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Original article

Efficacy and safety comparison between different types of novel design enhanced open-irrigated ablation catheters in creating cavo-tricuspid isthmus block

Rikuta Hamaya (MD), Shinsuke Miyazaki (MD)*, Takatsugu Kajiyama (MD), Tomonori Watanabe (MD), Shigeki Kusa (MD), Hiroaki Nakamura (MD), Hitoshi Hachiya (MD), Yoshito Iesaka (MD)

Cardiovascular Center, Tsuchiura Kyodo Hospital, Tsuchiura, Ibaraki, Japan

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ABSTRACT

Background: Clinical utility of irrigation-tip ablation catheters for cavo-tricuspid isthmus (CTI) ablation is established. Recently, new-generation enhanced-cooling irrigation-tip catheters were introduced into clinical use. This study compared the performance of different types of novel irrigation-tip catheters in CTI ablation.

Methods: One hundred patients undergoing CTI ablation with novel irrigated-tip catheters were included. Ablation was performed with a power output of 30–35 W using either 4-mm flexible tip catheters [FlexAbility (FAs) St. Jude Medical, St. Paul, MN, USA] or 3.5-mm enhanced-cooling ring-tip catheters without [ThermoCool SurroundFlow (SFs), Biosense Webster, Diamond Bar, CA, USA] and with contact force sensing [ThermoCool SmartTouch SurroundFlow (STSFs), Biosense Webster] in 32, 34, and 34 patients, respectively.

Results: The successful CTI block creation rate was significantly higher for FAs than SFs/STSFs [32/32 (100%), 30/34 (88.2%), and 27/34 (79.4%), $p = 0.006$]. In all 11 failed procedures, block was created by additional 5 (2–7) applications with 8-mm tip catheters. The radiofrequency (RF) application number ($p = 0.001$) and energy ($p = 0.021$) were significantly lower, and total RF time ($p = 0.005$) and procedure time ($p = 0.036$) significantly shorter in the FA than SF/STSF groups. The FA catheter was associated with significantly higher tip temperature readings (34.9 °C vs. 32.0/33.0 °C, $p < 0.001$) and lower initial impedances than SF/STSF catheters (both $p < 0.001$). The tip temperature reached the maximum temperature setting in 15/295 (5.1%) FA catheter applications among 11 (34.3%) patients, 0/521 (0%) ST applications, and 0/448 (0%) STSF applications. The mean RF power achieved during RF applications was significantly lower for FA than SF/STSF catheters (28.6 W vs. 30.4/30.8 W, $p < 0.001$). Audible steam pops were detected in 1/448 applications in only the STSF group.

Conclusions: In human CTI ablation, flexible irrigation-tip catheters showed a significantly better performance than rigid enhanced-cooling irrigation-tip catheters.

Introduction

The cavo-tricuspid isthmus (CTI) between the tricuspid valve and inferior vena cava is the established target for creating linear conduction block during catheter ablation of atrial flutter [1,2]. The anatomy in this area is highly variable in individual patients, and indeed intertrabecular recesses, trabecular bridges, and sub-Eustachian recesses are identified in 10–50% of the patients within this area [3,4]. These anatomical variations make creating linear conduction block more challenging. Previous studies evaluated the efficacy of several types of ablation catheters, and showed that the irrigation-tip catheters and conventional 8-mm tip catheters are similarly more effective than non-irrigated 4-mm tip catheters for CTI ablation [5,6].

Recently, new-generation irrigation-tip ablation catheters have been introduced to improve the irrigation efficacy while preserving the lesion size and depth, and are becoming the standard tools for

* Corresponding author at: Cardiology Division, Cardiovascular Center, Tsuchiura Kyodo Hospital, 4-1-1 Otsuno, Tsuchiura, Ibaraki 300-0028, Japan.
E-mail address: mshinsuke@k3.dion.ne.jp (S. Miyazaki).

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atrial fibrillation ablation. However, an alteration in the catheter tip design to permit for a reduced irrigation may alter the lesion generation and safety profile. Some experimental studies have compared the lesion size, safety, and procedural parameters between these new catheters in animal models [7–10]. However, few data are available focusing on the direct comparison of the performance between the different novel irrigation-tip catheters in human CTI ablation. This study aimed to evaluate the performance of the different types of the latest open-irrigated catheters available on the market in creating CTI block.

Methods

Study population

This study consisted of 100 consecutive patients undergoing CTI ablation using novel open-irrigation tip catheters. CTI block was created with either a 4-mm flexible tip catheter [FlexAbility (FA), St. Jude Medical, St. Paul, MN, USA] in 32 patients (Group FA), 3.5-mm enhanced-cooling ring-tip catheter [ThermoCool Surround Flow (SF), Biosense Webster, Diamond Bar, CA, USA] in 34 patients (Group SF), or 3.5-mm enhanced-cooling ring-tip catheter with a contact force sensor in 34 patients [ThermoCool SmartTouch Surround Flow (STSF), Biosense Webster] (Group STSF) (Fig. 1). The ablation catheter was selected per the operator's preference. All patients gave their written informed consent. The study protocol was approved by the hospital's institutional review board. The study complied with the Declaration of Helsinki.

Ablation protocol

All anti-arrhythmic drugs were discontinued for more than five half-lives prior to the procedure. A 7 Fr 20-pole three-site mapping catheter was inserted through the right jugular vein, and the eight distal electrodes were positioned in the coronary sinus (CS). In patients with paroxysmal atrial fibrillation (AF), a sole pulmonary vein isolation was performed using an irrigated-tip catheter or cryoballoon catheter (Arctic Front Advance, Medtronic, Minneapolis, MN, USA). In patients with persistent AF, additional substrate modification was performed in the left atrium (LA) if AF did not terminate during the pulmonary vein isolation [11]. Following the LA ablation, a 10-pole mapping catheter was positioned in the lateral right atrium (RA). The surface electrocardiogram and bipolar endocardial electrograms were continuously monitored and recorded (Bard Electrophysiology, Lowell, MA, USA). The activated clotting time was maintained at >300 s throughout the procedure. The intracardiac electrograms were filtered from 30 to 500 Hz and measured at a sweep speed of 100 mm/s. The system was configured to monitor and provide the mean power, temperature, and impedance during each radiofrequency (RF) application.

Subsequently, a CTI ablation was performed under electrophysiological and fluoroscopic guidance during pacing from the proximal coronary sinus or low lateral RA. In all groups, the ablation was performed from the ventricular aspect to the inferior vena cava by point-by-point RF applications with a duration of 30–50 s each. A long sheath (SL0, AF Division, SJM, Minneapolis, MN, USA) was used to stabilize the ablation catheter in all, while a steerable sheath was not used in any cases. A temperature-controlled RF delivery was performed with a power output of 30–35 W, and the temperature limit was 42 °C in the FA group and 40 °C in the SF/STSF groups. Following the manufacturers' recommendation, the irrigation flow rate was 8 ml/min (<39 °C) and 13 ml/min (>39 °C) for the FA catheter, and 8 ml/min (<30 W) and 15 ml/min (>30 W) for the SF/STSF catheters. The procedural endpoint was the creation of a bidirectional CTI block as described elsewhere [2]. In the case of a failed isthmus block, at the physician's discretion, the catheter was exchanged for a dumbbell shaped 8-mm tip catheter (Ablaze, Japan Life Line, Tokyo, Japan).

Statistical analysis

Continuous data are expressed as the mean ± standard deviation for normally distributed variables or as the median [25th, 75th percentiles] for non-normally distributed variables, and were compared using a Student's *t*-test or Mann–Whitney *U*-test, respectively. Categorical variables were compared using the chi-square test. A probability value of $p < 0.05$ indicated statistical significance.

Results

Patient characteristics

The clinical characteristics of the study population are summarized in Table 1. There was no significant difference between the groups for the clinical characteristics except for the LA diameter.

Procedural results

CTI block was successfully created by the initial catheter in 32 (100%), 30 (88.2%), and 27 (79.4%) patients in Groups FA, ST, and STSF, respectively ($p = 0.006$), and the success rate was significantly higher in Group FA than in Group SF ($p = 0.019$) and Group STSF ($p = 0.002$) (Fig. 2). The detailed procedural parameters of the first catheter in the 3 groups are shown in Table 2. There was a

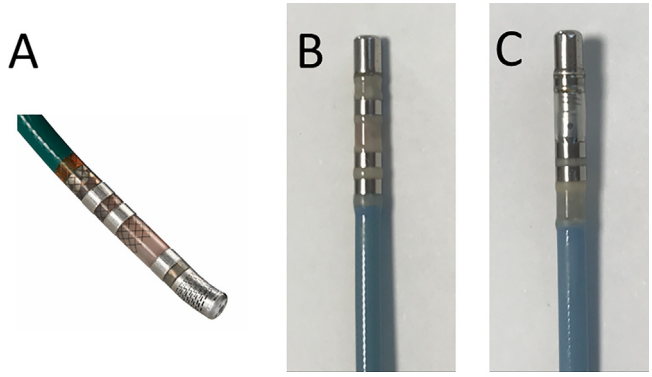

Figure 1. The tip of the novel-irrigated ablation catheters. (A) A 4-mm flexible tip catheter (FlexAbility, St. Jude Medical, St. Paul, MN, USA). (B) A 3.5-mm enhanced-cooling ring-tip catheter (ThermoCool Surround Flow, Biosense Webster, Diamond Bar, CA, USA). (C) A 3.5-mm enhanced-cooling ring-tip catheter with a contact force sensor (ThermoCool SmartTouch Surround Flow, Biosense Webster).

Table 1
Characteristics of the study population.

	FA	SF	STSF	*p*-Value
N	32	34	34	
Age, years	61.9 ± 12.3	65.8 ± 10.1	63.7 ± 10.1	0.339
Female, *n* (%)	7 (21.9%)	8 (23.5%)	11 (32.3%)	0.576
Hypertension, *n* (%)	12 (37.5%)	14 (41.2%)	15 (44.1%)	0.861
Body mass index, kg/m^2	24.1 ± 3.1	24.0 ± 4.3	25.4 ± 3.8	0.190
LA diameter, mm	38.1 ± 6.3	42.7 ± 7.3	40.9 ± 6.0	0.026
LV ejection fraction, %	62.8 ± 11.3	63.4 ± 8.1	62.5 ± 9.2	0.937

FA, FlexAbility, St. Jude Medical, St. Paul, MN, USA; SF, ThermoCool Surround Flow, Biosense Webster, Diamond Bar, CA, USA; STSF, ThermoCool SmartTouch Surround Flow, Biosense Webster; LA, left atrial; LV, left ventricular.

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