

Ablation of Typical Atrial Flutter: A Prospective Randomized Study of Cooled-tip versus 8-mm-tip Catheters

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Summary

Objective: Both ablation catheters with closed irrigated system and 8mm tip-catheters have been shown to be more effective for typical atrial flutter radiofrequency (RF) ablation when compared to conventional 4 mm tip catheter. Considering the differences in complexity and costs of both systems, a prospective study was designed to compare the efficacy and safety of cooled-tip and 8mm-tip catheters for atrial flutter ablation.

Methods: Fifty-two consecutive patients underwent RF ablation of cavotricuspid isthmus (CTI) for the treatment of typical atrial flutter, using catheter with closed irrigation system (n=26) or 8 mm-tip catheter (n=26). The RF pulses were applied point-by-point for 60 seconds, with power limited at 50 w for the irrigated catheter and by temperature control (60° / 70 w) for the 8mm catheter.

Results: The CTI block was successfully performed in 98.1%. Four patients in the irrigated group needed to switch to the other group. There was no significant difference with regard to ablation parameters, such as total time of RF ablation (591.1±309.0s vs 486.2±250.8s), total procedure duration (86.4±23.6 vs 78.1±22.5min) and time of fluoroscopy (17.0±6.7 vs 15.4±4.6min). During follow-up of 10.6 months in average, one patient in the irrigated group had recurrence of typical atrial flutter.

Conclusion: Efficacy and safety of CTI ablation was comparable between both techniques (irrigated catheter and 8mm-tip catheter). The complexity of irrigated catheter makes it less competitive.

Key words: Atrial flutter, catheterization; electrodes; catheter ablation.

Introduction

Typical atrial flutter is a macroreentrant atrial tachycardia with electrical activation through the cavotricuspid isthmus (CTI)¹, which is a critical part of this circuit¹. According to the electrophysiological mechanism and the anatomical structure, atrial flutter is classified as typical or reverse-typical depending on, respectively, the counterclockwise or clockwise direction of the activation wave through the CTI².

The efficacy of CTI ablation in the treatment of atrial flutter was initially demonstrated using 4-mm-tip electrode catheters³⁻⁷. However, bi-directional block of the CTI required an increased number of RF pulses, and that could not be achieved in 5 to 15% of patients³⁻⁷. In addition, recurrence rate was 10 to 25%³⁻⁷. Those results can be explained by the difficulty in obtaining a continuous, transmural lesion to guarantee a bi-directional block of the CTI with 4-mm-tip catheters³⁻⁷.

Randomized, prospective studies have shown that large-tip electrode catheters^{8,9} or catheters with open or closed irrigated systems^{10,11} are more effective than conventional 4-mm-tip catheters. Some authors consider the irrigated system catheter as the best option for the ablation of CTI¹², while others prefer the 8-mm-tip catheter^{8,9}. Recent studies have not found any

differences between the 2 systems^{13,14}.

Considering complexity and cost differences between cooled and noncooled electrode systems, a randomized, prospective study was designed to compare the efficacy and safety of the cooled-tip catheter (closed system) and the 8-mm-tip catheter for the ablation of CTI.

Methods

Study patients - Between January 2003 and March 2004, 52 consecutive patients were selected (44 males, mean age 56.5 ± 12.9 years) with CTI-dependent atrial flutter. After obtaining written informed consent, the patients were referred for RF ablation. Study protocol was approved by the Heart Institute Scientific Committee – (HCFMUSP) and by the Ethics Committee for the Analysis of Research Projects – CAPPesq – HCFMUSP.

Patients with spontaneous atrial flutter and further electrophysiological validation of the participation of CTI in the arrhythmia circuit were included in the study. Patients who had had previous ablation procedures were excluded.

The patients were chosen randomly for ablation with a cooled-tip catheter (Group I) or for ablation with an 8-mm-tip catheter (Group II).

The clinical characteristics of patients under study are summarized in Table 1. The groups were similar with regard

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to age, gender, and structural heart disease. Ten patients had documented episodes of paroxysmal atrial fibrillation (AF) prior to atrial flutter ablation. Left atrial thrombus was ruled out through transesophageal echocardiography in 32 patients with persistent atrial flutter¹⁵. Antiarrhythmic drugs were discontinued for 5 half-lives before the procedure, with the exception of Amiodarone (61.5% of patients), which was discontinued for 5 days.

Electrophysiological study - The patients were studied while fasting and while sedated with propofol, midazolam, and fentanyl, controlled by an anaesthesiologist. Serum levels of troponin 1 and myocardial bound creatine kinase (CK-MB) were determined before and 12 hours after the procedure.

Three catheter electrodes were inserted via one femoral vein. A multipolar catheter (5-French, 2/8/2 mm, decapolar, St. Jude Medical, INC., MN, USA) was positioned around the tricuspid annulus to record the right atrial activation sequence. A deflectable, 5-French decapolar electrode catheter (5-French, 2/5/2 mm, decapolar, Irvine Biomedical, Inc., CA, USA) was introduced into the coronary sinus with the proximal electrode pair located in the ostial region. The third catheter was positioned in the CTI for RF ablation.

Heparin was administered intravenously (5,000 UI) before RF delivery. If the procedure lasted for more than 1 hour, an additional dose of 2,500U was given.

The registration of the intracavitary potentials was done with a digital system (Electrophysiologic Measurement System – EMS – University of Limberg – The Netherlands) with up to 32 electronic channels simultaneously (12 peripheral and 24 intracavitary) with a cutoff frequency between 50-500Hz and registration speed up to 300mm/s.

If sustained atrial flutter was present at baseline, isthmus dependence was proved by entrainment pacing¹⁶. If only nonsustained counterclockwise atrial flutter was documented, we proceeded with ablation without further attempts of reinduction. In patients with clockwise atrial flutter, proof of isthmus dependence by entrainment²³ pacing was obligatory for inclusion of the patient into the study.

RF ablation - RF pulses was first delivered near the tricuspid annulus, with stable electrograms (atria smaller than the ventricular electrograms). RF pulses were delivered point-by-point for 60 seconds, following a line corresponding to 6 hours from the tricuspid annulus (LAO) until inferior vena cava. No RF ablation was performed in either group on the septal side of the isthmus to minimize the risk of atrioventricular block, lesion of the coronary artery, or myocardial perforation¹⁷.

RF application system - Cooled-tip Catheter (Group I): A closed cooled-tip catheter system (7-French, 4-mm-tip, Chilli Cooled Ablation System, Cardiac Pathways Corporation, Sunnyvale, California, USA) was used in temperature-controlled RF delivery mode, by an RF generator (EPT-1000 XP Cardiac Ablation Controller 110 VAC RF power generator- CA, USA) with a power limit of 50w and a target temperature of 50°C maximum. During ablation, an internal circulating fluid (distilled water) of 36mL/min was infused. Power output started at 25w and was increased in 5-w steps up to 50w every 5 to 10 seconds during RF application when impedance decreased or tended to be stable¹⁸. RF application was stopped when the audible “pop” phenomenon occurred¹⁸ (ie, intratissue explosive vaporization) or when the impedance rose to > 30 Ω. In this situation, the catheter was removed for verification of possible occurrence of charring¹⁸.

Table 1 – Characteristics of the study population

	Cooled-Tip Catheter (Group I)	8-mm-Tip Catheter (Group II)	p Value
Nº. of patients (n)	26	26	
Females	5	3	0.703
Age (years)	55.2 ± 13.7	57.8 ± 12.1	0.476
Typical atrial flutter	24	25	1
Reverse typical atrial flutter	2	1	1
Cycle length (msec)	287.3 ± 48.2	282.9 ± 37.6	0.716
Atrial fibrillation	3	7	0.159
Paroxysmal atrial flutter	10	13	0.402
Incessant atrial flutter	16	13	0.402
Dilated cardiomyopathy	8	5	0.337
Valvular heart disease	1	0	1
Coronary heart disease	2	6	0.248
COPD	1	1	1
Previous cardiac surgery	4*	2†	0.668

*Revascularization of the myocardium, corrective surgery of interatrial communication, valve replacement (1 patient). † Revascularization of the myocardium (2 patients); COPD - chronic obstructive pulmonary disease.

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System with an 8-mm tip catheter (Group II) - In this group, an 8-mm-tip electrode with 2 temperature sensors (7 French Steerable Curve – Dual thermistor quadripolar ablation catheter - Irvine Biomedical, Inc., CA, USA) was used in a temperature-controlled mode with a maximal power output of 70 w and a maximal temperature of 60°C for 60 seconds at each point of application⁸. The catheters were moved in the same way as the cooled-tip ones.

The end point was bidirectional isthmus block. A complete line of block was defined by recording of widely separated (>100 ms), local double potentials alongside the ablation line during atrial pacing^{19,20} and sequence criteria obtained during pacing on both sides of the ablation line according to the following protocol³. First, during atrial pacing with a cycle length of 500 to 600 msec from the low lateral right atrium adjacent to the ablation line, a counterclockwise isthmus block was assumed when activation of the coronary sinus occurred later than the anterior septum as evidence by the His-bundle potential recorded by the ablation catheter⁴. Furthermore, with the ablation catheter positioned over the isthmus ablation line, the second component of the local double potential had to be later than all potentials recorded from the proximal coronary sinus³. Second, during pacing from the coronary sinus ostium, a clockwise block was assumed when a craniocaudal activation sequence of the entire lateral right atrial wall was observed, and the second component of the local double potential recorded by ablation catheter positioned over the ablation line was later than the potential recorded from the lower lateral right atrium³ (Figure 1). The status of the isthmus conduction was reassessed under isoproterenol infusion (1 to 3 µg/min)²¹ and 20 minutes after the last RF applications. The timing of the procedure was counted from the start of the femoral vein

puncturing until the end of the ablation, with final tests and the observation period included. Fluoroscopy time was considered to be from the positioning of the ablation catheter and the RF application until bidirectional block of the CTI was obtained. If 20 RF applications were unsuccessful, the patient crossed over to ablation with the other catheter¹⁰.

Postablation care - Transthoracic echocardiography was performed after ablation. A 12-lead ECG was recorded to ensure that no adverse effects, including silent myocardial ischemia or AV conduction impairment, occurred²². Permanent anticoagulation was performed for 3 months after ablation²³.

Clinical evaluations were done 1, 3, 6, and 12 months after RF ablation. Resting ECG was performed during every visit; 24-hour Holter monitoring was performed at least once, usually 3 months after hospital discharge. If the patient experienced any palpitations, a 24-hour Holter or an event monitor, or both, was used. When RF ablation was successful in patients without previous AF, antiarrhythmic drugs were discontinued.

Continuous variables are expressed as mean ± SD and compared by using the Mann-Whitney rank test. Categorical data were analyzed with the chi-square test with Yate's correction or Fisher's exact test. P<0.05 was considered statistically significant.

Results

Efficacy of atrial flutter ablation - Bidirectional block of the CTI was obtained in 51 patients (98.1%). Procedure showed 4 (15.4%) failures among group I patients, and no failures in group II (p=0.110). These 4 patients from group I, in whom 20 RF applications were unsuccessful, were moved to group

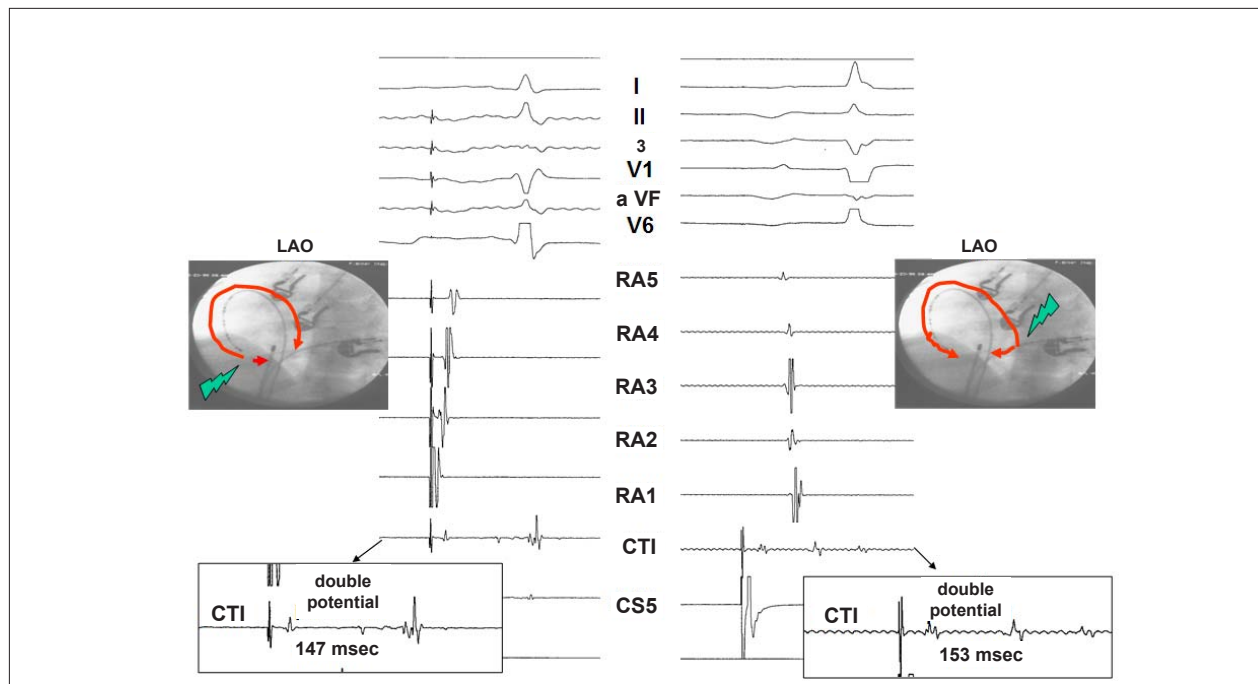


Fig. 1 - Illustration of CTI block: double potential > 100 ms at RF application site when stimulating low right atrium and proximal coronary sinus. LAO – Left anterior oblique; RA - right atrium; CTI - cavotricuspid isthmus; RF - radiofrequency; CS - coronary sinus.

II, and ablation was successful in 3 of them by applying 7, 11, and 2 additional pulses, respectively. Patients in whom success was not achieved remained in therapy to control their heart rate as decided by their doctor.

Analysis of procedural ablation data with regard to the overall number of RF applications, RF application times, and ablation duration revealed significant differences between the closed cooled-tip and 8-mm-tip ablation technique. Analysis of fluoroscopy time showed no differences. In contrast, analysis of all ablation procedures without crossover revealed no significant differences between groups (Table 2).

Safety of ablation - During ablation, charring was observed in the distal tip in the group where the cooled-tip catheter was used (13 patients – 25%). Four patients in group I (15.4%) and 1 in group II (3.8%) reported an audible “pop” phenomenon.

One patient in group II experienced a temporary total transitory atrioventricular block during the manipulation of the catheters. Two patients had a pseudo-aneurysm of the femoral artery afterwards. This was an accidental minor lesion of the artery and needed corrective surgery. Four patients had a haematoma in the area of the puncture and experienced spontaneous resolution. One patient experienced paroxysmal atrial flutter the day after the ablation, with an electrocardiogram effect similar to that of clinical atrial flutter. Two days after the first procedure, we performed another one without reinducing arrhythmia, and the CTI block remained bidirectional. In 1 patient in group II a pericardial effusion was found incidentally at control echocardiography. This did not cause any haemodynamic compromise and resolved spontaneously.

When comparing serum levels of troponin I and CK-MB in both groups before ablation significant increase occurred after ablation procedure ($p < 0.001$; $p < 0.001$ respectively). No significant differences were seen between groups in regard to markers mean values before and after ablation procedure ($p < 0.289$, $p < 0.527$, respectively).

Follow-up - During follow-up of 10.6 ± 3.3 months (median = 10 months), one patient (out of 26 = 3.8%) from group I experienced recurrent atrial flutter 11.6 months after the procedure. Eleven patients needed antiarrhythmic drugs in the follow-up due to episodes of symptomatic AF recorded on the 24-hour Holter and/or 12-lead ECG. Out of 11 patients (21.6%) with AF during follow-up, 9 (81.8%) had no previous arrhythmia. **One patient from group II** reported emergency hypertension condition 6 months after the procedure, triggered by a cerebrovascular accident turned into haemorrhage.

Discussion

This randomized study demonstrated that cooled-tip and 8-mm catheters are equally efficient and safe for atrial flutter catheter ablation. Both techniques had excellent results in terms of immediate success and low arrhythmia recurrences. Moreover, no serious complications occurred and both ablation techniques were safe.

Comparison with other studies - Evidence shows that ablation of CTI with both irrigated^{10,12} and 8-mm-tip catheters⁹ is superior to ablation with 4-mm-tip conventional catheters. This superiority is obtained through techniques that optimize the application of RF to obtain larger diameter and deeper injury, while at the same time minimizing impedance increase due to the formation of clots on the tip of the catheter electrode and the presence of charred tissue^{23,24}.

Irrigated ablation system efficacy may be influenced by a number of factors: contact between tissue and the electrode²⁵, irrigation flow direction, how long it takes to cool²⁶, and the type of irrigation (open or closed)²⁶. In our study, closed irrigation with distilled water was used, at room temperature and 36 ml/min flow^{13,14}.

Experimental studies have demonstrated that both open and closed systems produce similar injuries in regard to depth and extension, and are equally safe depending on irrigation flow level²⁶.

In 8-mm-tip electrode catheters, the deep, extended injuries are caused by 2 mechanisms²³. First, a greater area between the blood-electrode interface, due to the size of the electrode, especially in high blood flow regions as the area of the CTI, causes cooling of the electrode, which can free up more energy²³. Second, parallel orientation of the electrode in relation to the tissue causes a greater area of the tissue to be cauterized²³.

Safety of ablation - Charring with cooled-tip catheters could be observed in 25% of patients and an audible pop in 15.4%. In the 8-mm group, 3.8% of patients had pop phenomenon and no charring. Schreieck et al¹⁴ reported a 4% incidence of audible pops in patients undergoing cooled-tip catheter ablation for AF and 6% charring with 8-mm-tip catheters. Jaïs et al¹² and Schreieck et al¹⁴ limited temperature to 42 and 48°C, respectively, to minimize such complication.

The optimal method for adjusting power during saline irrigation RF ablation has not yet been clearly defined. Stevenson et al²⁴ suggest performing ablation in a power-controlled mode, typically starting at 20-30 w and gradually increasing power to achieve evidence of tissue heating or damage.

Table 2 - Procedural parameters of ablation (without crossover)

	Cooled-Tip Catheter (n=22)	8-mm-Tip Catheter (n=26)	p Value
RF applications	10.9±5.5	8.2±4.2	0.058
RF application time (sec)	591.1±309.0	486.2±250.8	0.200
Procedure duration (min)	86.4±23.6	78.1±22.5	0.220
Fluoroscopy time (min)	17.0±6.7	15.4±4.6	0.345

As for markers of myocardial damage, Brueckmann et al²⁸ reported a significant increase in mioglobine after RF ablation with 8-mm-tip catheters (50-60w power and 70°C temperature). Our study demonstrates a significant increase in troponin I and CK-MB levels in both groups, but with no statistical differences between cooled-tip and 8-mm tip catheters. Dorwarth et al²⁹ have demonstrated that that the irrigation system causes lesions with similar diameters, but significantly deeper than lesions caused by the 8-mm tip catheter; however, lesion volume was not significantly different between the 2 types of catheters.

As demonstrated in other randomized studies^{13,14}, the 2 techniques (cooled-tip catheter system versus catheter with the 8-mm electrode tip) are equivalent in regard to safety, efficacy, immediate success, and arrhythmia recurrence, as well as in total RF application time and fluoroscopy time. As far as ease of operation, the 8-mm tipped catheter is easier when

compared to the cooled-tip catheter, since the latter needs irrigation apparatus, constant attention towards irrigation flow, distilled water supply, and the ability to manually start and stop irrigation during RF application.

Conclusion

CTI ablation was effective and safe for the control of atrial flutter with both cooled-tip and 8-mm-tip ablation catheter techniques. Considering the greater operational complexity required for cooled-tip catheters, the use of 8-mm-tip catheters for RF ablation of CTI is preferable.

Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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