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ORIGINAL PAPER

First clinical experience of a dedicated irrigated-tip radiofrequency ablation catheter for the ablation of cavotricuspid isthmus-dependent atrial flutter

Sven Knecht[1,2] · Fabian Burch[1] · Tobias Reichlin[1,2] · Florian Spies[1,2] · Aline Mühl[1,2] · David Altmann[3] · Peter Ammann[3] · Beat Schaer[1,2] · Stefan Osswald[1,2] · Christian Sticherling[1,2] · Michael Kühne[1,2]

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Abstract

Background Different types of irrigated-tip ablation catheters are available for ablation of atrial flutter (AFL). The aim of this study was to compare an established with a novel dedicated Gold irrigated-tip catheter for ablation of AFL.

Methods and results We compared consecutive patients undergoing ablation of AFL using a standard 3.5 mm irrigated-tip platinum–iridium (Pt–Ir) catheter (Thermocool, TC-group) and a 3.5 mm irrigated gold-tip catheter (Gold-group) specifically designed for cavotricuspid isthmus ablation (CTI). The primary endpoint was acute efficacy (net RF time) to achieve block across the CTI. Secondary endpoints included procedure time, fluoroscopy duration, complications, and recurrence of AFL.153 patients (age 68 ± 11 years, 74% male) were included. Net RF time to achieve CTI block was not different between the TC-group (793 ± 503 s) and the Gold-group (706 ± 422 s; $p=0.406$). Total procedure time was not significantly different between the TC-group (70 ± 26 min) and the Gold-group (70 ± 27 min; $p=0.769$). A significant difference between the groups was identified for the fluoroscopy duration (TC-group: 934 ± 537 s, Gold-group: 596 ± 362 s, $p<0.001$). There were no major complications observed in the groups. Recurrence of AFL occurred in 3 of 66 (5%) in the TC-group and in 2 of 87 (2%) in the Gold-group ($p=0.652$).

Conclusions In conclusion, acute and chronic efficacy of the irrigated Pt–Ir and gold-tip catheters were comparable. However, the dedicated catheter design was associated with decreased fluoroscopy duration.

Keywords Atrial flutter · Radiofrequency ablation · Catheter ablation · Irrigated gold-tip

Introduction

Radiofrequency (RF) catheter ablation of the cavotricuspid isthmus (CTI) for the treatment of typical atrial flutter (AFL) is an established procedure and has been routinely performed since the early 1990s [1, 2]. At that time, non-irrigated 4 mm tip catheters with low power settings (16–30 Watts) were used to create a contiguous lesion between the tricuspid annulus and the inferior vena cava to obtain a line of block at the level of the CTI. With the aim of increasing the efficacy and efficiency of the ablation procedure, different modifications have been introduced. These include the size, the design and the material of the catheter tip, the choice of energy source, and adding internal or external cooling of the electrode using irrigation [3–5]. Compared to platinum–iridium (Pt–Ir) alloy tips, gold-tip catheters were presumed to create more effective RF lesions due to the superior heat conductive behavior of gold [6]. This was confirmed in a comparison with a non-irrigated Pt–Ir tip catheter, where the use of a non-irrigated gold-tip catheter was associated with a higher ablation success rate and a lower incidence of char and coagulum formation [7]. Beside the tip design and material properties, the mechanical catheter behavior including the stability of the shaft has a potential impact on

Sven Knecht and Fabian Burch contributed equally to this manuscript.

✉ Michael Kühne
michael.kuehne@ubs.ch

1 Cardiology/Electrophysiology, University Hospital Basel, University of Basel, Petersgraben 4, 4031 Basel, Switzerland

2 Cardiovascular Research Institute Basel, University Hospital Basel, University of Basel, Basel, Switzerland

3 Cardiology/Electrophysiology, Kantonsspital St. Gallen, St. Gallen, Switzerland

the efficacy and safety of ablation of AFL. This aspect has been addressed with the recently released dedicated flutter ablation catheter on the platform of an irrigated 3.5 mm gold-tip catheter (AlCath Flutter Flux G eXtra, Biotronik, Berlin, Germany).

The aim of this comparison was to compare the efficacy and safety of an established open-irrigated catheter commonly used for RF ablation for the treatment of AFL with a dedicated flutter catheter with an irrigated gold-tip.

Methods

Consecutive patients with a 12-lead ECG documentation of typical AFL referred for CTI ablation between December 2012 and April 2015 were included in the study. For the retrospective analysis, patients below 18 years of age, patients undergoing concomitant pulmonary vein isolation and patients with a history of a previous right atrial procedure were excluded from the analysis. The study protocol complies with the Declaration of Helsinki and informed consent was obtained from all patients and the study was approved by the local ethics committee. Two different types of open-irrigated catheters were used in the study: (1) TC-group: a standard 6-hole 3.5 mm irrigated-tip Pt–Ir catheter (Celsius Thermocool® (TC), F-curve, Biosense Webster, Diamond Bar, CA, USA) and (2) Gold-group: a 12-hole 3.5 mm irrigated gold-tip catheter dedicated for ablation of atrial flutter (AlCath Flutter Flux G eXtra, Black-curve, Biotronik, Germany) (Fig. 1), introduced in November 2013 replacing the Pt–Ir catheter at our centre. Compared to other established irrigated catheters, this catheter was designed with improved shaft braiding and a reduced length of the catheter of 95 cm.

Fig. 1 Irrigated-tip ablations catheters used. Left: Celsius Thermocool (TC-group) catheter; right: AlCath Flutter Flux G eXtra catheter (Gold-group)

Electrophysiologic procedure

A deflectable diagnostic electrophysiology catheter was positioned in the coronary sinus for pacing. If the patient was in AFL, the ablation catheter was positioned at the CTI to perform an entrainment maneuver at the isthmus for confirmation of CTI-dependent AFL. The ablation catheter was positioned at the ventricular aspect along the CTI at a 6 o'clock position under fluoroscopic guidance. Standard power was 35 Watts with a maximum temperature of 48 °C in power controlled mode, but increasing or reducing power was allowed at the physician's discretion. As recommended by the respective manufacturers, the irrigation fluid flow rate during ablation was set to 30 ml/minute. The idle flow rate was 2 ml/minute. During ablation, the ablation catheter was gradually retracted to the inferior vena cava. After termination of atrial flutter, the CTI line was checked for unidirectional block during pacing from the proximal electrode of the catheter within the coronary sinus. For block confirmation, a descending wave front along the lateral wall to the ablation lesion assessed using the ablation catheter and an interval between the double potential along the lesion > 90 ms was required. If complete block could not be documented, ablation was continued during pacing from the coronary sinus until complete block was reached. In patients with sinus rhythm at the beginning of the procedure, the ablation was performed during pacing from the coronary sinus until complete block was reached. If termination of atrial flutter or complete block along the CTI could not be achieved after the first pass, the catheter was repositioned at the ventricular side of the CTI and withdrawn along the line to identify gaps. If complete CTI block could not be achieved within up to 15 min of net RF time, the use of a steerable long sheath (Agilis NxT, St Jude Medical, St. Paul, MN, USA) to improve stability and maneuverability was allowed according to our local protocol. A switch to a different ablation catheter was allowed if CTI block could not be achieved within a total of 30 min of net RF time. Final testing for bidirectional block was performed at least 10 min after the last RF delivery.

Study endpoints

The primary endpoint was the net duration of RF energy delivery to achieve complete conduction block across the CTI (net RF time). The secondary endpoints of the study were the recurrence of atrial flutter during a follow-up of 6 months, total duration of the procedure (time on the table), fluoroscopy duration, time from the first to the last RF energy application, the need of a steerable sheath, the need for switching to another ablation catheter, and the occurrence of complications. The biophysical parameters (temperature, impedance, power, energy) were analyzed descriptively.

Follow-up

Patients were discharged the day after the procedure. Clinical and ECG follow-up was performed 6 months after ablation at an outpatient clinic to identify any recurrences of AFL.

Statistical analysis

Baseline characteristics as well as biophysical parameters were summarized for the two catheter groups reporting mean ± standard deviation for continuous variables and frequencies and percentages for categorical variables. Statistical comparisons were performed using Mann–Whitney *U* tests and Chi-squared tests, respectively. To investigate potential temporal effects not related to the introduction of the dedicated flutter catheter, both groups were split into half and individual comparison between the 4 groups was performed. To graphically display the primary endpoint we show Kaplan–Meier curves for net duration of the RFA procedure for both catheter type and applied a log-rank test to compare the curves.

Table 1 Baseline characteristics

Variable	TC-group, $n=66$	Gold-group, $n=87$	p value
Age (years)	66 ± 11	70 ± 10	0.130
Male [n (%)]	49 (74)	64 (74)	0.925
Weight (kg)	84 ± 21	82 ± 19	0.889
Height (cm)	175 ± 8	173 ± 9	0.160
CHA_2DS_2-VASc			0.707
0	8	7	
1	8	9	
2	15	14	
3	15	22	
4	11	21	
≥ 5	8	15	
LVEF (%)	52 ± 12	50 ± 13	0.338
Hypertension	47 (71)	63 (72)	0.870
Diabetes	9 (14)	15 (17)	0.431
Hypercholesterolemia	20 (30)	35 (40)	0.205
Smoking	10 (15)	13 (15)	0.971
Previous smoker	21 (32)	28 (32)	0.962
HCD	4 (6)	13 (15)	0.083
CAD	25 (38)	29 (33)	0.560
VHD	16 (24)	26 (30)	0.439
DCM	2 (3)	2(2)	0.779
Family history of CVD	13 (20)	15 (17)	0.562

LVEF left ventricular ejection fraction, *HCD* hypertensive cardiovascular disease, *CAD* coronary artery disease, *CVD* cardiovascular disease, *VHD* valvular heart disease, *DCM* dilated cardiomyopathy

Results

Study subjects

Baseline characteristics of the 153 patients are shown in Table 1. Mean age was 68 ± 11 years and 74% of the patients were male. Of the 153 patients, 66 were in the TC-group (43%) and 87 in the Gold-group (57%). Of the 66 patients, 7 were treated using the Pt–Ir catheter after the introduction of the gold-tip catheter in November 2013 based on catheter availability. All interventions were performed by five experienced physicians, of whom two performed 74% of all ablations.

Primary endpoint

The mean net RF duration to achieve complete block was 793 ± 503 s in the TC-group and 706 ± 422 s in the Gold-group ($p=0.406$). The net RF duration of the two catheters shows a comparable temporal dynamic as a function of the cumulative proportion of achieved CTI block as shown in Fig. 2.

Secondary Endpoints

The mean total procedure time (defined as time on the examination table) was not significantly different between the 2 groups (TC-group: 70 ± 26 min; Gold-group: 70 ± 27 min, $p=0.769$). The time needed to perform the ablation (total RF delivery time from the first to the last energy application) was 30 ± 21 min for the TC-group and 28 ± 20 min for the Gold-group, respectively ($p=0.484$). Total fluoroscopy duration was significantly lower ($p<0.001$) in the Gold-group compared to the TC-group (596 ± 362 s and 934 ± 537 s, respectively) (Table 2). Individual analysis of the 4 sub-groups revealed that fluoroscopy duration was significantly reduced with the introduction of the dedicated flutter catheter in November 2013 (Fig. 3). Fluoroscopy duration of the 7 Pt–Ir catheters used after the introduction of the dedicated gold-tip catheter was 957 ± 667 s, similar to the procedures using Pt–Ir catheters before the introduction of the gold-tip catheter.

A steerable long sheath was used in 21 patients (32%) in the TC-group, and in 19 patients (22%) in the Gold-group, without significant differences between groups ($p=0.195$).

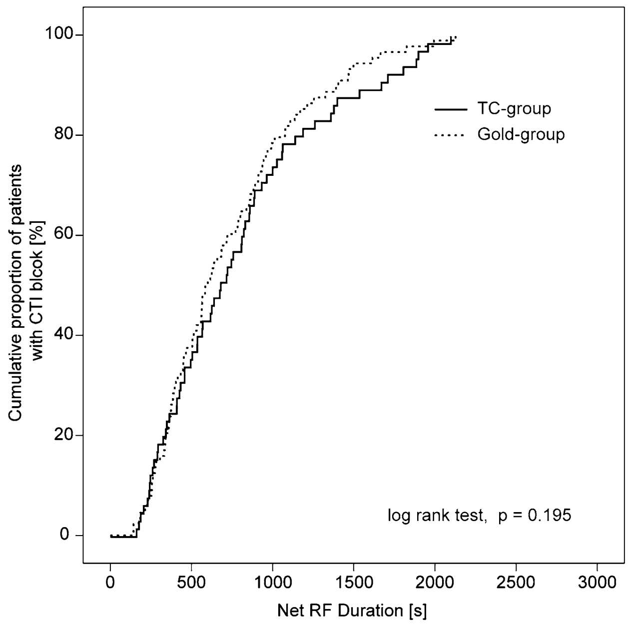

Fig. 2 Cumulative success in achieving CTI block as function of the net RF duration

Switching to another ablation catheter during the procedure was performed in 1 patient in the Gold-group (1.1%), with a technical problem with the irrigation system. No complications were observed. Recurrence of atrial flutter was not different between the groups and occurred in 3 of 66 patients (5%) in the TC-group, and in 2 of 87 patients (2%) in the Gold-group ($p = 0.652$).

Biophysical parameters

Mean average and mean maximum temperature were 38.5 ± 2.6 and 46.9 ± 5.9 °C for the TC-group, and 35.0 ± 2.5 and 40.6 ± 5.7 °C for the Gold-group (Table 2). Mean average and mean maximum impedance were 116 ± 10 and 164 ± 27 Ω for the TC-group, and 112 ± 11 and 157 ± 25 Ω for the Gold-group. Mean average and mean maximum power were 29.7 ± 2.9 watts and 34.4 ± 4.6 watts for the TC-group, and 30.8 ± 3.1 watts and 34.2 ± 4.7 watts for the Gold-group. The mean energy applied was 23,722 ± 15,572 joules for the TC-group, and 21,841 ± 13,802 joules for the Gold-group, respectively.

Discussion

In this comparison, we assessed the efficacy and safety of a dedicated irrigated gold-tip flutter ablation catheters compared to an established Pt–Ir irrigated-tip catheter commonly used for RF ablation of CTI-dependent AFL. The main findings of this study are: (1) Both ablation catheters were highly effective for ablation of AFL and there were no significant differences with regard to acute efficacy (net RF time). (2) There were no major complications in the groups. (3) The recurrence rate of atrial flutter at 6 months was 2–5% overall and there were no significant differences between the groups suggesting a high chronic efficacy for both catheters. (4) The use of the dedicated irrigated gold-tip flutter ablation catheter was associated with shorter fluoroscopy duration.

Typical AFL is a common arrhythmia and can be treated by ablation of the isthmus between the tricuspid annulus and the inferior vena cava with a reported success rate of > 90% and a low complication rate [8]. Creating a transmural lesion along the entire isthmus may be challenging due to variations in CTI anatomy preventing contact and therefore transfer of sufficient energy to the tissue. Although imaging studies to better define the CTI have been performed [9, 10], most prior studies have focused their investigations on different types of catheter tip sizes, designs and the type of energy used for ablation. Cryoablation for atrial flutter has been shown to be effective and well tolerated, but appears to be associated with longer procedure duration and ablation times and in some studies also a decreased success rate compared to RF ablation [4, 11, 12].

Table 2 Procedural and biophysical parameters

Variable	TC-group, $n = 66$	Gold-group, $n = 87$	p value
RF duration (s)	793 ± 503	706 ± 422	0.406
Total procedure time (min)	70 ± 26	70 ± 27	0.769
Total RF delivery time (min)	30 ± 21	28 ± 20	0.484
Total fluoroscopy duration (s)	934 ± 537	596 ± 362	< 0.001
Temperature (°C)	38.5 ± 2.6	35.0 ± 2.5	< 0.001
Max. temperature (°C)	46.9 ± 5.9	40.6 ± 5.7	< 0.001
Impedance (ohms)	116 ± 10	112 ± 11	0.012
Max. impedance (ohms)	164 ± 27	157 ± 25	0.120
Power (W)	29.7 ± 2.9	30.8 ± 3.1	0.310
Energy (J)	23,722 ± 15,572	21,841 ± 13,802	0.657

Max maximal, *RF* radiofrequency

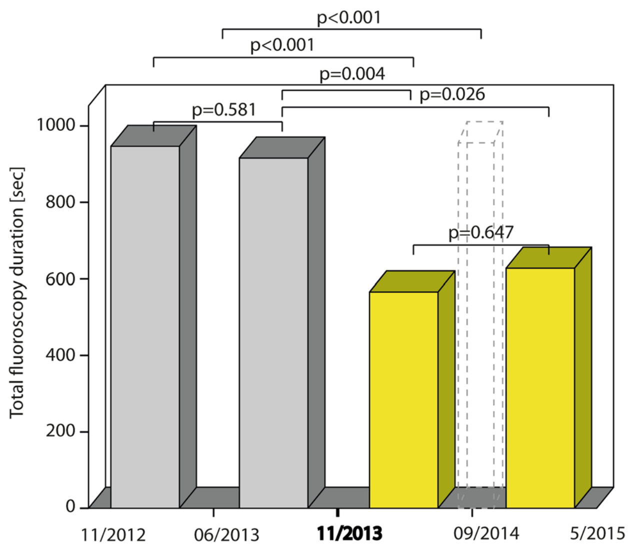

Fig. 3 Fluoroscopy duration for the divided standard Pt–Ir (grey bars) and dedicated irrigated gold-tip flutter catheter (yellow bars) over the duration of the study. The irrigated gold-tip flutter catheter was introduced in November 2013 replacing the irrigated Pt–Ir catheter. Transparent dashed bar reflects the fluoroscopy duration of the 7 Pt–Ir catheters used during the period of the gold-tip catheter

For RF ablation, the lesion size depends on the amount and density of the energy transferred from the catheter tip to the tissue. This is determined by the preset power defined by the ablation generator, the contact area (and tip design) defining the fraction of the preset energy delivered to the tissue and the stability of the contact over time.

To prevent catheter tip overheating during energy application which limited the preset power delivery of the generator, irrigated-tip (cooled-tip) RF ablation catheters were introduced. In a randomized controlled trial using 4 mm tip electrodes, Jais et al. showed that irrigated-tip catheters were more effective and more efficient in reaching complete isthmus block during ablation of typical AFL [3]. Although, in a randomized comparison of an extra-large (10 mm) tip catheter with an open-irrigated tip catheter, complete CTI could be achieved more rapidly with the 10 mm tip catheter [13], regular size irrigated-tip catheters (4 mm) are still frequently used for their good signal quality, e.g., when identifying gaps in ablation lines.

Gold-tip electrodes were introduced as a novel “deep lesion” technology for RF catheter ablation [6]. Because of the thermal conductivity of gold that is almost four times higher compared to Pt–Ir, it was hypothesized that gold catheters would create deeper lesions. An in vitro study with non-irrigated catheters, comparing lesion depths in pig hearts confirmed this and showed significantly deeper lesions of nearly 5 mm with gold-tip compared to only close to 3 mm depth with Pt–Ir catheters [6]. These findings could be reproduced in a second in vitro study with non-irrigated catheters, but the difference in lesion depth disappeared when comparing irrigated tip catheters [14]. In a clinical trial, comparing non-irrigated 8 mm tip gold to Pt–Ir catheters, the primary endpoint of cumulative RF time to achieve complete isthmus block was not different between groups, but total acute success rate was higher (94%) with the non-irrigated gold-tip catheter compared to the non-irrigated Pt–Ir tip catheter (89%) [7].

To our knowledge, this is the first study comparing the dedicated flutter catheter with a 12-hole irrigated gold-tip and catheter shaft modifications to an established 6-hole irrigated Pt–Ir tip catheter for ablation of AFL. Our study reflects the in vitro results of Linhart et al. in that the enhanced thermal conductivity of gold does not increase the performance of a catheter when the tip is cooled by external irrigation [14] despite significant differences in the biophysical parameters. Furthermore, the number and distribution of the irrigation holes did not seem to affect the efficacy or safety of AFL ablation. No charring of the catheter tip was observed in any of the patients.

To ensure good tissue contact, advanced contact force sensing catheters are currently available. However, in a recent study, real-time contact force monitoring resulted in similar net RF times required to complete CTI block compared to our study where no contact force sensing catheters were used [15]. Furthermore, most notably, clinical outcomes were as well not different.

Apart from catheter tip design, cooling, and contact, the catheter stability is important during CTI ablation. In a small randomized study with 40 patients, the use of a steerable sheath was associated with significant reduction of net RF duration to achieve complete CTI block [16]. In our study, we only used steerable sheaths when complete CTI block could not be reached after a pre-defined ablation duration, and although there were numerically fewer steerable sheaths used in the gold-group, this difference was not statistically significant. A catheter-specific aspect that can improve stability is the design of the catheter shaft itself. This point was addressed when designing the irrigated gold-tip catheter used in this study by improving lateral stabilization of the tip segment by high-density braiding and shortening of the shaft. However, these features did not result in significant differences in the primary endpoint and none of the secondary endpoints except for fluoroscopy duration. Whether the decrease in fluoroscopy duration was due to the abovementioned mechanical enhancements and a resulting improved stability and steerability on the CTI cannot be proven, but is conceivable. This is further supported by the non-gradual decrease of fluoroscopy duration over time shown in Fig. 3 and the data of the 7 Pt–Ir irrigated used after the introduction of the gold-tip catheter.

Limitations

This is a single-center, retrospective comparison focusing solely on two irrigated-tip catheters. Interventions were performed by 5 experienced electrophysiologists following all the above described protocol. However, selective analysis of the two physicians performing together 74% of the ablations resulted in the same observations that a difference between the two catheter types could only be observed for the fluoroscopy duration.

Since this is a retrospective analysis of consecutive patients, a temporal bias might have occurred due to a learning curve of the operators. But this impact seems to be negligible as shown by the analysis of the data in quartiles revealing only a significant difference in fluoroscopy duration with the introduction of the dedicated flutter catheter but not in the other procedural parameters. However, to confirm our observation, larger, randomized multicenter studies are needed.

Conclusion

In this comparison of an established irrigated-tip catheter with a dedicated catheter designed for ablation of AFL, acute and chronic efficacy of a standard Pt–Ir catheter and a gold-tip catheter were comparable. However, the irrigated gold-tip catheter was associated with a shorter fluoroscopy duration.

Compliance with ethical standards

Conflict of interest Sven Knecht—received compensation for advisory boards with Boston Scientific and Biotronik. Fabian Burch—no conflict of interest. Aline Mühl—no conflict of interest. Florian Spies—no conflict of interest. Tobias Reichlin—no conflict of interest. Beat Schaer—no conflict of interest. David Altmann—no conflict of interest. Peter Ammann—no conflict of interest. Stefan Osswald—no conflict of interest. Christian Sticherling—Advisory Board of Medtronic and Biotronik, received educational grants from Biotronik and research Grant from Biosense Webster (outside the submitted work). Michael Kühne—proctor for Medtronic, speakers bureau for Boston Scientific, St Jude Medical, and Biotronik.

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Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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