Randomized Comparison of Multipolar, Duty-Cycled, Bipolar-Unipolar Radiofrequency Versus Conventional Catheter Ablation for Treatment of Common Atrial Flutter

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Comparison of Radiofrequency Versus Conventional Catheter Ablation. ***Introduction:*** **Radiofrequency (RF) catheter ablation has been established as an effective and curative treatment for atrial flutter (AFL). Approved methods include a drag-and-drop method, as well as a point-by-point ablation technique. The aim of this study was to compare the acute efficacy and procedural efficiency of a multipolar linear ablation catheter with simultaneous energy delivery to multiple catheter electrodes against conventional RF for treatment of AFL.**

Methods: **Patients presenting to our department with symptomatic, typical AFL were enrolled consecutively and randomized to conventional RF ablation with an 8-mm tip catheter (ConvRF) or a duty-cycled, bipolar-unipolar RF generator delivering power to a hexapolar tip-versatile ablation catheter (T-VAC) group. For both groups, the procedural endpoint was bidirectional cavotricuspid isthmus block.**

Results: **Sixty patients were enrolled, 30 patients each assigned to ConvRF and T-VAC groups. Total procedure time (40.2 ± 15.8 min vs 60.5 ± 12.7 min), energy delivery time (8.5 ± 3.7 min vs 14.7 ± 5.2 min), radiation dose (14.5 ± 3.5 cGy/cm^2 vs 31.7 ± 12.1 cGy/cm^2), and the minimum number of RF applications needed to achieve block (4.2 ± 2.4 vs 8.9 ± 7.2) were significantly lower in the T-VAC group. In 7 patients treated with the T-VAC catheter, bidirectional block was achieved with less than 3 RF applications, versus no patients with conventional RF energy delivery.**

Conclusion: **The treatment of typical AFL using a hexapolar catheter with a multipolar, duty-cycled, bipolar-unipolar RF generator offers comparable effectiveness relative to conventional RF while providing improved procedural efficiency.** *(J Cardiovasc Electrophysiol, Vol. 21, pp. 1109-1113, October 2010)*

arrhythmia, atrial flutter, catheter ablation, cavotricuspid isthmus

Introduction

Radiofrequency (RF) catheter ablation has been established as an effective treatment for atrial flutter (AFL), with good long-term outcomes and low procedural complications.[1,2] Creation of a line of block at the cavotricuspid isthmus using RF energy eliminates a critical limb of the reentrant circuit, thus successfully terminating the arrhythmia. Acute termination of the arrhythmia and chronic procedural success is predicated on successful production of a complete line of electrical block by the ablation catheter—failure to do so predisposes the patient to arrhythmia recurrence. Established protocols for creating this line include a "drag-and-drop" method, a gradual linear repositioning of the catheter from the tricuspid valve annulus to the inferior vena cava (IVC) during single applications of RF energy, or a point-by-point ablation technique, during which single discrete RF lesions are placed in series. While outcomes have been good, efforts continue to develop technologies that decrease procedure and fluoroscopy time while maintaining and potentially improving efficacy. Recently, an RF catheter and generator system (Medtronic Ablation Frontiers, Carlsbad, CA, USA) has been introduced that allows simultaneous unipolar and bipolar energy delivery to multiple-catheter electrodes.[3] Conventional unipolar application provides familiar depth of lesion, while bipolar energy delivery between electrodes provides continuity of the lesion, providing the ability to place a line of block with single RF applications. The aim of this study was to compare the acute efficacy and procedural efficiency of a multipolar linear ablation catheter against conventional RF for treatment of AFL.

Methods

Study Population

From January 2008 to October 2008, 60 patients presented with symptomatic, typical AFL. Diagnosis of typical AFL was made by 12-lead electrocardiogram. More than half (55%) of the patients had failed antiarrhythmic

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TABLE 1
Patient Characteristics and Results

Patient Demographics and Ablation Outcomes	8 mm	T-VAC	P-value
n (patients)	30	30	NS
Male/Female	25 / 5	22 / 8	NS
Age (years)	69 ± 3	65 ± 8.5	NS
Failed antiarrhythmic drugs (n)	1.2 ± 0.5	1.1 ± 0.6	NS
Total procedure time (min)	60.5 ± 12.7	40.2 ±15.8	0.04
RF time (min)	14.7 ± 5.2	8.5 ±3.7	0.02
Radiation dose (cGy/cm^2)	31.7 ± 12.1	14.5 ± 3.5	<0.001
RF applications (60 seconds)	8.9 ± 7.2	4.2 ± 2.4	<0.001
Bidirectional isthmus block (Yes/No)	30/30	29/30	NS
Average number of RF applications to achieve Block	18	12	<0.001
Recurrence after 4-month follow-up (n)	2	2	NS
Bidirectional block achieved with less than three RF applications	0	7	<0.01
Bidirectional block achieved with single-energy delivery	0	2	<0.01

T-VAC = tip-versatile ablation catheter; RF = radiofrequency; NS = not significant.

medications before ablation. Study population is described in Table 1. Prior to the ablation procedure, patients were randomized 1:1 to conventional RF ablation with an 8-mm tip catheter (ConvRF) or a duty-cycled, bipolar-unipolar RF generator delivering power to a hexapolar tip-versatile ablation catheter (T-VAC – Medtronic Ablation Frontiers, Carlsbad, CA, USA). Patients were consecutively enrolled and provided written informed consent per institutional protocol.

Electrophysiology study

Transesophageal echocardiography was performed prior to the procedure to exclude the presence of atrial thrombi.[4] A diagnostic electrophysiologic study was performed in each patient following appropriate sedation and anticoagulation. Diagnostic catheters were placed to record local electrograms at the His, tricuspid annulus, and within the coronary sinus (CS). These were continuously monitored and recorded (Prucka, GE Medical, Waukesha, WI, USA) along with the surface electrocardiogram.

Conventional mapping was performed with a 20-polar diagnostic "halo" catheter (Biotronic GmbH, Berlin, Germany/Viacath 20 pol.) If the patients came with AFL, different mapping techniques were used to confirm "typical" AFL. Otherwise, patients were induced into AFL. If they were not inducible, a pacing maneuver to confirm conduction was performed.

In 59 of 60 patients, AFL at the beginning of the ablation procedure was inducible or already present. In these cases entrainment mapping to confirm typical AFL was possible. With involvement of the cavotricuspid isthmus confirmed as the critical isthmus, RF applications were initiated at the tricuspid annulus after a stable electrocardiogram was observed with a small atrial and large ventricular potential at the distal tip. The endpoint of the procedure was a line of conduction block from the IVC to the tricuspid annulus, and from the tricuspid annulus to the CS ostium.

Ablation Techniques

Conventional group

Patients randomized to the ConvRF group underwent ablation using a 7F 8-mm tip quadripolar catheter (Scorpion, Bard, MA, USA) and a conventional unipolar RF generator (HAT 300 HF Generator, Osypka, Rheinfelden, Germany). RF energy was delivered for 60-second increments while performing a slow drag of the catheter tip from the tricuspid annulus toward the IVC. The average drag time was 30 seconds. Point-by-point ablation was employed when small conduction gaps were identified by pacing and/or mapping. The power parameters were in the conventional group: 50W; 65°C.

T-VAC group

Patients randomized to the T-VAC group underwent ablation using a 9F hexapolar catheter with asymmetric bidirectional steering (T-VAC, Medtronic Ablation Frontiers). The 6 electrodes all contain 2 thermocouples, on opposite sides of the ring face, each directed toward the endocardial surface when the device is steered, allowing optimal sensing of endocardial surface temperature. The electrodes are 100% platinum, with a 4-mm tip electrode and five 2-mm band electrodes, all on 3-mm intra-electrode spacing (Fig. 1). RF was delivered from a multichannel, duty-cycled, bipolar/unipolar generator that has been previously described for use in multielectrode ablation of atrial fibrillation (AF).[5,6] The generator delivers energy in a temperature-controlled, power-limited manner. When used with the T-VAC device, the generator will deliver sufficient power to reach the user-defined target temperature, but only up to a maximum of 45 W at the tip and 20 W for each ring. As a result of this configuration, a 30-mm-long contiguous linear lesion can be created with one RF application (Fig. 1). The ratio of unipolar to bipolar was set to 2:1. It was not necessary to position the distal electrode into pouch/diverticulum but lay the entire catheter in a flat fashion across the isthmus. In the present study, all lesions were delivered with a target temperature of 60°C with energy duration (60 seconds in all cases). While delivering RF, the T-VAC position was not altered. Because the device creates a deep and long lesion with each energy delivery, complete cavotricuspid isthmus block is conceptually possible with one RF application.[7]

To avoid the gaps in the isthmus the T-VAC catheter was not just laid on the isthmus, rather it was pressed on the isthmus by pulling caudally the entire catheter.

There is potential risk to withdraw the catheter by pulling. In both groups, no long sheaths were used.

Procedural Endpoint

For both groups, the procedural endpoint was bidirectional cavotricuspid isthmus block. Isthmus block was confirmed when pacing from the proximal CS ostium resulted in a craniocaudal activation sequence of the entire lateral right atrial wall. For all patients, when pacing from the proximal CS ostium, isthmus block was assumed when pacing from the proximal CS ostium resulted in a craniocaudal activation sequence of the lateral right atrial wall. Craniocaudal activation may be present with slow conduction across a small gap in the isthmus. A block across tricuspid annulus to CS was confirmed by pacing at the CS ostium and the activation

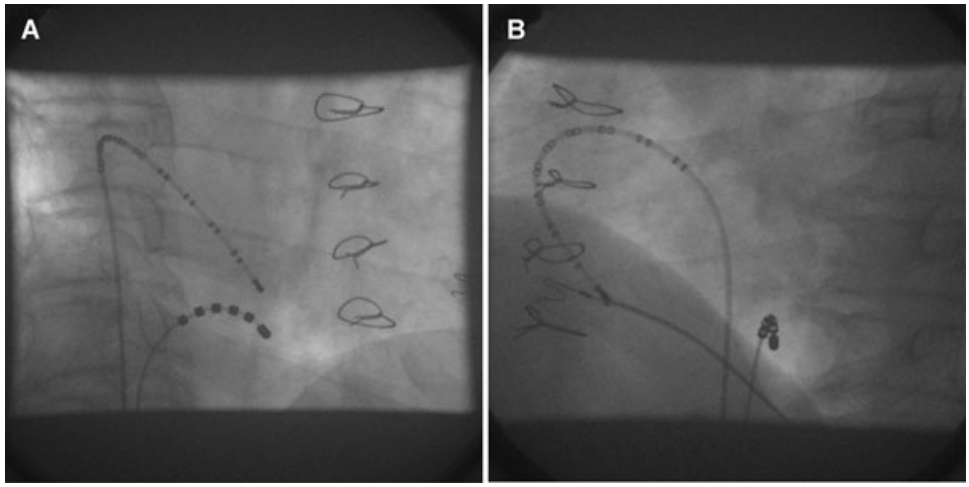

Figure 1. *(A and B) The tip-versatile ablation catheter (T-VAC) is positioned for ablation at the isthmus.*

sequence between CS and low right atrium. For the T-VAC group, local double potentials along the ablation line could be observed during atrial pacing in the low right atrium. In this case, block was assumed when the second component of the local double potential recorded by the T-VAC, positioned over the ablation line, was later than the potential recorded from the low lateral right atrium.[8] Additionally, by pacing from the low lateral right atrium adjacent to the ablation line, a counterclockwise block was confirmed by a previously described differential pacing method.[9] The waiting phase after confirming bidirectional block was 20 min. Any procedure-related complications were noted. Procedural data related to efficiency were recorded, including duration, radiation exposure, and applied RF energy.

Recurrent atrial fibrillation was documented with holter electrocardiogram (ECG) during follow-up time in 3 of 30 (10%) in the RF group and in 4 of 30 (13.3%) in the T-VAC group. Event monitoring was not performed so that asymptomatic episodes were not detected.

Patients, pain during ablation was measured with a common score (visual analog scale).[10]

Results

Sixty patients were enrolled, with 30 patients each assigned to ConvRF and T-VAC groups. No procedural complications or adverse events at follow-up were noted in either group. There were no significant differences regarding age, gender, acute success in achievement of bidirectional block, or follow-up recurrence. Significant differences were demonstrated in several procedure-related parameters. Total procedure time, radiation dose, the average number of RF applications, and minimum number of RF applications needed to achieve block were all significantly lower in the T-VAC group (Table 1). Energy delivery time in the T-VAC group was 8.5 ± 3.7 min compared to 14.7 ± 5.2 ($P < 0.02$) in the ConvRF group (Fig. 2A). Procedure duration was 40.2 ± 15.8 min versus 60.5 ± 12.7 min ($P < 0.04$) for ConvRF (Fig. 2B).

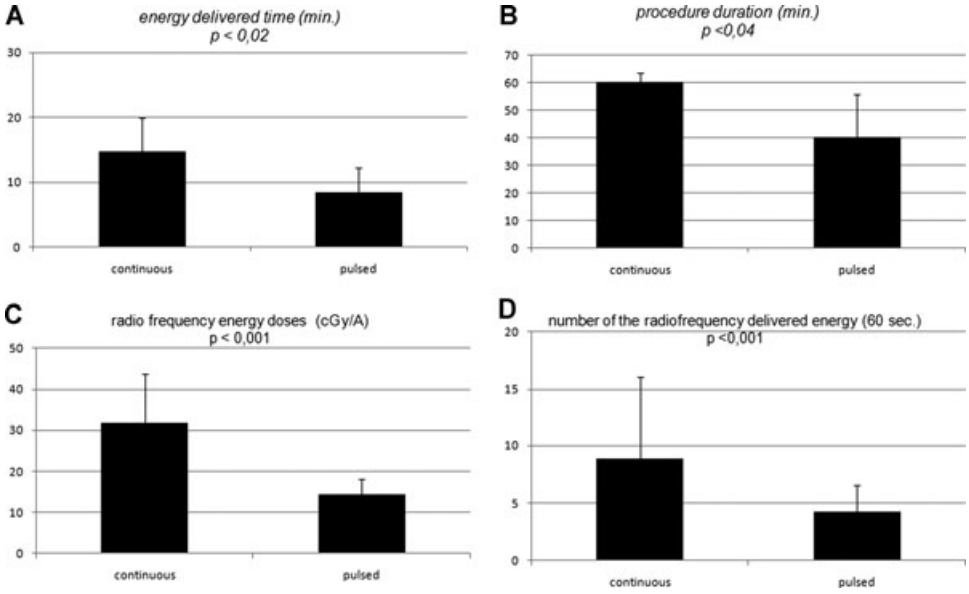

Figure 2. *(A-D) Relevant procedure data: "continuous vs duty cycled."*

Finally, total radiation dose was lower in T-VAC (14.5 ± 3.5 cGy/cm^2) compared to ConvRF (31.7 ± 12.1 cGy/cm^2) (Fig. 2C). Importantly, the minimum number of RF applications needed to achieve block was significantly lower in the T-VAC group (4.2 ± 2.4 vs 8.9 ± 7.2, $P < 0.001$) (Fig. 2D). In 7 patients in the T-VAC group (23%), bidirectional block was achieved with less than 3 RF applications.

Follow-Up

Patients were discharged home following echocardiogram and electrocardiogram controls, and the AA medication was stopped. All patients were on anticoagulation medication (aspirin or warfarin) regarding the European Society of Cardiology (ESC) guidelines. The patients were seen out of hospital after 1 week (symptomatic interrogation and clinical examination), and after 4 months (Holter ECG, respectively). Documented AFL was counted as a recurrence and procedural failure.

Four patients (2 in both groups) had recurrence of AFL during follow-up time of 4 months (3 of them documented in the Holter ECG and in one case on a 12-lead ECG). No other atrial tachycardia occurred. Any adverse event that could be attributed to the ablation procedure was not observed. All 4 patients were symptomatic.

Discussion

We prospectively compared to conventional RF the effectiveness and procedural efficiency of a novel multipolar RF system for the curative treatment of typical AFL. This multipolar RF system can simultaneously deliver energy to all electrodes on a linear array resulting in a linear ablation lesion. Given the procedural goal of creation of an anatomical line of conduction block, the utility of such a linear ablation device is compelling. In this study, patients were randomized 1:1 against the conventional unipolar-only RF technique. Even with a relatively modest patient population of 30 per group, there were significant decreases in procedure time, RF time, and fluoroscopy exposure—suggesting that the multipolar ablation technique increases the efficiency of AFL treatment. Since bidirectional block could be achieved with less than three RF applications, the system appears capable of effectively creating durable linear lesions, which may be of clinical benefit. In 2 cases, single RF application with T-VAC was sufficient to achieve bidirectional block.

Study Limitations

Intended as an initial report describing the utility of a novel multielectrode RF catheter for patients with AFL, this study has some limitations. The purpose of the study was to evaluate the acute endpoint of bidirectional block and parameters related to procedural efficiency in a moderate sample size of 60 patients. A recently published meta-analysis of more than 150 published studies, analyzing approximately 10,000 patients undergoing ablation for AFL, reported success rates greater than 90% with complication rates of 2.6%.[11] In the present study no complications were observed and each group had 2 patients with AFL in follow-up. Although randomized against a well-established therapeutic option, this study was not powered to significantly demonstrate long-term safety and efficacy compared to conventional methods. A larger study would be required to prove safety and efficacy benefit.

Follow-up time was relatively short at 4 months. However, previous studies have shown that the recurrence rate of AFL does not increase significantly with time, implying that an extended evaluation period would not provide additional clinical relevance.

We did not compare the T-VAC results with irrigated tip ablation. In 2004, Scavee *et al.* from Haissaguerre's laboratory concluded some advantages for externally irrigated ablation of AFL when compared with 8 mm RF ablation.[12] This might also be a limitation of this study due to the fact that the advantages of T-VAC over 8 mm may not be similar for T-VAC compared to externally irrigated RF. For example, these data demonstrated number of RF applications, RF duration, fluoroscopy duration, and procedural times with externally irrigated tip catheter ablation and even 8-mm catheter RF ablation that are comparable to or even better than results reported in the current manuscript with T-VAC.

We also did not compare the T-VAC technique with the maximum-voltage-guided (MVG). With this technique the authors were able to achieve a bidirectional block with a mean ablation time of 6.85 min.[13]

Finally, the study did not evaluate the optimal energy modes and ablation parameters of the multichannel RF system. For example, adjusting the duration of energy delivery, changing the unipolar:bipolar ratio, and/or setting a different target temperature might create a more effective lesion, and thus further reduce the RF time. Further studies are warranted for determining the optimum settings for ablation in the cavotricuspid isthmus.

Conclusions

Treatment of typical AFL is safe and effective using a hexapolar catheter with a multipolar, duty-cycled, bipolar-unipolar RF generator. Significant improvements in procedural efficiency were observed when compared against conventional, unipolar-only RF delivered to an 8-mm tip catheter.

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