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Complications in Catheter Ablation of Atrial Fibrillation in 3,000 Consecutive Procedures

Balloon Versus Radiofrequency Current Ablation

K.R. Julian Chun, MD, Laura Perrotta, MD, Stefano Bordignon, MD, Jan Khalil, MD, Daniela Dugo, MD, Athanasios Konstantinou, MD, Alexander Fürnkranz, MD, Boris Schmidt, MD

ABSTRACT

OBJECTIVES The aim of this study was to identify predictors of cardiac tamponade (CT) during atrial fibrillation (AF) ablation using different technologies and strategies.

BACKGROUND The major cause of death during catheter ablation of AF is related to CT. The risk for CT may be linked to different procedural steps (transseptal puncture, catheter manipulation during left atrial and pulmonary vein mapping and ablation).

METHODS All AF ablation procedures undertaken from May 2010 to July 2015 at a single center were included. Two ablation groups were defined: group A, radiofrequency current, and group B, balloon. Group A was divided into groups A1 (pulmonary vein isolation [PVI] only) and A2 (PVI plus additional ablation). In group A, 2 transseptal punctures were performed, followed by wide-area circumferential point-by-point PVI (group A1) within a 3-dimensional left atrial map and complex fractionated atrial electrograms and/or linear lesions (group A2). In group B, 1 transseptal puncture by balloon-based PVI (cryoballoon, laser balloon). All episodes of CT were analyzed.

RESULTS In total, 3,000 AF ablation procedures were performed, 2,125 in group A (group A1, n = 1,559; group A2, n = 566) and 875 in group B (cryoballoon, n = 589; laser balloon, n = 286). The rate of CT was 1.1% (32 of 3,000) and was significantly lower in group B than in group A: 0.1% (1 of 875) versus 1.5% (31 of 2,125) (p = 0.001). The reduced CT risk remained if PVI only (group B vs. group A1) was compared: 0.8% (13 of 1,559) versus 0.1% (1 of 875) (p = 0.024). The greatest CT risk was seen in group A2: 3.2% (18 of 566). Radiofrequency current ablation beyond PVI was a predictor of CT.

CONCLUSIONS The risk for CT in patients undergoing AF ablation at a single high-volume center was decreased with the use of balloon catheters. Extensive radiofrequency current ablation beyond PVI leads to an increased perforation risk. (J Am Coll Cardiol EP 2017;3:154-61) © 2017 by the American College of Cardiology Foundation.

Catheter ablation of atrial fibrillation (AF) has been established as an effective therapeutic option in patients with symptomatic AF (1). However, AF ablation remains a complex procedure linked to potentially life-threatening complications. Cardiac tamponade (CT) (2) has been identified as the major cause of death during AF ablation (3). Therefore, strategies to minimize and manage this complication are clearly warranted. Traditionally, manual left atrial (LA) mapping and "point-by-point" radiofrequency current (RFC) energy ablation has been performed as the standard approach to achieve the endpoint of pulmonary vein isolation (PVI) (4). Novel ablation technologies using balloon-based energy deployment

From Cardioangiologisches Centrum Bethanien, Medizinische Klinik 3, Markuskrankenhaus, Frankfurt am Main, Germany. Drs. Fürnkranz, Bordignon, and Chun have received speaking honoraria from Medtronic. Dr. Chun has received speaking honoraria from Biosense Webster. Dr. Schmidt has received speaking honoraria from Cardiofocus. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose. Drs. Chun and Perrotta contributed equally to this work. All authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the *JACC: Clinical Electrophysiology* author instructions page.

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have been introduced to facilitate the ablation procedure (5,6). Moreover, recently published data indicate that additional ablation beyond PVI does not contribute to an improved outcome but may complicate the procedure (7). We therefore sought to identify predictors of CT during AF ablation using different ablation technologies and ablation strategies.

METHODS

DATABASE. All AF ablation procedures performed at Cardioangiologisches Centrum Bethanien between May 2010 and July 2015 were prospectively collected in the center's ablation registry. Prior to ablation, written informed consent was obtained. All baseline characteristics and procedural data, including ablation technique, first or repeat procedure number, complications, and acute outcomes, were noted. If CT occurred, detailed complication management information was available.

Two groups of procedures were defined according to the ablation technology used: group A, RFC ablation, and group B, balloon ablation. Group A consisted of groups A1 (PVI only) and A2 (PVI plus). In group A1, the procedural endpoint was confined to PVI. In group A2, additional ablation beyond PVI, including complex fractionated atrial electrograms (CFAEs) and/or linear lesions, was performed according to the operator's discretion.

ELECTROPHYSIOLOGICAL STUDY AND TRANSSEPTAL PUNCTURE. After written informed consent was obtained, all patients underwent transesophageal echocardiography before the procedure. Before ablation, uninterrupted oral anticoagulation (OAC) therapy was allowed, targeting an international normalized ratio of 2.0 to 2.5. Novel OAC was stopped at 24 h before ablation. All procedures were performed under deep sedation using midazolam, fentanyl, and a continuous infusion of propofol. Two standard diagnostic electrophysiological catheters were positioned at the His bundle region and inside the coronary sinus to visualize anatomic landmarks before pressure-guided transseptal puncture.

RFC POINT-BY-POINT PVI (GROUP A). Two SL1 sheaths (St. Jude Medical, St. Paul, Minnesota) were advanced to the left atrium using a modified Brockenbrough technique. After transseptal catheterization, intravenous heparin was administered, targeting an activated clotting time of 300 s (30-min intervals). Transseptal sheaths were continuously flushed with heparinized saline. Selective PV angiograms were obtained in all patients in standard angulations (right anterior oblique, 30°; left anterior oblique, 40°). Three-dimensional electroanatomic LA reconstruction using either CARTO 3 (Biosense Webster, Diamond Bar, California) or the NAVX Ensite Velocity system (St. Jude Medical) was performed, followed by RFC ablation using an irrigated 3.5- or 4-mm-tip catheter (ThermoCool NaviStar, Thermocool Surround Flow, and Thermocool Smarttouch [Biosense Webster]; Alcath Flux G Extra [Biotronik, Berlin, Germany]). Power settings were the following: 30 to 40 W (maximum 30 W for posterior and inferior LA wall and maximum 40 W for anterior LA wall) and a flush rate of 17 to 25 ml/min or 8 to 15 ml/min with the second-generation catheter. Maximal tip temperature was set at 43°C.

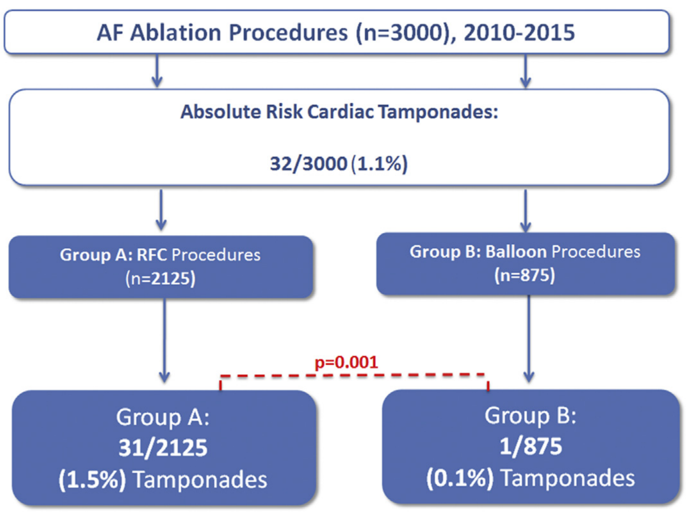
Point-by-point wide-area circumferential PVI was performed in all patients. The endpoint of PVI was defined as the elimination of the PV spike potential recorded with the spiral catheter, as previously described (group A1) (4). If patients demonstrated nonshockable AF despite PVI or if AF was converted into atrial tachycardia (AT) or atrial flutter, additional ablation was performed according to the operator's discretion and classified as PVI plus (group A2).

BALLOON-BASED ABLATION PVI (GROUP B). Balloon-based PVI has been described in detail (8,9). In brief, a single SL1 sheath (St. Jude Medical) was advanced to the left atrium using a modified Brockenbrough technique. After transseptal catheterization, intravenous heparin was administered, targeting an activated clotting time of 300 s (30-min intervals). Selective pulmonary vein (PV) angiograms were obtained in all patients in standard angulations and baseline PV signals recorded. To monitor luminal esophageal temperature changes, a temperature probe was inserted (SensiTherm, St. Jude Medical). In group B, the transseptal sheath was exchanged for the steerable cryoballoon (CB) (12-F, Flexcath) or laser balloon (LB) sheath (12-F) and continuously flushed with heparinized saline. In all CB cases (Arctic Front and Arctic Front Advance, Medtronic, Minneapolis, Minnesota), an intraluminal spiral catheter (20-mm Achieve, Medtronic) was used to visualize real-time PV recordings and to prove PVI; in LB cases (HeartLight, CardioFocus, Marlborough, Massachusetts) after sequential PV ablation, a spiral catheter (Lasso, Biosense Webster) was used to prove PVI. In CB cases, cryothermal energy was deployed for 240 s (300 s with first-generation CBs) at each PV followed by 1 "bonus" application (240 s; 300 s with first-generation CBs) after successful PVI. In LB cases, ablation lesions were deployed in a contiguous

ABBREVIATIONS AND ACRONYMS

AF = atrial fibrillation
AT = atrial tachycardia
CB = cryoballoon
CFAE = complex fractionated atrial electrogram
CT = cardiac tamponade
LA = left atrial
LB = laser balloon
OAC = oral anticoagulation
PV = pulmonary vein
PVI = pulmonary vein isolation
RFC = radiofrequency current

FIGURE 1 **Overall Risk for Cardiac Tamponade in 3,000 Procedures**

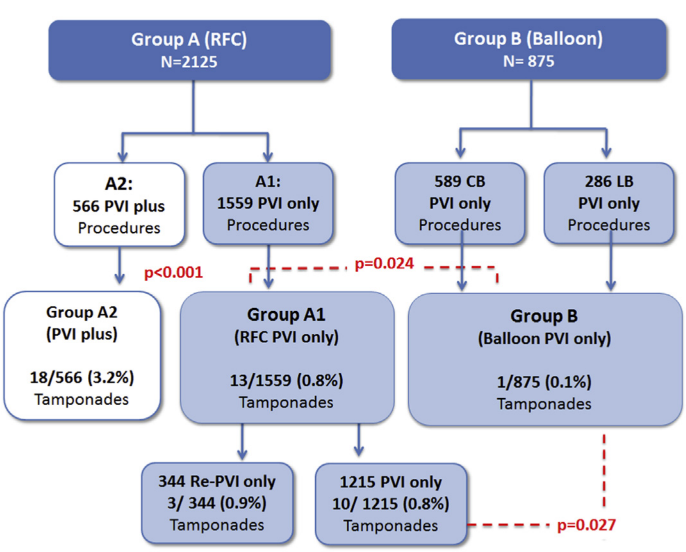


The overall risk for cardiac tamponade was significantly reduced if a balloon-based ablation strategy has been performed. AF = atrial fibrillation; RFC = radiofrequency current.

fashion under visual guidance, titrating the energy from 5.5 to 12 W (ablation time 20 to 30 s) according to the degree of tissue exposure (10).

REPEAT PROCEDURE ABLATION. Repeat electrophysiologic procedures were performed for recurrent atrial tachyarrhythmias. Double transseptal puncture was performed in all cases. In all patients, RFC energy in conjunction with a 3-dimensional electroanatomic mapping system was used. In the first step, the durability of PVI was assessed regardless of the underlying rhythm (sinus rhythm or atrial tachyarrhythmia), followed by focal closure of all detected PV conduction gaps resulting in electric PV reisolation. Additional ablation (CFAEs and/or linear lesions) was performed only if: 1) direct-current cardioversion failed after repeat PVI; 2) patients demonstrated no PV reconduction; or 3) patients presented in AT. In patients presenting in sinus rhythm without PV reconduction, atrial tachyarrhythmia was induced from the coronary sinus and/or LA appendage before additional ablation. If AT was the index arrhythmia, the underlying AT mechanism was elucidated and ablated. If patients converted to AT or did not terminate to sinus rhythm despite extensive ablation (CFAEs at LA, right atrial, and coronary sinus sites), linear lesions (anterior line, roof line, left isthmus line, and cavotricuspid isthmus line) were deployed according to the operator's discretion. No repeat procedures were routinely performed with the LB or CB. Repeat balloon ablation was allowed only in clinical studies (FIRE AND ICE and RFC vs. Laserballoon). These procedures were excluded from data analysis.

FIGURE 2 **Comparison of Ablation Technology (Radiofrequency Current vs. Balloon)**



The overall risk for cardiac tamponade was significantly reduced if a balloon-based ablation strategy was performed, even if patients undergoing pulmonary vein isolation (PVI) only are compared (group A1 vs. group B). RFC = radiofrequency current.

POST-PROCEDURAL MANAGEMENT AND FOLLOW-UP. At the end of the procedure, acute pericardial effusion was ruled out in the electrophysiology laboratory by transthoracic echocardiography. All patients were transferred to the cardiology surveillance unit and underwent up to 48 h of electrocardiographic monitoring. After exclusion of major bleeding complications, OAC or novel OAC therapy was resumed for at least 2 months on the basis of the patient's individual CHA_2DS_2-VASc score. After 24 to 48 h, an echocardiographic reevaluation was performed. After hospital discharge, patients presented to our outpatient clinic (at 3, 6, and 12 months and thereafter in 12-month intervals). At outpatient follow-up visits, transthoracic echocardiography, 12-lead electrocardiography, and 3- to 7-day Holter monitoring were performed. All procedure-related complications were prospectively noted in the Cardioangiologisches Centrum Bethanien database.

DEFINITION OF CT. CT was defined as the occurrence of hemodynamically relevant intra- or post-procedural pericardial effusion detected by transthoracic echocardiography resulting in an intervention (percutaneous drainage).

MANAGEMENT OF CT. If CT became evident during the procedure, ablation was terminated. In all cases, immediate fluoroscopy-guided subxiphoid pericardial access (8-F) was obtained. A 6-F pigtail catheter was introduced into the pericardial space to drain the effusion. Protamine and prothrombin complex were administered to reverse anticoagulation effects. The amount of drained blood was counted and retransfused. After complete drainage and a waiting time of at least 60 min, the patient was transferred to the intensive care unit. Anticoagulation therapy remained paused for at least 12 h. If possible, the pigtail catheter was removed the next day after repetitive echocardiographic controls. Patients with symptoms of pericarditis received nonsteroidal anti-inflammatory medications. If CT could not be managed with percutaneous drainage, patients were promptly transferred to a cardiothoracic surgery unit.

STATISTICAL ANALYSIS. Statistical analysis was performed using SPSS version 20.0 for windows (SPSS, Inc., Chicago, Illinois). A p value <0.05 was considered to indicate statistical significance. Continuous variables are summarized as mean ± SD or as medians and interquartile ranges as appropriate. Qualitative variables are expressed using frequencies and percentages. Comparisons between groups were performed using analysis of variance (continuous variables), chi-square tests (categorical variables), and nonparametric rank tests (Mann-Whitney *U* tests). Post hoc analysis was made by means of Bonferroni test (analysis of variance) when the overall p value indicated significance.

RESULTS

PATIENTS. A total of 3,000 AF ablation procedures in 2,433 patients were performed at our institution between May 2010 and July 2015. Group A (RFC) consisted of 2,125 ablation procedures (71%) (Figure 1) with PVI only (group A1) in 1,559 procedures (73%) and PVI plus (group A2) in 566 procedures (27%) (Figure 2). Group B included a total of 875 balloon-based PVI procedures (29%) (CB, n = 589 [67%]; LB, n = 286 [33%]) (Figure 1). Patients in group B were younger, had lower CHA_2DS_2-VASc scores, had smaller LA diameters and were more often defined as having paroxysmal AF. Detailed patient characteristics are summarized in Table 1.

PROCEDURAL PARAMETERS. Key procedural parameters, such as fluoroscopy, and procedure time, were lower in group A compared with group B. The procedural endpoint of acute electric PVI was obtained in group A (100% [n = 2,125]) and group B (99% [n = 875]). A total of 690 repeat procedures were analyzed. Because of our center's strategy, all repeat procedures were performed in group A (Table 2) (mean procedural number per patient 1.4 ± 0.7 vs. 1.0). Comparative procedural details are summarized in Table 2.

ABLATION TECHNOLOGY AND RISK FOR CT. Point-by-point RFC versus balloon AF ablation. The overall risk for CT was 1.1%. The risk for CT was significantly lower in group B compared with group A (0.1% [1 of 875] vs. 1.5% [31 of 2,125], p = 0.024) (Figure 1). Importantly, the observed reduced risk for CT in group B remained statistically significant even if simple PVI procedures were compared (0.8% in group A1 vs. 0.1% in group B, p = 0.001) (Figure 2). In group B, the single episode of CT (1 of 875 patients) occurred in 2011 and was related to the stiff nose of the historical second-generation LB (1 of 286). After the introduction of the current LB generation, no further episodes of tamponade occurred. CT never occurred in the CB group (0 of 589) (Figure 2).

TABLE 1 Baseline Characteristics

	All (n = 3,000)	Group A (n = 2,125)	Group B (n = 875)	p Value
Age (yrs)	66 ± 11	67 ± 11	64 ± 11	<0.001*
Male	1,832 (61)	1,319 (62)	513 (59)	0.084
PAF	1,572 (52)	924 (43)	648 (74)	<0.001*
Hypertension	2,187 (73)	1,573 (74)	614 (70)	0.035*
Diabetes	323 (11)	232 (11)	91 (10)	0.753
Previous stroke/TIA	196 (6)	144 (7)	52 (6)	0.373
CAD	527 (17)	392 (18)	135 (15)	0.044*
CHA_2DS_2-VASc score ≤1	955 (32)	647 (30)	308 (35)	0.011*
LA diameter (mm)	42 ± 6	42 ± 6	40 ± 5	<0.001*
LVEF (%)	59 ± 11	58 ± 11	61 ± 10	<0.001*

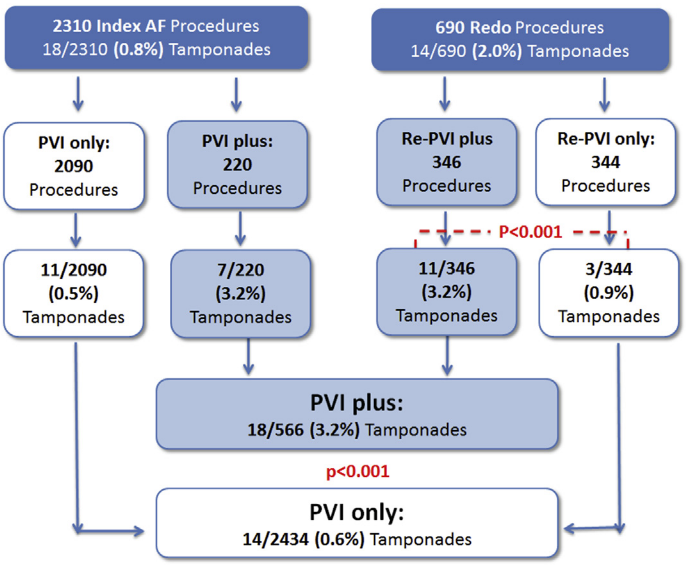
Values are mean ± SD or n (%). *p < 0.05.
CAD = coronary artery disease; group A = radiofrequency current; group B = cryoballoon plus laser balloon; LA = left atrial; LVEF = left ventricular ejection fraction; PAF = paroxysmal atrial fibrillation; PVI = pulmonary vein isolation; TIA = transient ischemic attack.

TABLE 2 Procedural Details

	All (n = 3,000)	Group A (n = 2,125)	Group B (n = 875)	p Value
Procedure time (min)	103 ± 37	101 ± 37	106 ± 38	0.004*
Fluoroscopy time (min)	12 ± 8	12 ± 8	13 ± 8	<0.001*
First procedure (index)	2,310 (77)	1,435 (67)	875 (100)	<0.001*
Number of procedures	1.3 ± 0.6	1.4 ± 0.7	1	<0.001*
PVI only	2,434 (81)	1,559 (73)	875 (100)	<0.001*
PVI plus	566 (19)	566 (27)	0	<0.001*

Values are mean ± SD or n (%). *p < 0.05.
Abbreviations as in Table 1.

FIGURE 3 **Comparison of Ablation Strategy (Pulmonary Vein Isolation Only vs. Pulmonary Vein Isolation Plus Ablation)**



Pulmonary vein isolation (PVI) plus ablation comprises all patients in whom additional ablation (complex fractionated atrial electrograms and linear lesions) beyond PVI were performed. In the group with PVI only, in repeat ablation, only repeat PVI was performed. The risk for cardiac tamponade was significantly lower if the PVI-only ablation strategy was followed (0.6% vs. 3.2%, $p < 0.001$).

COMPARISON OF ABLATION STRATEGIES (PVI ONLY VS. PVI PLUS). RFC ablation beyond PVI was associated with an increased risk for CT. The procedural flowchart (Figure 3) illustrates that among 3,000 AF procedures, a PVI-only ablation strategy was pursued in 2,434, compared with PVI plus in 566 procedures. The risk for CT was significantly lower if the PVI-only ablation strategy was followed (0.6% vs. 3.2%, $p < 0.001$). In group A, the risk for CT during PVI only was significantly lower compared with complex ablation (PVI plus): 0.8% (13 of 1,559) in group A1 versus 3.2% (18 of 566) in group A2 ($p < 0.001$) (Figure 2).

PREDICTORS OF CT. Univariate analysis identified: 1) ablation technology (RFC ablation); 2) ablation strategy (PVI plus); and 3) the number of procedures per patient as predictors of CT (Table 3).

TABLE 3 **Univariate Analysis: Predictors of Cardiac Tamponade**

	All (n = 3,000)	Cardiac Tamponade (n = 32)	No Cardiac Tamponade (n = 2,968)	p Value
Age (yrs)	66 ± 11	70 ± 10	66 ± 11	0.047*
Male	1,832 (61)	18 (56)	1,814 (61)	0.588
Hypertension	2,187 (73)	25 (78)	2,162 (73)	0.566
Diabetes	323 (11)	1 (3)	322 (11)	0.364
Previous stroke/TIA	196 (6)	0 (0)	196 (7)	0.258
CAD	527 (17)	6 (19)	521 (18)	0.760
CHA_2DS_2-VASc score ≤1	2,097 (70)	21 (66)	2,076 (70)	0.281
LA diameter (mm)	42 ± 6	43 ± 6	42 ± 6	0.472
LVEF (%)	59 ± 11	57 ± 9	59 ± 10	0.414
Group A vs. group B	2,125 vs. 875	31 vs. 1	2,094 vs. 874	<0.001*
Number of procedures	1.3 ± 0.6	1.6 ± 0.7	1.3 ± 0.6	0.011*
PVI plus	566 (19)	18 (56)	548 (18)	<0.001*

Values are mean ± SD or n (%). *$p < 0.05$.
Abbreviations as in Table 1.

MANAGEMENT AND OUTCOMES OF CT. CT occurred in 32 of 3,000 (1.1%) AF ablation procedures. Successful percutaneous access to the pericardial space could be obtained in all patients. The majority of episodes of CT (97% [31 of 32]) could be managed without need for cardiac surgery after drainage of a median of 450 ml (interquartile range: 300 to 800 ml) of blood. Details regarding the acute management of CT are summarized in Table 4.

ANNUAL RISK FOR CT. Our center's annual rate of CT in AF ablation is depicted in Figure 4. The annual risk ranged between 0.6% and 1.7% from 2010 to 2015. There was no obvious learning-curve effect. However, the proportion of balloon-based AF ablation procedures appeared to increase over the past 2 years. In addition, in 2014, RFC contact force catheters were introduced at our center, but no evident reduction in CT has been observed.

GENERAL COMPLICATIONS. Overall AF ablation-related procedural complications in 3,000 procedures are summarized in Table 5. In group B, there was an increased complication rate (2.9% vs. 5.4%) beyond CT, which was driven primarily by phrenic nerve palsies persistent at patient discharge (15 of 875 [1.7%]; 11 of 589 with CBs [1.9%] vs. 4 of 286 with LBs [1.4%]; p = 0.616).

DISCUSSION

We investigated the differential risk for CT during AF ablation in a real-world, "all-comers" AF patient cohort treated at a high-volume center. The major findings are as follows: 1) there was a low incidence of CT with a PVI-only strategy; 2) this incidence was further reduced using balloon catheters; 3) there was an increased incidence of CT if ablation beyond PVI was performed; and 4) cardiac surgery was rarely required for management of CT.

The risk for CT has been identified as the major cause of death in patients undergoing AF ablation (3). The overall rate of CT in this study (1.1%) is well in line with recently published worldwide data.

TABLE 4 Management of Cardiac Tamponade (n = 32)

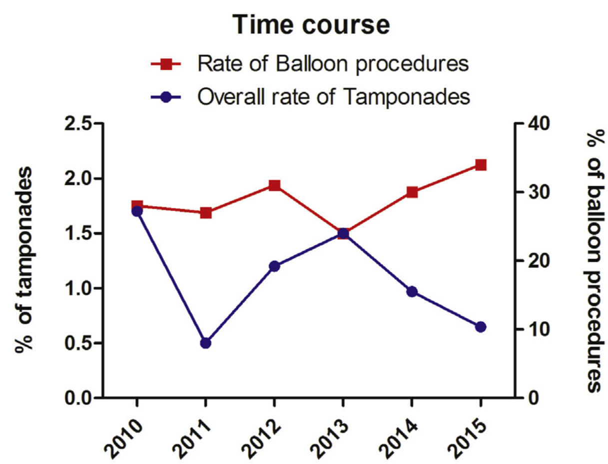
Warfarin	12 (38)
Dabigatran	5 (16)
Rivaroxaban	13 (40)
Apixaban	2 (6)
Pericardiocentesis	31/32 (97)
Surgical	1 (3)
Median blood aspiration (ml)	450
Use of PCC	19 (59)
Median protamine units	10,000

Values are n (%) except as indicated.
PCC = prothrombin complex.

However, reports of CT are highly inconsistent (1.3% to 6%) and are predominantly available for RFC AF ablation (3). Importantly, contemporary prospective multicenter data (RAAFT-2 [Radiofrequency Ablation vs. Antiarrhythmic Drugs as First-Line Treatment of Paroxysmal Atrial Fibrillation] trial) emphasize the need to improve the safety of RFC ablation, reporting a 6% incidence of CT (11). In theory, CT may occur during different procedural steps, such as transseptal puncture, catheter manipulation, and energy deployment. Traditionally, RFC energy has been the gold standard in AF ablation. However, recently, balloon-based AF ablation has attracted increased attention (5,6,12).

In most RFC cases, 2 transseptal LA punctures are required, housing 1 ablation and 1 diagnostic spiral catheter. In contrast, simplification of balloon PVI allowed the use of a single transseptal access (8). In addition, in balloon ablation, no detailed 3-dimensional electroanatomic LA mapping is performed, which requires distinct catheter manipulations. Importantly, during RFC ablation, contiguous point-by-point lesions are deployed, encircling the ipsilateral PVs. To obtain a complete circumferential lesion with the endpoint of PVI, the operator needs to control catheter position, local electrogram, biophysical parameters, and catheter-to-tissue contact. Interestingly, a recent analysis in >93,000 procedures demonstrated that the safety of RFC AF ablation depends on both operator and institutional experience (13). One may speculate that the recent introduction of contact force technology (RFC ablation) may improve the outcomes and safety of AF ablation. If optimal contact force were obtained, improved durability of PVI could be demonstrated (14). However, this additional information did not reduce the risk for mechanical complications. Initial clinical experience using contact force measurements in AF ablation reported surprisingly high rates of CT (2.5% to 8.0%) (14–16). Importantly, RFC-guided contact force ablation is limited by the fact that stable catheter positions cannot be obtained in all LA and PV regions, for anatomic reasons (17). In addition, RFC ablation is linked to the occurrence of steam pops, causing uncontrolled tissue trauma, resulting in potential cardiac perforation. In contrast, balloon AF ablation shares the risk of transseptal LA access, but no additional LA mapping and point-by-point catheter positioning are required. Importantly, CB navigation can be facilitated using the intraluminal spiral catheter. The soft tip of the spiral catheter

FIGURE 4 Annual Rate of Cardiac Tamponade (From 2010 to 2015), According to Different Ablation Technology



# of Procedures	180	403	567	664	721	465
Group A	128	293	390	502	506	306
Group B	52	110	177	162	215	159

The overall rate of cardiac tamponade (CT) ranged between 0.5% and 1.7% and is depicted in **red**. There was no evident learning-curve effect. The **blue line** describes the increasing rate of balloon procedures in the last 2 years, with a corresponding decrease in the overall rate of CT. In the table, the total number of procedures per year stratified by group is reported.

TABLE 5 Procedural Complications (Group A vs. Group B)

	All (n = 3,000)	Group A (n = 2,125)	Group B (n = 875)	p Value
Overall	110 (3.7)	63 (2.9)	47 (5.4)	0.001*
Death (4 weeks)	0	0	0	
AE fistula	1 (0.03)	1 (0.05)	0	0.520
Hemothorax	4 (0.13)	2 (0.09)	2 (0.2)	0.359
Stroke/TIA	9 (0.3)	5 (0.2)	4 (0.4)	0.31
PV stenosis >50%	0	0	0	
Phrenic nerve palsy	15 (0.5)	0	15 (1.7)	<0.001*
Vascular access	81 (2.7)	55 (2.6)	26 (2.9)	0.556

Values are n (%). *$p < 0.05$.
AE = atrioesophageal; PV = pulmonary vein; TIA = transient ischemic attack.

allows nontraumatic LA and PV mapping while displaying real-time electric information guiding PV mapping and ablation. The only instance of CT in group B was caused by the historical first-generation LB in 2011. This old version was equipped with a stiff nose and perforated while inadvertently mapping the LA appendage. This catheter design limitation has been overcome with the introduction of the current balloon version, carrying a soft and flexible nose, reducing the risk for mechanical trauma. Importantly, the risk for steam pops during CB ablation is absent. In summary, these differences may explain the reduced risk for CT during balloon AF ablation. Interestingly, so far, all comparative studies have reported increased rates of CT in RFC ablation compared with CB (18–22). Also, the recently published FIRE AND ICE data appear to be in line with our observation. Despite not reaching statistical significance, the total rate of CT was higher with RFC ablation: 5 of 376 (1.3%) with RFC PVI only versus 1 of 374 (0.3%) with CB PVI only ($p = 0.22$) (22). In contrast, in our large patient cohort (3,000 AF procedures) we could demonstrate for the first time a statistically reduced risk for CT in balloon AF ablation.

ADDITIONAL RFC ABLATION BEYOND PVI. Ablation beyond PVI was identified as a predictor of CT in this univariate analysis. Not surprisingly, the highest rate of CT was present in patients undergoing CFAE and linear lesion ablation. Therefore, in a first AF procedure, avoidance of CFAE ablation and prospective linear lesions dissecting regular voltage atrial tissue should improve the safety profile. Following this path, a recently published randomized prospective trial comparing extensive ablation with PVI (7) demonstrated no additional clinical benefit. Importantly, if only repeat PVI was performed in our patients during a repeat procedure, the risk for CT remained low. We identified ablation technology (RFC energy) and ablation strategy (PVI plus) as predictors of CT. Therefore, differential ablation strategies and associated procedural risks need to be discussed and evaluated before performing extensive ablation beyond PVI. These findings should be taken into consideration when counseling patients before ablation.

MANAGEMENT OF CT. The majority of our patients experiencing CT (97% [31 of 32]) could be stabilized with percutaneous drainage alone. Immediate pericardial access and successful drainage are crucial in the management of this complication. The patient requiring surgical correction demonstrated a perforation at the LA roof caused by an RFC-induced steam pop (group A). Interestingly, despite different pre-procedural OAC and novel OAC therapies, empiric antagonization (protamine, prothrombin complex) appeared to be a viable option to control CT. In future, the specific novel dabigatran antidote idarucizumab may facilitate bleeding management (23). Delayed CT requiring pericardial drainage was not observed in our patient cohort. To observe this rare complication, an even larger number of procedures may be required (24).

STUDY LIMITATIONS. This was a large single-center retrospective analysis, not a prospective randomized trial, comparing manual RFC and balloon ablation. Different generations of 3-dimensional navigation software and/or catheter technologies have been introduced in both groups since 2010. Therefore, potential data bias attributable to learning-curve effects cannot be fully excluded. However, all operators followed the same institutional staged AF ablation approach and were trained for many years at a high-volume AF center. Because of the relatively low absolute number of episodes of CT, no general management rules can be given. Especially in the light of different anticoagulation pre-treatment, more data are required. However, immediate drainage and reversal of anticoagulation appears to minimize the need for a surgical intervention.

CONCLUSIONS

The risk for CT in patients undergoing AF ablation at a single-high-volume center was decreased with the use of balloon catheters. Extensive RFC ablation beyond PVI leads to an increased perforation risk.

ADDRESS FOR CORRESPONDENCE: Dr. K.R. Julian Chun, Cardioangiologisches Centrum Bethanien, Wilhelm-Epstein Strasse 4, 60431 Frankfurt/Main, Germany. E-mail: j.chun@ccb.de.

PERSPECTIVES

COMPETENCY IN MEDICAL KNOWLEDGE: Catheter ablation of AF is linked to risk for CT. This specific complication is reduced if balloon catheters are used and if AF ablation is limited to PVI only.

TRANSLATIONAL OUTLOOK: More prospective comparative data are required regarding the safety and efficacy of different ablation technologies in AF ablation.

REFERENCES

1. Camm AJ, Lip GYH, De Caterina R, et al. 2012 focused update of the ESC Guidelines for the management of atrial fibrillation: an update of the 2010 ESC guidelines for the management of atrial fibrillation. Developed with the special contribution of the European Heart Rhythm Association. Eur Heart J 2012;33:2719–47.

2. Cappato R, Calkins H, Chen S-A, et al. Updated worldwide survey on the methods, efficacy, and safety of catheter ablation for human atrial fibrillation. Circ Arrhythm Electrophysiol 2010;3:32–8.

3. Cappato R, Calkins H, Chen S-A, et al. Prevalence and causes of fatal outcome in catheter ablation of atrial fibrillation. J Am Coll Cardiol 2009;53:1798–803.

4. Ouyang F, Bänsch D, Ernst S, et al. Complete isolation of left atrium surrounding the pulmonary veins: new insights from the double-Lasso technique in paroxysmal atrial fibrillation. Circulation 2004;110:2090–6.

5. Chun K-RJ, Schmidt B, Metzner A, et al. The "single big cryoballoon" technique for acute pulmonary vein isolation in patients with paroxysmal atrial fibrillation: a prospective observational single centre study. Eur Heart J 2009;30:699–709.

6. Schmidt B, Metzner A, Chun KRJ, et al. Feasibility of circumferential pulmonary vein isolation using a novel endoscopic ablation system. Circ Arrhythm Electrophysiol 2010;3:481–8.

7. Verma A, Jiang C, Betts TR, et al. Approaches to catheter ablation for persistent atrial fibrillation. N Engl J Med 2015;372:1812–22.

8. Chun KJ, Bordignon S, Gunawardene M, et al. Single transseptal big Cryoballoon pulmonary vein isolation using an inner lumen mapping catheter. Pacing Clin Electrophysiol 2012;35:1304–11.

9. Schmidt B, Gunawardene M, Urban V, et al. Visually guided sequential pulmonary vein isolation: insights into techniques and predictors of acute success. J Cardiovasc Electrophysiol 2012;23:576–82.

10. Bordignon S, Chun K-RJ, Gunawardene M, et al. Energy titration strategies with the endoscopic ablation system: lessons from the high-dose vs. low-dose laser ablation study. Europace 2013;15:685–9.

11. Morillo CA, Verma A, Connolly SJ, et al. Radiofrequency Ablation vs Antiarrhythmic Drugs as First-Line Treatment of Paroxysmal Atrial Fibrillation (RAAFT-2): a randomized trial. JAMA 2014;311:692–700.

12. Luik A, Radzewitz A, Kieser M, et al. Cryoballoon versus open irrigated radiofrequency ablation in patients with paroxysmal atrial fibrillation: the prospective, randomized, controlled, noninferiority FreezeAF study. Circulation 2015;132:1311–9.

13. Deshmukh A, Patel NJ, Pant S, et al. In-hospital complications associated with catheter ablation of atrial fibrillation in the United States between 2000 and 2010: analysis of 93 801 procedures. Circulation 2013;128:2104–12.

14. Kautzner J, Neuzil P, Lambert H, et al. EFFICAS II: optimization of catheter contact force improves outcome of pulmonary vein isolation for paroxysmal atrial fibrillation. Europace 2015;17:1229–35.

15. Natale A, Reddy VY, Monir G, et al. Paroxysmal AF catheter ablation with a contact force sensing catheter: results of the prospective, multicenter SMART-AF trial. J Am Coll Cardiol 2014;64:647–56.

16. Kuck K-H, Reddy VY, Schmidt B, et al. A novel radiofrequency ablation catheter using contact force sensing: Toccata study. Heart Rhythm 2012;9:18–23.

17. Makimoto H, Tilz RR, Lin T, et al. Incidence and anatomical locations of catheter instability during circumferential pulmonary vein isolation using contact force. Int Heart J 2014;55:249–55.

18. Schmidt M, Dorwarth U, Andresen D, et al. Cryoballoon versus RF ablation in paroxysmal atrial fibrillation: results from the German Ablation Registry. J Cardiovasc Electrophysiol 2014;25:1–7.

19. Squara F, Zhao A, Marijon E, et al. Comparison between radiofrequency with contact force-sensing and second-generation cryoballoon for paroxysmal atrial fibrillation catheter ablation: a multicentre European evaluation. Europace 2015;17:718–24.

20. Aryana A, Singh SM, Kowalski M, et al. Acute and long-term outcomes of catheter ablation of atrial fibrillation using the second-generation cryoballoon versus open-irrigated radiofrequency: a multicenter experience. J Cardiovasc Electrophysiol 2015;26:832–9.

21. Mugnai G, Irfan G, de Asmundis C, et al. Complications in the setting of percutaneous atrial fibrillation ablation using radiofrequency and cryoballoon techniques: A single-center study in a large cohort of patients. Int J Cardiol 2015;196:42–9.

22. Kuck K-H, Brugada J, Fürnkranz A, et al. Cryoballoon or radiofrequency ablation for paroxysmal atrial fibrillation. N Engl J Med 2016;374:2235–45.

23. Pollack CV, Reilly PA, Eikelboom J, et al. Idarucizumab for dabigatran reversal. N Engl J Med 2015;373:511–20.

24. Cappato R, Calkins H, Chen S-A, et al. Delayed cardiac tamponade after radiofrequency catheter ablation of atrial fibrillation: a worldwide report. J Am Coll Cardiol 2011;58:2696–7.

KEY WORDS atrial fibrillation, cardiac tamponade, catheter ablation, cryoballoon, laser balloon, radiofrequency current