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Microwave ablation for the surgical treatment of permanent atrial fibrillation—a single centre experience[☆]

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Abstract

Objective: Microwave ablation (MW) has been established as a safe and efficient procedure for the treatment of permanent atrial fibrillation (pAF) resulting in conversion to sinus rhythm (SR). For further improvement of clinical results, a new ablation line concept has been introduced. We present the first clinical results using this new concept in comparison with the results of previous ablation line concepts. **Methods:** Ablation lines were performed using microwave energy (Flex 2 and Flex 4 device). We compared two groups, including patients (pts) with mitral valve disease (MVD), coronary artery disease (CAD), and aortic valve disease (AVD). Group A included 137 patients, age 68.4 ± 7.8 , with ejection fraction 32–80%, left atrial diameter 52.6 ± 9.6 mm, suffering from MVD ($n = 87$), CAD ($n = 59$), or AVD ($n = 17$) with pAF for 6.5 ± 9.2 years using the original ablation line concept. Group B included 112 patients, age 68.1 ± 8.0 , ejection fraction 20–83%, left atrial diameter 53.1 ± 8.7 mm with pAF for 6.8 ± 7.0 years suffering from MVD ($n = 72$), CAD ($n = 33$) or AVD ($n = 36$) performing a modified ablation line. **Results:** Survival rate of group A was 98.5% and 97.3% in group B. In the 6-month follow-up for group A, 62% of patients with MVD, 68% with CAD and 78% with AVD were in SR. For group B, 88% of patients with MVD, 78% with CAD and 85% with AVD were in SR. **Conclusions:** MW has become an efficient option with an excellent benefit/risk ratio for the treatment of pAF in patients with other cardio surgical disease. The modified ablation line concept in association with the introduction of a new ablation catheter resulted in a 10% higher success rate. Therefore we have established this new lesion line concept as our standard for microwave ablation.

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Keywords: Endocardial microwave ablation; Lesion line modification; Permanent atrial fibrillation

1. Introduction

Atrial fibrillation (AF) is the most frequent supraventricular arrhythmia that is associated with significant symptoms and morbidity. AF affects 1% of the population [1]. It can be found mainly in the elderly and is often predicted by cardiac failure and rheumatic heart disease. To date, the results of pharmacological treatment have been disappointing and various alternative methods have been discussed since the first MAZE procedure by Cox

and co-workers [2]. Although effective, this long operation is rather complex and causes severe damage of the atria. Therefore, this procedure was not routinely used to cure AF in patients undergoing cardiac surgery.

During mitral valve replacement/repair and aortic valve replacement and coronary bypass grafting and permanent AF [3] an atriotomy offers the possibility to create linear lesions under direct vision. Our first preliminary clinical studies have indicated that microwave ablation (MW) represents an efficient and safe option for curative treatment of AF in patients with additional cardio-surgical disease [4–6]. In this study we report about the short- and mid-term follow-up after MW for the treatment of AF in 234 consecutive patients, where the original lesion line concept according to Alessie was modified after 137 patients.

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2. Material and methods

The study was performed as a prospective registry study. Included were consecutive patients with permanent AF who underwent mitral valve replacement/repair and aortic valve replacement and coronary bypass grafting. Patients with paroxysmal AF and patients younger than 18 years of age were excluded. Additional exclusion criteria were: emergency operations and congestive heart failure (NYHA IV).

The patients were admitted to hospital before the operation and all anti-arrhythmia drugs were stopped, although the remaining cardiovascular medication was continued. After the operation, Sotalol was given to all patients to stabilise rhythm and anti-coagulation with Phenprocoumon with a target INR of 2.0–3.0, with a mechanical mitral or aortic valve of 3.0–4.0. For all patients who showed a stable sinus rhythm (SR) at the 3-month follow-up and who had not received a mechanical valve, the anticoagulation was discontinued.

The benefits and risks of ablation were explained to all patients before operation. An informed consent was obtained from all patients prior to surgery. The patients also agreed to the inclusion of their data anonymously in a registry for scientific evaluation.

The AFx microwave surgical ablation devices (Flex 2 and Flex 4) were used to produce linear lesions on the endocardial surface. The devices were designed to allow the application of microwave energy to tissue through an antenna. Details of the method are published elsewhere [7].

The first 137 patients underwent ablation according to Allesie's concept [8]. 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. The next lesion line starts at the same depth but at the contra lateral site (Fig. 1).

With the next 112 patients, the course of the lesion lines was modified. The left atrial appendage was included in the line concept, but the right atrial appendage was only entered through the septum, when ablation of the isthmus was also carried out. The pulmonary veins were also isolated [9] (Fig. 2).

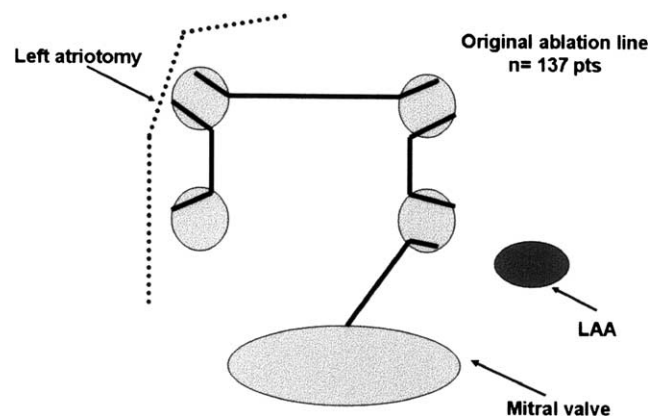


Fig. 1. Line concept I.

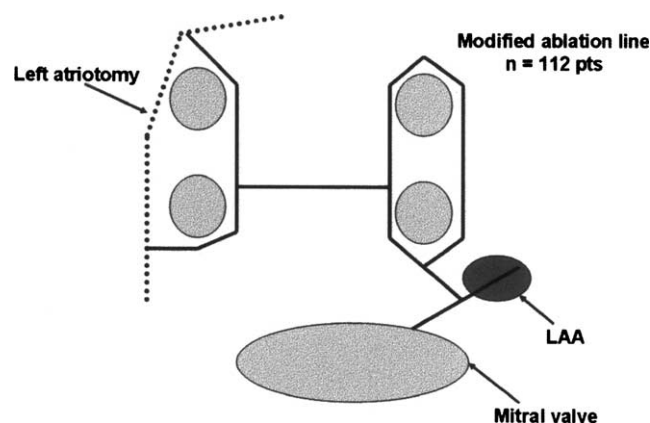


Fig. 2. Line concept II.

The lesion line concept is independent of the type of surgery performed or the patient characteristics. In patients with atrioseptal defect, surgery of the tricuspid valve and reoperations a transeptal approach to the left atrium was used. Atrial reduction surgery, additional incisions, and stand alone MW techniques were not performed.

Data are expressed as mean value \pm standard deviation or percentage. χ^2 and two-tailed, unpaired Student's *t*-test were used to compare the two patient groups. Differences were considered significant at $P < 0.05$.

3. Results

Up to now 249 patients were included in the registry. It was possible to follow up all patients, so there was no dropout. Table 1 shows patient demographics and clinical data.

The demographics and clinical data were comparable for both patient groups before surgery. The duration of the intraoperative ablation procedure was 13 ± 5 min for both

Table 1
Demographic and clinical data of both patients groups

	Lesion line concept I (group A)	Lesion line concept II (group B)	<i>P</i>
Number of patients	137	112	
Female/male	71/66	57/55	ns
Age (years)	68.4 \pm 7.8	68.1 \pm 8.0	ns
EF (%)	56.1 \pm 11.9	56.9 \pm 11.9	ns
Range	32–80	20–83	
LA (mm)	52.6 \pm 9.6	53.1 \pm 8.7	ns
Range	30–102	38–76	
LA \geq 60 mm (%)	18.2	17.4	ns
Duration of AF (years)	6.5 \pm 9.2	6.8 \pm 7.0	ns
Range	0.5–57.2	0.1–42.2	
Duration > 7 years (%)	24.8	37.0	ns
Mitral valve disease	87	72	
Coronary artery disease	59	33	
Aortic valve disease	17	36	

EF, ejection fraction; LA, left atrial diameter; AF, atrial fibrillation.

left atrial lesion concepts. Carrying out the lesion lines in the right atrium lengthened the ablation procedure by approximately 3 min.

Complications related to the procedure, such as haemorrhage, perforation of the oesophagus or later stenosis of the pulmonary veins did not occur in any of the cases. The survival rate in group A was 97.8% and 96.4% in group B and did not differ between the lesion line concepts ($P > 0.05$). Seven patients died perioperatively; the causes of death were low cardiac output syndrome ($n = 3$), multi-organ failure ($n = 2$), and right ventricular failure ($n = 2$).

In group A 65% of patients, who were treated using lesion line concept 1, showed stable SR after 6 months, while this was the case in 80% of group B, where patients underwent ablation using the modified lines concept ($P = 0.1573$).

In the 6-month follow-up in group A, 62% of patients with mitral valve disease (MVD), 68% with coronary artery disease (CAD) and 78% of patients with aortic valve disease (AVD) were in stable SR. In group B, 88% of patients with MVD, 78% with CAD and 85% of patients with AVD were in stable SR ($P = 0.1991$).

All patients with stable SR demonstrated good biatrial transport function in echocardiography [5].

After 6 months 26% of all patients had a pacemaker. Five of these patients already had a pacemaker before operation (2 VVI, 3 DDD).

4. Discussion

The results of this registry study show that MW represents a safe surgical procedure for curative treatment of AF. So far, none of the patients treated did suffer any complications related to the procedure, nor did any of the patients die.

In 62–88% of all patients, MW has led to a stable SR, depending on the cardiac disease. This represents a lower success rate compared to Cox's standard MAZE-procedure, in which a success rate of approximately 90% has been reported [2].

However, it should be pointed out that several factors can have a negative effect on the success rate of the ablation treatment, such as the greater age of the patients, long-standing AF, a severely enlarged atrium and existing organic heart disease [2,5,6,10].

In this registry study, however, these factors did not represent a reason for exclusion. Therefore, a comparison of the results obtained in this registry study with the earlier surgical ablation treatments carried out by Cox and colleagues is difficult:

- (i) Only patients with documented permanent atrial fibrillation (pAF) were included in this registry study (patients with paroxysmal and persistent AF were

excluded). In the early studies of Cox and colleagues on the MAZE III-procedure, less than 50% of the patients included had chronic AF [11].

- (ii) The average age of patients in this study was approximately 15 years greater than in the MAZE-comparative studies [11].
- (iii) The success criterion used was solely the existence of a stable SR, and not the 'non-occurrence' of AF, as in other ablation studies.
- (iv) All patients had an underlying organic heart disease, compared to 34% of patients in the Cox study [11].

The lesion line concept itself could also have influenced the success rate significantly. The circular ablation of the pulmonary veins (analogous to the box lesions of Cox, Melo and others [11,12]) in combination with the lesion line into the left atrial appendage including left atrial appendage occlusion led to a significant improvement in the results for all operations. The success rate was 8% better in AVD, 10% better in CAD and 16% better in MVD compared with the original line concept. The results of the modified line concept are comparable with those of Schuetz, who carried out a similar concept for endocardial MW [13].

It has also to be taken into account that the instruments for MW (Flex 4) available today, ensure a uniform energy dose, so that very good passage through the walls of the lesions can be obtained and electrical gaps can be avoided. This is supported by the fact that no further atypical flutter was observed in group B, while in the past this had occurred in up to 10% of cases after 1 year [5].

The more flexible tip of the new instruments also enables better handling than with the instruments used in the first 2 years. It is therefore quite possible that this contributed to the improved success rate, as for the most part the patients in group B were treated with the improved instruments.

In 34 out of 249 patients (13.7%) with preoperative bradyarrhythmia a dual chamber pacemaker was implanted after surgery due to sinus bradycardia or chronotropic incompetence. This is in good agreement with the studies of Doll, Gillinov, Sie, and Lemke [14–17] who reported a rate of pacemaker implantation of 14, 9, 11 and 4%, respectively. In 24 patients a single chamber pacemaker was implanted outside our unit with an unknown diagnosis.

Since the beginning of 2004 we have modified our approach towards reappearing atrial arrhythmias in that sense that we prolong the time interval to a cardioversion up to 6 weeks. Early results show a decline in the rate of pacemaker implantations.

5. Limitations of the study

Although this study is a retrospective review of prospective collected data, it is likely to suffer from

the inherent limitations of observational studies on non-randomized patient groups.

However, we were unable to control other factors such as patient's difference in extent or distribution of CAD or valve disease and the difference in performance between individual surgeons.

6. Conclusions

Microwave ablation has become an efficient option with an excellent benefit/risk ratio for the treatment of pAF in patients with an additional cardio surgical disease. The modified ablation line concept in association with the introduction of a new ablation catheter resulted in a 10% higher success rate. Therefore, we have established this new lesion line concept as our standard for microwave ablation.

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Appendix A. Conference discussion

Dr F. Mohr (Leipzig, Germany): In the literature there is some incidence and there are some reports about increased thrombus formation or even thromboembolism after microwave application to cardiac tissue. Do you have any concern about that? We also know about radiofrequency oesophageal injury, and do you have any precautions because of that? I know you do have very low numbers there, but did you have any extra treatment for that?

Dr Knaut: In our pilot study we observed the patients, it was a clear concept and a long follow-up, but we never found a special higher thromboembolic rate in these patients. Of course we saw all the strokes a longer period after the operation, but it was not related to the operation, and the patients were mobilized. It may be possible that it was another problem from the carotid arteries or whatever. But we found no differences.

And in the pilot study, in the years before, where we checked all patients in the EP lab, we never found any problems with this kind of ablation.

Dr P. Mortensen (Odense, Denmark): As I understood you, you open up the left atrium to do the ablation, also if the patient only is having a CABG. Is it justifiable to do this procedure and gain 78% of patients back to normal sinus rhythm instead of, for instance, using a technique where you didn't have to open the left atrium?

Dr Knaut: Pardon?

Dr Mortensen: Is it justifiable to open the left atrium during a CABG, which you normally would not have to do, using another technique?

Dr Knaut: I have done this. After more experience with this classic mitral valve surgery and ablation, I use it for all patients, also for isolated aortic valve stenosis and CABG surgery. But it is more difficult to treat these patients with this procedure. My intention is to do this ablation more epicardially. I have not presented these data yet.

So I have also patients with epicardial ablation. That is my intention, to use more epicardial for off-pump CABG or for these patients with aortic valve surgery on-pump. Of course that is the better way for this kind of surgery.

But I think the endocardial ablation is much more effective, whatever energy source you will use, and all these other types of energy work very good.

Dr Mohr: I just have a comment to this question. We as surgeons should not always acquire new techniques from an ethical basis, because the cardiologists don't ask us whether they should treat A-fib or not. They just do whatever they want and they will never ask us. I think we should support any effort to develop and be more successful in our field rather than always to acquire new approaches, and Dr Knaut has been reporting about a five-year experience, and I think we have to respect his new approach.

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