Surgical treatment of atrial fibrillation using radiofrequency ablation

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Saline-Irrigated, Cooled-Tip Radiofrequency Ablation Is an Effective Technique to Perform the Maze Procedure

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Background. We evaluated the effectiveness of the saline-irrigated-cooled-tip-radiofrequency ablation (SICTRA) to produce linear intraatrial lesions.

Methods. Thirty patients with chronic atrial fibrillation and mitral valve disease were consecutively randomized to have mitral valve operation either with a Maze procedure (group A) or without (group B). Intraatrial linear lesions were made with an SICTRA catheter (20 to 32 W; 200 to 320 mL/h saline). An echocardiography and 24-hour electrocardiogram were obtained 12 months postoperatively.

Results. The cumulative frequencies of sinus rhythm in group A and B were 0.80 and 0.27 (p < 0.01). Restored biatrial contraction was present in 66.7% (6 of 9) of the group A patients in sinus rhythm. One patient from each group received a permanent pacemaker because of bradycardia. A fatal renal bleeding and mediastinitis occurred in 2 group A patients, 6 weeks postoperatively. One group A patient had sudden cardiac death at home, 4 months after operation. One patient from each group had lethal respiratory failure, 7 and 10 months after operation. Survival after 12 months for group A and B was 73% and 93% (p = 0.131).

Conclusions. The SICTRA appeared to be an effective technique to perform the Maze procedure.

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Patients and Methods

Between February 1998 and October 1999, 30 patients with documented chronic atrial fibrillation, preexisting for more than 1 year, and mitral valve disease were randomized consecutively to have mitral valve operations either with a Maze procedure (group A) or without (group B). The SICTRA was used to create the intraatrial linear lesions. The clinical history, an electrocardiogram, an echocardiography, and a 24-hour electrocardiogram were obtained at 6 and 12 months postoperatively. The medical ethical committee of our institution approved the study and informed consent was obtained from each patient.

SICTRA Set Up

The SICTRA set-up constituted of a SICTRA catheter (Sprinklr; Medtronic, Minneapolis, MN), which had a 7F (2.33 mm) diameter, a 4-mm tip length, and 13 irrigation holes. The catheter was connected by a radio-frequency generator (CardioRythm-ATAKR, Medtronic). The flow rate for the first 4 patients was 200 mL/h, but was altered to 250 mL/h in next 4 patients, and was eventually changed to 320 mL/h in the last 7 patients. The reason for these changes was that the ablation took too much time; we believed that a higher irrigation volume could accelerate the ablation procedure. The catheter was also connected to a radiofrequency generator (CardioRythm-ATAKR, Medtronic). In the first 4 patients the ATAKR was programmed to
The saline irrigated cooled tip radiofrequency ablation was an effective technique to perform the maze procedure; a prospective randomized study.

Fig 1. Outer aspect of the right atrium as seen from the surgeon's side. The surgical incisions are S1, S2, and S3. The saline-irrigated, cooled-tip radiofrequency ablation lesions are R1 and R2. AV = atrioventricular; IVC = inferior caval vein; RA = right atrium; RAA = right atrial appendage; SA = sinoatrial; SCV = superior caval vein.

provide 20 W. Because we thought that the energy delivery was too low, we increased the energy supply to 32 W for the last 8 patients. The ATAKR was also connected to a 300 x 175 mm indifferent electrode, which was placed firmly between both scapulas of the patient, and to a foot pedal to switch the ATAKR generator on.

Maze Procedure

A standard median sternotomy was performed. The aorta, the superior caval vein (SCV), and the inferior caval vein (ICV) were cannulated. The “cut and sew” incisions (abbreviated as S-lesions) and the SICTRA lesions (abbreviated as R-lesions) are shown in Figures 1, 2, and 3. The right appendage was excised (S1). A perpendicular incision 3 to 4 cm long was made from the middle of the S1 lesion, traversing over the lateral free wall of the right atrium (S2). A curved incision was made from the atrioventricular (AV) groove, about 2 to 3 cm cranially and anterior from the IVC, and continuing posterocranially behind the sulcus terminalis (S3). Then the R1 and R2 lesions were created from, respectively, the posterocranial end of S3 into the SCV and from the posterocaudal end of S3 into the IVC (Fig 1). Lesion R3 was made from the anterior edge of S3, close to the AV groove, traversing over the endocardium to the middle of the posterior part of the tricuspid annulus. Lesion R4 was made from the medial cut edge from the right appendage to the anteroseptal commissural area of the tricuspid valve (R4). The R5 lesion was made from the posterocranial edge of S3 traversing to the posterior area of the foramen ovale continuing to the posterior rim of the coronary sinus orifice, then curving toward the inferior caval vein, ablating the so-called isthmus (Fig 2).

The aorta was cross-clamped and cold antegrade blood cardioplegia was administered. The left atrium was opened in the interatrial groove and its dome (S4) (Fig 3).

Fig 2. The inner aspect of the right atrium as opened through the curved incision (S3). View from the surgeon's side (see text). The saline-irrigated, cooled-tip radiofrequency ablation (SICTRA) lesions are R3, R4, and R5 (white lines). AV = atrioventricular; FO = foramen ovale; IVC = inferior caval vein; TV = tricuspid valve; SC = coronary sinus; SCV = superior caval vein; TK = triangle of Koch.

The endocardial rim of the ostium of the right superior and inferior (R6) as well as the left superior and inferior (R7) pulmonary vein was ablated. Lesion R8 was the connection between R6 and R7. From the left inferior pulmonary vein, lesion R9 was created to the midportion of the posterior mitral annulus. Then lesion R10 was

Fig 3. The inner aspect of the left atrium after opening its dome and the interatrial septum (S4). The dashed line is the posterior part of the mitral annulus. The saline-irrigated, cooled-tip radiofrequency ablation (SICTRA) lesions are R6-R10, S4, and S5 (white lines) (see text). AMV = anterior mitral valve; CX = circumflex; FO = foramen ovale; LAA = left atrial appendage; LIPV = left inferior pulmonary vein; LSPV = left superior pulmonary vein; RIPV = right inferior pulmonary vein; RSPV = right superior pulmonary vein.
made from the left lateral rim of the orifice of the left inferior pulmonary vein to the rim of the left atrial appendage orifice. The left atrial appendage was resected (SS) or ablated, if adhesions prevented its resection, and closed with Prolene 4-0 suture (Ethicon, Somerville, NJ). The left atrium was closed with a single row of running Prolene 4-0 suture. The cross-clamp was removed and the incisions of the right atrium were closed with a pledget-buttressed mattress Prolene 4-0 running suture. The heart was paced with the Atrium atrium inhibition mode (AAI), if possible, or DDD mode. The patient was weaned from cardiopulmonary bypass and the chest closed in a standard way.

Postoperative Care
The patients were kept on atrium atrium inhibition mode (AAI) or double double double mode (DDD) pacing if the heart rate was slower than 75 beats per minute during the first 7 postoperative days. If an atrial fibrillation persisted, a cardioversion was performed during the first 24 postoperative hours. However, this early cardioversion was abandoned in the last 10 patients because the procedure did not contribute to any long-term cardiac rhythm stability. Sotalol 40 mg twice a day (bid) was started on the first postoperative day. The dose was increased to 80 mg bid on the third postoperative day and eventually to 160 mg bid if no bradycardia was noticed. All patients received Coumadin (warfarin sodium), started on the first postoperative day.

Follow-Up
All data were collected between February 1998 and October 2000. Data acquisition was obtained for each patient on the first postoperative day, 12th postoperative day (predischarge), and after the third, sixth, and ninth postoperative month. The medical history, clinical examination, and an electrocardiogram (ECG) were obtained at each visit. A 24-hour ECG analysis was performed after 6 and 12 months. A transesophageal echocardiography, including transmural and transtricuspid Doppler examination, was obtained on the 12th postoperative day, after 6 and 12 months. Sotalol, at least 80 mg bid, was continued for 6 months and replaced by metoprolol, at least 95 mg per day. All patients received Coumadin targeting an international normalized ratio value between 2.2 and 2.5. If an atrial fibrillation was observed after the 12th postoperative day, 3rd, or 6th month, a cardioversion with 240 to 360 J was performed twice with two different defibrillator pad positions, twice during the follow-up period.

Analysis
Continuous variables were expressed as mean (standard deviation (median)). Student’s unpaired t test (two-tailed) was used for comparison in between the two groups. Differences were considered significant at a p value less than 0.05. The survival rate and maintenance rate of sinus rhythm (SR) were calculated according to Kaplan-Meier method and groups were compared using log rank-test (significant difference postulated at \( p < 0.05 \)).

Results
The patient characteristics, except for age (64.7 versus 69.7 years; \( p = 0.05 \)) and sex distribution (female to male ratio: 9:6 versus 12:3), were similar in both groups. Table 1 shows the operative data. The 30-day mortality was zero. Postoperative morbidity included respiratory insufficiency (1 patient in group B), superficial wound infection (3 patients in group A, 1 patient in group B), and sernal instability (1 patient in group A, 1 patient in group B patient). During follow-up, fatal renal bleeding and mediastinitis occurred in 2 patients in group A, 6 weeks postoperatively. One group A patient had a sudden cardiac death at home, 4 months after the operation. One patient from each group had lethal respiratory failure, 7 respectively and 10 months after the operation. One patient from each group received a permanent pacemaker because of a bradycardia. The 12-month follow-up was complete, although 2 group B patients were unable to revisit our outpatient cardiology clinics. Both patients, however, had an ECG, which showed atrial fibrillation. Survival after 12 months for group A and B was 73% (11 of 15 patients) and 93% (14 of 15 patients) (\( p = 0.131 \)). The respective cumulative frequencies of SR after 6 and 12 months for the group A and B patients were 0.733 and 0.267 for group A and 0.800 and 0.267 for group B (\( p = 0.005 \)) (Fig 4). The number of group A patients who were in SR with an atrial contraction (transmitral A-wave) was 5 of 8 (62.5%) after the 12th postoperative day, 7 of 10.

Table 1. Operative Data

<table>
<thead>
<tr>
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<th>Group A ((n = 15))</th>
<th>Group B ((n = 15))</th>
<th>(p)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operative time ((\text{min}))</td>
<td>270 (232-323)</td>
<td>190 (128-314)</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>CPB time ((\text{min}))</td>
<td>188 (165-230)</td>
<td>127 (60-197)</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>X-time ((\text{min}))</td>
<td>103 (86-134)</td>
<td>84 (38-112)</td>
<td>&lt; 0.05</td>
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<tr>
<td>MVP ((\text{n}))</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Mechanical valve ((\text{n}))</td>
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<td>13</td>
<td></td>
</tr>
<tr>
<td>Biological valve ((\text{n}))</td>
<td>1</td>
<td></td>
<td></td>
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</table>

CPB = cardiopulmonary bypass; MVP = mitral valve plasty; X-time = aortic cross-clamp time.

Fig 4. Postoperative cumulative frequencies of sinus rhythm (SR). (Y-axis = the cumulative frequency of SR; X-axis = postoperative days.)
The SICTRA is an alternative source of energy to produce intraatrial linear functional transmural lesions. It is performed with a cooled porous radiofrequency ablation catheter, which was originally used by Wittkampf and colleagues [2]. The use of such a catheter impedes an impedance upstroke because the electrode-tissue surface temperature will drop due to the continuous saline irrigation. Therefore, the total amount of radiofrequency energy that can be delivered will be higher and consequently a deeper tissue lesion can be created. Sie and colleagues [3] proposed the intraoperative use of the SICTRA to treat patients with chronic atrial fibrillation. Nakagawa and associates [4] investigated and compared the induced lesion geometry of the temperature-controlled, radiofrequency ablation, the conventional "dry" radiofrequency ablation, and the SICTRA. They reported that the SICTRA induced the largest and the deepest tissue lesions, which was predominantly caused by direct resistive heating, which occurred in the deeper tissue layers. The lesion was not created primarily by heat conduction from the tissue surface to the deeper layers.

The size of the SICTRA-induced tissue lesion is determined by the amount of delivered energy through the cooled-tip radiofrequency catheter. The power (Watts), the saline irrigation speed (milliliters per minute), the electrode diameter, and the application delivery time are the main factors, which determine the total amount of the delivered radiofrequency energy. The higher the power, the more energy per second will be given. However, this will lead to a higher tissue surface temperature upstroke with a subsequent impedance rise, which is associated with a higher risk of tissue carbonization (charring). Once the tissue surface is carbonized, no ablation of the underlying tissue layers is possible because of the extremely high impedance of the carbonized tissue surface. Therefore carbonization, in our opinion, should always be avoided. However, the lower the power, the longer the ablation time will be. Initially we used 20 W with a saline irrigation speed of 220 mL/h in the first 4 patients. The time to create an intraatrial lesion length of 3 cm was estimated to be about 60 to 100 seconds. Therefore, we increased the power to 25 W, which reduced the application time to approximately 45 to 75 seconds to create a similar tissue lesion. Ultimately we increased the power to 32 W. However, we noticed a higher risk of carbonization and were therefore forced to increase our saline irrigation speed from 220 to 250 mL/h. The risk of carbonization formation was reduced, but not enough, in our opinion. Ultimately the irrigation speed was further increased to 320 mL/h. At the same time, however, the risk of "tissue-popping" increased as well. Tissue pop-

ping is a sudden release of steam, which is formed in the deeper tissue layers. This steam finds its way out of the tissue in an explosive manner, causing tissue cracks or even a complete tissue breakdown. We speculated that increasing the irrigation speed would lead to a higher formation of resistive heat in the deeper tissue layer, which in turn would increase the size of the induced lesion. However, the risk of tissue "popping" with rupture would be higher. We ultimately used a 32-W power supply with a saline irrigation speed of 320 mL/h, which proved to be satisfactory, because a smooth linear lesion could be created without causing any charring or "tissue popping." The application time was about 10 to 25 seconds to create a 3-cm linear lesion. We used the Sprinklr catheter, with a 2.33-mm diameter, throughout the entire study. During intraoperative handling, the catheter was moved slowly up and down over the atrial endocardium until a whitish blistering of the superficial endocardial cell layer was observed. This whitish blistering reflected the acute swelling of the atrial myocytes, which occurred because of the resistive heating, which was formed in the deeper atrial tissue layers. Once this whitish blistering was visible, the radiofrequency application was stopped and the catheter was advanced to another area.

Rationale of the Lesion Pattern Design as Used in This Study
Figures 1, 2, and 3 shows the lesion pattern, which was used in this study. The aim was to block the multiple wavelet reentrant circuits to extinguish atrial fibrillation, but still preserving the sinoatrial and AV conduction pathway [1]. But we also tried to target and exclude the reinitiating pulmonary trigger zones to prevent the recurrence of atrial fibrillation. Haissaguerre and colleagues [5] reported the occurrence of ectopic beats, located in the pulmonary veins and around their orifices, especially in the superior left and right pulmonary veins. These foci trigger atrial fibrillation. The most significant changes between our SICTRA lesion pattern and the Maze III blueprint is the way in which the pulmonary vein orifices were isolated. Whereas, the Maze III procedure isolates all four pulmonary vein orifices as an entire one-piece-tissue island, our lesion pattern isolated each pulmonary vein orifices separately, but over its complete orifice circumference. We did not ablate within the pulmonary vein orifices to avoid any risk of pulmonary vein stenosis. The superior and inferior orifices on either side were then interconnected. These two lesions patterns, one on the left side and the other on the right, were again interconnected with an additional SICTRA lesion. Ultimately a figure of "H" was created. Whether this variation will have any significant effect on the postoperative results remains unclear.

Spontaneous Conversion From Atrial Fibrillation to Sinus Rhythm
GROUP A. Between the 12th postoperative day and the 6th postoperative month, 3 patients showed a spontaneous conversion from atrial fibrillation to SR. A potential
CHAPTER 4

GROUP B. A spontaneous conversion occurred in 4 of 15 patients (26.6%). This finding is in accordance with the reported spontaneous conversion rate as reported by Obadia and colleagues [7], who analyzed 191 mitral valve repair patients and found a spontaneous conversion rate of 36% (5 of 14) in patients with chronic atrial fibrillation, preexisting longer than 1 year. Our patients had a preoperative duration of atrial fibrillation for at least 1 year (mean = 3.6 years). The spontaneous conversion rate of our study group was expected to be between 4.5% and 35.7%, according to the data of Obadia. Whereas the group A patients converted between the 12th postoperative day and 6th postoperative month, the group B patients converted almost immediately after operation, within the 12th postoperative day. This difference suggested that the beneficially changed postoperative hemodynamics contributed to the spontaneous conversion in these patients, whereas the reinnervation of the autonomous nervous system and the change of the refractory time probably played a key role in the spontaneous conversion in the group A patients.

Postoperative Morbidity

Three group A patients had a superficial wound infection, which was successfully treated without any invasive surgical treatment. The prolonged operation time was a risk factor. Sternal instability, necessitating surgical refixation, occurred in 1 patient from each group.

Follow-Up

One group A patient died from mediastinitis on the 45th postoperative day. The prolonged operative time in this obese, diabetic patient was a clear risk factor. Another group A patient had a fatal Coumadin-related renal bleeding. In our opinion, this prosthesis-associated complication is not related to the SICTRA procedure itself. One group A patient experienced sudden cardiac death at home, possibly due to the proarrhythmic effects of sotalol, although a procedure-related adverse event could not be excluded. Our postoperative prescription of sotalol was changed from 6 months to 1 month and then replaced by metoprolol. One group A and one group B patient died after 7 and 9 months, both as a result of pulmonary complications related to their preexisting chronic obstructive pulmonary disease. In both patients, the dose of \( \beta \)-blocker was, from the immediate postoperative time on, reduced or even deleted. One group A patient received a DDD pacemaker because of a sinus bradycardia, although the beta blockade was omitted. One group B patient had a ventricle-ventricle-inhibition mode pacemaker because of a bradycarrhythmia.

Treatment Failures and Study Limits

At 12 months 2 patients remained in atrial fibrillation, indicating that the SICTRA was ineffective in these 2 patients. We speculated that a nontransmural functional lesion was created in these 2 patients, which potentially reflected the technical inadequacies of the SICTRA system or the surgical technique. The energy delivery and irrigation speed in these 2 patients were 20 W and 220 mL/h and 25 and 250 mL/h, respectively. The lack of a postoperative mapping was a drawback in these patients. The difference in age (64.7 versus 69.7 years; \( p = 0.05 \)) and sex distribution (female to male ratio: 9:6 versus 12:3) between both groups might have affected the results as well. Finally, the small group of patients inevitably encompasses potential statistical errors, which can be avoided only if larger groups of patients are studied.

Comparison With the International Literature

The "cut and sew" technique is the golden standard to create linear transmural lesions. The unsurpassed success of 99%, reported by Cox and colleagues in 346 patients, is unique [1]. Melo and colleagues [8] used the Cerablate (Sulzer Osypka, Grenzach-Wyhlen, Germany) radiofrequency ablation catheter intraoperatively in 43 patients undergoing mitral valve operations who had chronic atrial fibrillation with a mean duration of 6 ± 5 years. This catheter contained four electrodes, which were firmly attached to the atrial endocardium. Two oval lesions around the superior-inferior pulmonary vein orifices on either side were created. Before starting the ablation, Melo and colleagues infused cold saline into and outside the atrium, apparently to acquire a certain level of cooling and to improve the tissue-electrode contact. The left atrial appendage was closed from the inside. The 3-month follow-up was complete for 33 patients; 10 (30%) patients had SR with atrial contraction, 12 patients remained in atrial fibrillation (36%), and 11 had various types of supraventricular rhythms. Compared with our data, the incidence of postoperative SR in Melo's study was lower. The absence of a continuous stable irrigation saline flow to create a deep atrial wall lesion is, in our opinion, a potential explanation for the lower postoperative SR rate. In addition, the variation in atrial wall thickness is not taken in consideration when the Cerablate catheter is applied for a fixed time on every part of the atrial wall. Moreover, the simple surgical closure of the left atrial appendage, does not, in our opinion, automatically lead to an electrophysiological isolation of the left appendage.

Melo's group, thereafter, also used a different temperature-controlled, radiofrequency ablation catheter, Thermal-Ep technologies, to produce similar lesions in a group of 46 patients with chronic atrial fibrillation. At the 6 month follow-up of the 25 patients, 13 patients remained in atrial fibrillation, 8 had SR with atrial contrac-
tion, and 4 patients had an undefined supraventricular rhythm.

Benussi and colleagues [9] used epicardial radiofrequency ablation in conjunction with mitral valve operations in 40 patients with chronic atrial fibrillation with a mean duration of $43 \pm 51.9$ months. The ablation was performed with a temperature-controlled, multipolar radiofrequency catheter to produce, from the epicardial side, two encircling lesions around the orifices of the right and left pulmonary veins. Then the left atrium was opened and these two epicardial lesions were interconnected with an endocardial ablation line. The mitral valve procedure was then performed and the left appendage was sutured. At a mean follow-up of 11.6 months, 77% (30 of 39 patients) were in SR with atrial contraction. In contrary to the dry ablation, the temperature-controlled radiofrequency ablation can create deeper tissue lesion, which will certainly contribute to a higher success rate. The intraoperative epicardial handling of the radiofrequency catheter to secure a constant and firm tissue-electrode surface contact on a beating heart can be technically difficult, however, especially if a substantial amount of epicardial fat is present.

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References