that this strategy resulted in a relatively high incidence of pacemaker implantations, we have modified our strategy. Since the beginning of 2004, an electrical cardioversion attempt is not made before the sixth postoperative week. Based on our preliminary results, this resulted in a lower pacemaker implantation rate, around 6%. The result was a more liberal strategy for DDD pacemaker implantation.

Sinus rhythm as assessed by surface ECG recording allows only limited conclusions about the long-term stability. However, the repeated examination after 1, 3, 6, and 12 months as well as the performance of a 24-hour Holter ECG after 12 months strengthens the assessment of the success criterion. Nevertheless, periods of intermittent AF cannot be ruled out with the described procedure. This is a limitation of our study. This open question might be solved by the implantation of event recorders.

One aim of the restoration of sinus rhythm is to avoid long-lasting anticoagulation therapy. We stopped anticoagulation after 3 months if there was stable sinus rhythm and a good E to A ratio in echocardiography. Additional criteria to stop anticoagulation after 3 months were the absence of a mechanical mitral valve prosthesis and an ejection fraction over 30%.

Since 2004, we treat patients who require CABG and/or aortic valve surgery with epicardial microwave ablation. The future will show whether it is possible to achieve comparable success rates with this new strategy.

CONCLUSION

Our results demonstrate that microwave ablation combined with CABG or mitral valve surgery can be performed with comparable and acceptable success rates from 69% to 78% for CABG patients and 63% to 72% for patients who required mitral valve surgery. The additional ablation procedure does not create an elevated risk for the patient, which was proven by our low mortality rates and the absence of procedure-originated complications.

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