

Radiofrequency Ablation of the Cavotricuspid Isthmus in Typical Atrial Flutter: Standard Catheter Versus Irrigated-Tip Catheter. A Randomized Prospective Study

Gonzalo Peña Pérez, Antonio Hernández Madrid, José María González Rebollo, Aníbal Rodríguez, Manuel Gómez Bueno, Asunción Camino and Concepción Moro

Unidad de Arritmias. Servicio de Cardiología. Hospital Ramón y Cajal. Departamento de Medicina. Universidad de Alcalá de Henares. Madrid.

Introduction and objectives. An important limitation of the ablation with standard catheter is the volume and limited depth of the lesions created. The irrigated catheters, due to a larger and deeper lesion could be useful in patients with typical atrial flutter. The aim of this study was to prospectively compare the ablation procedure with an irrigated-tip catheter versus the standard catheter in this group of patients.

Methods. A total of 37 consecutive patients referred to ablation of the cavotricuspid isthmus for typical atrial flutter were randomized either to be performed by a standard catheter (20 patients with mean age of 62 ± 18 years, 18 males) or an irrigated-tip catheter (17 patients with mean age 71 ± 4 years, 13 males).

Results. With standard catheters, complete ablation of the cavotricuspid isthmus was achieved in 18 patients (90%). With a mean of 19 ± 15 applications. With the irrigated-tip catheters the complete ablation of the isthmus was achieved with a mean of 8 ± 7 applications ($P < .001$). Both mean duration of the procedure (164 ± 56 versus 70 ± 35 minutes) and fluoroscopic time (40 ± 16 versus 16 ± 8 minutes) was significantly less with irrigated catheters ($P < .001$). There were no significant clinical complications during the procedure nor later on. No patient presented ischemic symptoms nor alterations on the ST segment.

Conclusions. The employment of irrigated-tip catheters achieved a high success rate with safety shortening the procedure time and radiation exposure.

Key words: Catheter ablation. Radiofrequency. Atrial flutter.

Ablación del istmo cavotricuspídeo. Estudio prospectivo aleatorizado sobre ablación mediante radiofrecuencia con catéteres irrigados frente a catéteres estándar

Introducción y objetivos. Una limitación importante de la ablación con catéter estándar es el volumen y la profundidad limitada de sus lesiones. Los catéteres irrigados, debido al mayor tamaño de la lesión, podrían ser útiles en los pacientes con aleteo auricular típico. El propósito de este estudio fue comparar, de forma prospectiva, la ablación con catéter estándar frente a irrigado en estos pacientes.

Métodos. Se aleatorizó a 37 pacientes consecutivos remitidos para ablación del istmo cavotricuspídeo por aleteo auricular típico. En 20 pacientes se realizó ablación con catéter convencional (edad media 62 ± 18 años, 18 varones). En 17 pacientes se realizó ablación del istmo con catéter irrigado (edad media de 71 ± 4 años, 13 varones).

Resultados. Con los catéteres estándar se consiguió ablación completa del istmo cavotricuspídeo en 18 pacientes (90%), con una media de 19 ± 15 aplicaciones. Con los catéteres irrigados se consiguió ablación completa del istmo en todos ellos, con una media de 8 ± 7 aplicaciones ($p < 0,001$). Tanto la duración media del procedimiento (164 ± 56 frente a 70 ± 35 min) como la de escopia (40 ± 16 frente a 16 ± 8 min) fue significativamente menor con los catéteres irrigados ($p < 0,001$). No hubo complicaciones clínicas durante el procedimiento, ni tampoco posteriormente. Ningún paciente presentó síntomas isquémicos ni alteraciones del segmento ST.

Conclusiones. Con el empleo de los catéteres irrigados se puede realizar la ablación del istmo de forma muy efectiva, reduciendo el tiempo total del procedimiento y escopia.

Palabras clave: Ablación. Radiofrecuencia. Aleteo auricular.

Correspondencia: Dra. C. Moro.
Unidad de Arritmias. Hospital Ramón y Cajal.
Ctra. de Colmenar Viejo, km 9.100. 28003 Madrid.
Correo electrónico: cmoro@hrc.insalud.es

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INTRODUCTION

Atrial flutter results from a microreentry circuit in the right atrium, which necessarily involves the cavotricuspid isthmus.¹⁻⁵ Catheter radiofrequency

TABLE 1. Study population

	Standard (n = 20)	Irrigated-tip (n = 17)	P
Previous atrial fibrillation	8 (40%)	5 (30%)	NS
No. of previous antiarrhythmic agents	1.34 ± 1.37	1.55 ± 0.52	NS
No. of previous episodes of atrial flutter	2.75 ± 2.76	2.64 ± 2.62	NS
Organic heart disease	7 (35%)	9 (52%)	NS
Ischemic heart disease	3	4	
Cardiomyopathy	2	2	
Cardiac valve disease	2	3	
Obstructive pulmonary disease	3	4	
Left atrial enlargement	9 (45%)	8 (47%)	NS
Isthmus length (cm)	3.48 ± 0.7	3.19 ± 0.8	NS
LV ejection fraction (%)	51 ± 5.4	50 ± 3.1	NS
Cycle length (ms)	223 ± 27	237 ± 35	NS
Ablation performed during flutter	10 (50%)	10 (59%)	NS

ablation of this zone is used very effectively and extensively, with success rates of more than 85%.^{6,7} The technique is carried out by creating a line of ablation that completely crosses the length and thickness of the cavotricuspid isthmus.⁸ Bidirectional conduction block of the isthmus is the most effective endpoint for verifying the procedure and ensuring long-term success.⁹⁻¹¹

Using the classic procedure with standard catheters, ablation fails to achieve bidirectional block in 5%-15% of cases. In addition, 10% of patients suffer recurrence after verifying bidirectional block of the isthmus.^{12,13} There are many causes that preclude creating an effective ablation line, leaving zones of transitory conduction (*gaps*). The variability of isthmus anatomy, particularly its width and thickness, is one of the most relevant factors.¹⁴ This could explain in part the variability in the number of applications required for ablation and the duration of the procedure, as well as the recurrence rate.

The limitation of standard catheters is that they produce small (5-7 mm) lesions that are insufficient for large isthmuses.^{15,16} Irrigated-tip catheters produce larger and deeper lesions (50% of lesions are transmural, compared with 15% with standard catheters).¹⁷ Preliminary studies of this type of catheters indicate that they have advantages over standard catheters, and improve the success rate of catheter ablation.¹⁸⁻²⁰

The aim of our study is to compare the effectiveness of radiofrequency ablation of the cavotricuspid isthmus using Irrigated-tip catheters compared with standard 4-mm catheters in a prospective randomized study of patients referred for ablation for typical atrial flutter.

PATIENTS AND METHOD

The study included a total of 37 consecutive patients with typical atrial flutter who visited the arrhythmia clinic of the hospital for a first ablation of the cavotricuspid isthmus. The population consisted of 30 males and 7 females ranging in age from 39 to 79 years (mean 62 ± 11). The mean number of episodes of flutter before ablation was 2.7 ± 2.63. Forty-three percent (17/37) of the patients had organic heart disease, most frequently ischemic heart disease (19%).

The patients had used 1.47 ± 0.87 antiarrhythmic drugs. In addition, 13 patients (35%) had experienced episodes of paroxysmal atrial fibrillation. The general characteristics of the two groups are shown in table 1.

A total of 20 patients were assigned randomly to ablation with a conventional 4-mm catheter (Cordis Webster® or Mariner®, Medtronic) and the remaining 17 patients were assigned to ablation with a liquid-cooled 4-mm catheter (Chilli® Cardiac Pathways). There were no significant differences between the two groups in gender, age, etiology of heart disease, use of antiarrhythmic agents, or presence of atrial fibrillation (Table 1).

Radiofrequency ablation protocol

The ablation of the atrial flutter circuits was carried out during tachycardia. However, if the patient presented sinus rhythm and the existence of typical flutter had been documented electrocardiographically, ablation was performed during atrial pacing. Activation through the cavotricuspid isthmus was demonstrated with conventional electrophysiological

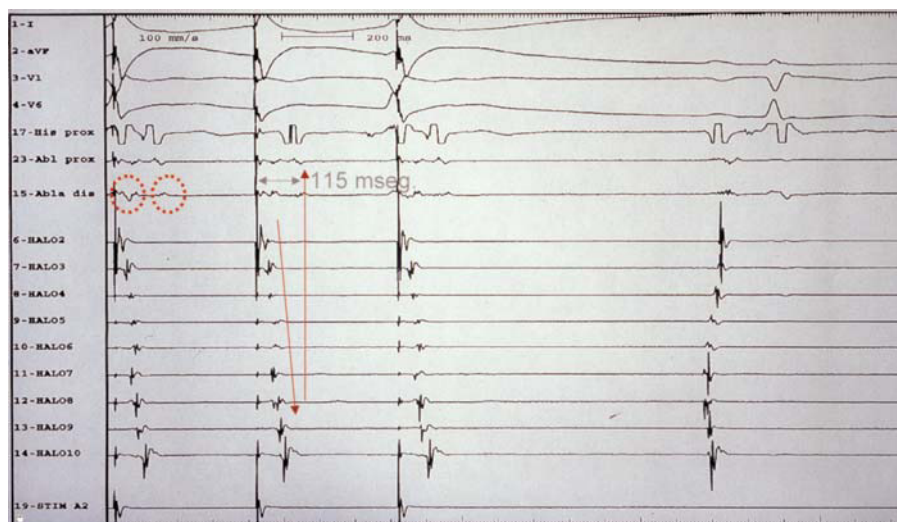


Fig. 1. Confirmation of bidirectional block of the cavotricuspid isthmus after an ablation procedure by stimulation in the coronary sinus and sequential proximal-to-distal activation of the Halo catheter. The appearance of double potentials separated 115 ms was detected in the ablation catheter.

cal mapping techniques using the Halo catheter and quadripolar catheters.²¹ Endocardial electrograms were recorded on a Cardiolab multichannel polygraph, version 4.1. The ablation technique used in both groups was point-by-point application of radiofrequency to create lesions forming an uninterrupted line around the isthmus, then confirming bidirectional isthmus block.

The default application of radiofrequency was 60 s, maximum temperature 70°C, for the standard catheters. A Stockert® (Cordis) or Ataker® (Medtronic) generator was used.

Irrigated-tip catheters were used for 60-s applications with a default energy of 25 W. Depending on the difficulty in achieving isthmus blockade, the energy was increased to 50 W. Saline solution was circulated at 36 ml/min with an infusion pump (model 8004, Cardiac Pathways) during radiofrequency application. The temperature was monitored with a thermocouple sensor on the electrode tip, which interrupted the application when temperatures over 50°C were detected. The voltage, current, temperature, and impedance were recorded for each application. Long venous sheaths were used in the patients in which an adequate contact and stability in the isthmus were not achieved with any of the catheters.

The patients received a protocol of oral anticoagulants similar to that of atrial fibrillation²² 3-4 weeks before and 4 weeks after ablation, maintaining INR for 2 to 3 weeks. Oral anticoagulants were replaced by low-molecular-weight heparin 2 days before the procedure, then resumed the day after the procedure.

The endpoint of the electrophysiological study was bidirectional isthmus block, which was confirmed by the mapping activation fronts during sequential pacing from the lower right lateral atrium

and coronary sinus near the line of ablation (Figure 1).⁹ The creation of a complete line of blockade was defined by recording double potentials along the ablation line.²³ After concluding the procedure, we waited 30 min before checking the stability of the block. The time of the procedure was defined from the moment access was obtained for introducing the catheter until the isthmus block was verified, excluding the 30-minute wait.

Post-ablation care

The hospital stay was 24 to 48 h, with a daily ECG and physical examination, as well as continuous monitoring of the sinus rhythm to detect recurrence or other arrhythmias (atrial fibrillation). Patients were released without antiarrhythmic drugs, unless required for atrial fibrillation. One month later, patients were followed-up in the clinic by echocardiography and 24-h ambulatory Holter recording. Oral anticoagulants were discontinued at this visit, if possible. Unless new events appeared, patients were scheduled for follow-up at 6 months and one year, which consisted in an interview, physical examination, and ECG.

Statistics

Data are expressed as mean \pm standard deviation. Continuous variables were compared using the two-sided Student t test. Values of $P < .05$ were considered statistically significant. Categorical variables were described in terms of absolute frequency and relative frequency, in percentages, and were analyzed with the χ^2 test. In all cases, an alpha level of 5% was established for the two-sided formulation.

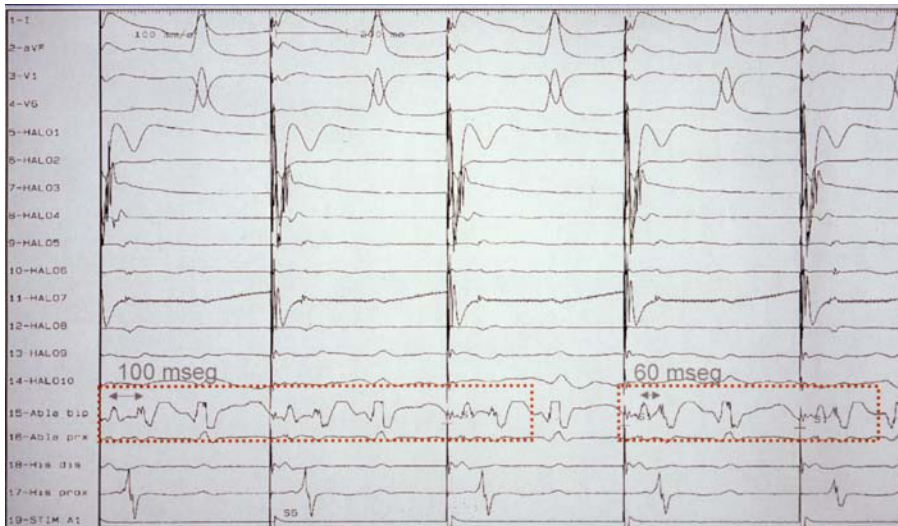


Fig. 2. Transitory block of the cavotricuspid isthmus during an ablation procedure with a standard 4-mm catheter. The difference in potentials is appreciated with recovery of conduction through the cavotricuspid isthmus. After numerous applications, we switched to a Irrigated-tip catheter, which finally produced complete isthmus block. DP1 indicates first double potential; DP2, second double potential.

RESULTS

Efficacy

Both catheters had high success rates (Table 2), although the Irrigated-tip catheters achieved demonstrated isthmus block in all 17 patients in which it was used (100%). In the 2 patients in which bidirectional block was not achieved, this was verified using a Irrigated-tip catheter. In one of these patients, only intermittent isthmus block was achieved after various applications (30) and the standard catheter was replaced by a Irrigated-

tip catheter (Figure 2). With the Irrigated-tip catheter, the number of applications decreased significantly, from 19 ± 5 to 8 ± 7 . Although there was no statistically significant difference between the number of ablation lines made during the procedure (1.55 ± 0.67 versus 1.16 ± 0.37), there were differences between the Irrigated-tip and standard catheter in the percentage of patients who achieved isthmus block with the first ablation line (82% versus 60%, respectively). In turn, the duration of the procedure (70 ± 35 min for the Irrigated-tip catheters and 164 ± 56 min for standard catheters)

TABLE 2. Results

	Standard (n = 20)	Irrigated-tip (n = 17)	P
Procedure time (min)	164 ± 56	70 ± 35	< .001
Imaging-guidance time (min)	40 ± 16	16 ± 8	< .001
Isthmus block with one ablation line	12 (60%)	14 (82%)	NS
No. of ablation lines	1.55 ± 0.67	1.16 ± 0.37	< .05
No. of radiofrequency applications	19 ± 5	8 ± 7	< .001
Use of sheaths	2 (10%)	2 (11%)	NS
Success of procedure	18/20 (90%)	17 (100%)	NS
Need for antiarrhythmic treatment at release	5/20 (25%)	5/17 (27%)	NS

TABLE 3. Results

	Standard (n = 20)	Irrigated-tip (n = 17)	P
Temperature (°C)	53 ± 6	34 ± 3	< ,001
Energy (W)	43 ± 6	27 ± 2	< ,001
Maximum impedance (ohms)	137 ± 12	128 ± 6	< ,05
Minimum impedance (ohms)	101 ± 9	103 ± 4	NS

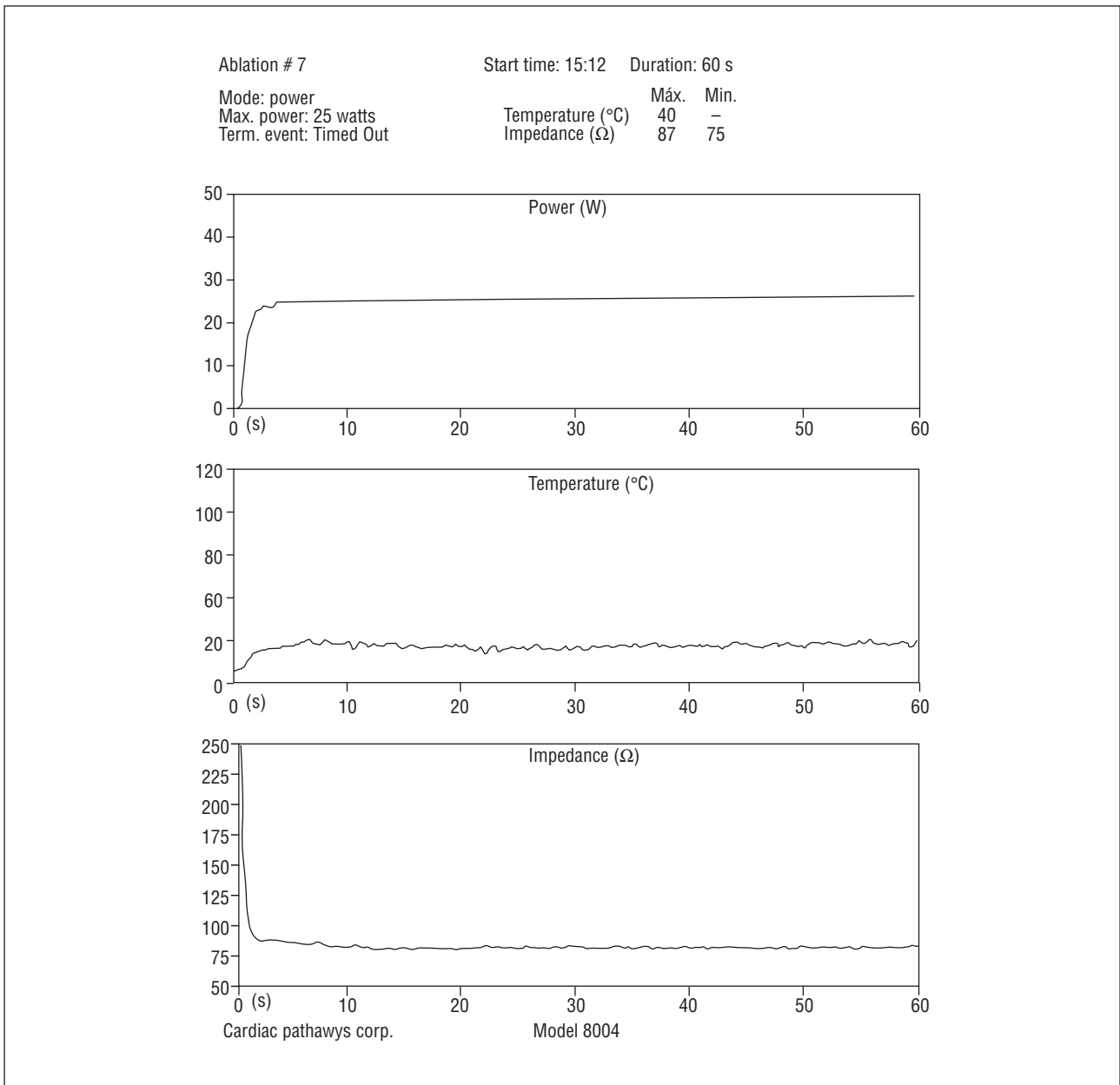


Fig. 3. Graph of a radiofrequency application to the cavotricuspid isthmus, 25 W for 60 s, using a Irrigated-tip catheter. The stability of the temperature of the tip of the catheter is noted, as well as the absence of impedance spikes during application.

and imaging-guidance were significantly shorter with Irrigated-tip catheters (from 40 ± 16 to 16 ± 8). Shafts were used in two patients in each group to stabilize the catheter in the cavotricuspid isthmus.

During the ablation procedure with Irrigated-tip catheters, the mean energy recorded was lower than with standard catheters (27 ± 2 versus 43 ± 6 W, respectively). In turn, higher temperatures were reached with standard catheters ($53 \pm 6^\circ\text{C}$) than with Irrigated-tip catheters ($34 \pm 3^\circ\text{C}$). There were significant differences between catheters in maximum

impedance, but no differences were detected between minimum impedances (Table 3). There was less variation in impedance between applications and patients with the Irrigated-tip than with the standard catheters (Figure 3).

Safety

No major complications appeared with either catheter during or after the procedure. No patient developed clinical or electrocardiographic signs of ischemia.

Follow-up

During a mean follow-up of 8 ± 3 months, there were no recurrences in the group of patients in which ablation was performed with the Irrigated-tip catheter. One patient in the standard-catheter group had a recurrence, evidencing new conduction through the isthmus in the electrophysiological study. A second ablation performed with the Irrigated-tip catheter was successful in this patient.

DISCUSSION

The number of patients referred to electrophysiology laboratories for ablation of the cavotricuspid isthmus in typical atrial flutter is increasing progressively for different reasons: *a)* ablation of atrial flutter is a potentially curative procedure that can eliminate the need for regular administration of antiarrhythmic drugs, and the risk of side effect; consequently, some working groups consider ablation to be the first-choice technique²⁴, and *b)* recent findings from the literature reveal the clinical benefit of a combined approach with ablation and antiarrhythmic drugs in patients with atrial fibrillation and flutter.²⁵ The recurrence rate has decreased in recent years with the use of endpoints based on confirming the bidirectional block created by the ablation line. Recurrence probably reflects the recovery of conduction by the isthmus, although isthmus block is verified at the end of the procedure, so it is important to verify the stability of the block by waiting at least 30 min after the procedure.²⁶ With conventional 4-mm catheters, there is a group of patients (about 10%) in which it is difficult or impossible to achieve bidirectional isthmus block. About 10% of the patients with confirmed bidirectional block experience recurrence of atrial flutter. An important limitation of standard catheters is the small size of the lesion that they create, which makes gaps in the ablation line more likely, as well as acute lesions that recover conduction capacity after the acute inflammatory process disappears. While the ablation line is being made, it is important to recognize that the mere fact that radiofrequency energy is released at the correct point does not ensure that a transmural lesion has been created. The creation of a transmural lesion depends on different factors: the contact surface between the catheter and atrial myocardium, blood flow, irregular energy release due to catheter heating, myocardial thickness, and morphological variations in the size and architecture of the isthmus (long recesses). It is likely that the variability in isthmus anatomy, particularly its width and thickness, is one of the most relevant factors. The mean width of the isthmus is 3.1 ± 0.7

cm (range 1.8 to 5 cm).¹⁴ The variability of the anatomy of the posterior isthmus around the Eustachian crest, the so-called septal isthmus, also affects the functional width of the isthmus and probably conditions the effectiveness of ablation.²⁷ These anatomic and functional differences could explain the different number of applications needed and variations in the duration of the procedure, as well as its rate of recurrence.

The creation of larger lesions than those that can be made with standard catheters has confirmed the clinical importance of lesion size in the ablation of atrial flutter. Thus, the 8-mm catheter has demonstrated its effectiveness and is used routinely in many electrophysiology units, although optimal electrode-tissue contact is necessary and this can sometimes be difficult to achieve. An unstable contact with the atrial tissue reduces energy release,²⁰⁻²² so the catheter that produces the best contact should be used. This, in turn, prevents tip overheating during energy release. A Irrigated-tip catheter makes it possible to create larger and deeper lesions in a safe and effective way, as has been described in an earlier study.¹⁸ It has been demonstrated that cooling the catheter tip allows larger lesions to be made, including a larger percentage of transmural lesions.¹⁷ Cooling the catheter tip by irrigation with saline solution prevents the temperature of the catheter-atrium contact surface from rising. Such temperature elevations are a source of abrupt surges in impedance, which reduce the energy transmitted to the tissue and the size of the lesion. In our study, impedance was significantly lower, allowing more effective energy to be delivered to the atrial tissue. When the temperature of the catheter tip rises to over 50°C, the incidence of impedance surges increases more than 55%.²⁸

Irrigated-tip catheters presented a mean temperature of 34°C compared with 53°C for standard catheters. This facilitates energy release in a more constant, stable, and effective way, and may curtail the appearance of phenomena like thrombus formation and/or charring. The larger lesion volume achieved by the procedure is accompanied by a reduction in the number of applications and ablation lines necessary. Since the lesion is larger, there is less possibility of leaving gaps between cauterized areas, thus theoretically reducing the probability of recurrence. In our study, the mean energy used was 27 W, which was sufficient in most cases and had to be modified for only a few patients.

Over the years, electrophysiology and ablation techniques have evolved and endpoints like bidirectional isthmus block have been defined to ensure that ablation is successful. In our study, Irrigated-tip catheters not only produced more effective ablation,

they reduced the procedure and imaging-guidance times by half, as has been reported in other studies.

Limitations

With respect to study design, it would have been more rigorous to compare the same catheter used with and without a cooling system. However, our intention was to examine the clinical effectiveness and management of these catheters compared with those used in daily practice for the ablation of atrial flutter. Although 8-mm catheters are widely used in many electrophysiology laboratories, when this study was designed the most frequently used catheters were 4-mm catheters. In addition, since the Irrigated-tip catheters are 4 mm, it was thought a 4-mm standard catheter would be the most suitable for analyzing the closed irrigation system, since it would avoid introducing a variable that might obscure the interpretation of results. A more extensive study of these catheters would be appropriate to analyze possible differences in the ablation procedure.

CONCLUSIONS

Irrigated-tip catheters enable the cavotricuspid isthmus to be cauterized safely and effectively. Although the use of standard 4-mm catheters produce bidirectional isthmus block in a high percentage of cases, Irrigated-tip catheters achieve this goal it more effectively with fewer applications, thus allowing the procedure and imaging-guidance times to be reduced. The greatest clinical benefit may be obtained in patients with resistant atrial flutter, in those in which complete bidirectional isthmus block is not achieved or only transitory block is achieved with a standard catheter, probably because the isthmus is long and/or thick.

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