X-ray exposure in cryoballoon versus radiofrequency ablation for atrial fibrillation over 7 years: A single center study

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Abstract
Background: Facing an increasing number of radiofrequency ablation (RF) and cryoballoon ablation (CB) procedures for treatment of AF radiation exposure and its reduction is a focus point for interventional electrophysiologists.

Objective: This study evaluated the procedural parameters of the different ablation methods focusing on radiation exposure and the BMI of the patients.

Methods: One thousand one hundred and thirty-three first procedural cases of pulmonary vein isolation in patients with paroxysmal and persistent AF treated with RF and CB-based techniques were analyzed retrospectively over a period of 7 years focusing on the endpoints dose area product (DAP, cGycm²), fluoroscopy time (FT, min) and procedural time (PT, min).

Results: Of the 1133 patients (mean age 63.4 ± 11.4 years, BMI 28.9 ± 4.7) 335 patients received an RF procedure, 211 patients were treated with the cryoballoon first generation (CB1), and 587 patients with cryoballoon second generation (CB2), respectively. The mean DAP for the PVI was 508 ± 654 cGycm² in RF procedures, 1077 ± 683 cGycm² in CB1-procedures, and 587 ± 489 cGycm² in CB2-procedures with fluoroscopy times significantly shorter in RF procedures (9.6 ± 5.2 min) as compared to 17.7 ± 5.9 min in CB1- and 16.3 ± 6.3 min in CB2-procedures (p < .001). At the same time, the procedure duration using RF (115 ± 33.5 min) was significantly longer than both in CB1 (96 ± 16.8 min) and CB2 procedures (75 ± 15.9 min).

Conclusions: Despite longer fluoroscopy durations in the CB technique, the CB2 resulted in a comparable low radiation exposure in PVI as compared to RF, accompanied by shorter procedure durations.

KEYWORDS
atrial fibrillation, radiofrequency ablation, cryoballoon ablation, fluoroscopy, radiation exposure

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1 | INTRODUCTION

Radiofrequency (RF) ablation and cryoballoon (CB) ablation are common, safe, and effective methods for pulmonary vein isolation (PVI) in patients with symptomatic drug-resistant atrial fibrillation (AF) as recommended by the current ESC AF guidelines. However, RF and CB ablation do not only differ in biophysics but also in procedural duration and in radiation exposure.

The aim of the present study was the evaluation of the fluoroscopy exposure in atrial fibrillation ablation by PVI using radiofrequency and cryo-technology in a retrospective single-center study. Therefore we not only focused on the effect of restrictive fluoroscopy settings applying the ALARA-principle (As Low As Reasonably Achievable) but also on the BMI of the patients for comparison of the different ablation approaches.

Facing the increasing number of ablation procedures for treatment of AF worldwide, radiation exposure and its reduction is becoming an important issue for interventional electrophysiologists and the catheter lab staff as far as x-ray exposure increases the risk of malignancy. Even if there are many studies comparing radiofrequency and cryoballoon ablation for PVI demonstrating a comparable success rate of both technologies with longer procedural durations but shorter fluoroscopy times in RF ablation using 3-D mapping systems, there are only sparse information on the dose area product (DAP) as the most relevant parameter in estimation the periprocedural x-ray exposure for both patients as far as the cathlab-staff. More recently some publications on non-fluoroscopic ablation approaches up to zero fluoroscopy ablation came out, but these methods are not yet widespread used but actually limited to some specialized EP-centers.

On the other hand, cryoballoon PVI is associated with high procedural reproducibility and safety despite a shorter learning curve, so that this approach is gaining more and more acceptance. CB ablation is nowadays becoming the first choice in ablation of patients with paroxysmal atrial fibrillation even in centers without advanced fluoroscopy units and non-fluoroscopic imaging capabilities.

At this background, we evaluated the impact of a primary low-intensity fluoroscopy setup and a strong awareness of the potential detrimental effects of high cumulative radiation exposure on the procedural parameters of radiofrequency (RF), cryoballoon first generation (CB1) and cryoballoon second generation (CB2) ablation procedures for pulmonary vein isolation (PVI) in patients with atrial fibrillation. Hereby, we focused not only on procedure- and fluoroscopy times but also on the DAP and its relation to the BMI.

For a better comparability of the DAP values of different ablation techniques and fluoroscopy settings, we introduced the parameter DAP/BMI facing the fact of increasing obesity of the population in the modern countries.

2 | METHODS

2.1 | Patients

Over a period of 7 years all patients who underwent pulmonary vein isolation in paroxysmal and persistent AF with RF and CB-based techniques at our center were included into this retrospective registry. From this database, all first procedures were selected for this analysis. The patients included into our investigation were defined by the following baseline characteristics: age, gender, history of AF, body mass index (BMI), and CHA₂DS₂-vasc Score. We compared the different ablation methods based on the procedural data focusing on dose area product (DAP, cGy·cm²), DAP/BMI (cGy·cm²), fluoroscopy time (FT, min), and procedural time (PT, min).

Any complications during the hospital stay were evaluated for being procedure related. All ablation procedures were performed by five experienced operators in the same dedicated electrophysiology catheter lab with a biplane fluoroscopy system.

During the study period, the cryoballoon technique switched from the first to the second-generation cryoballoon, and the achieve catheter was introduced for online visualization of successful PV-isolation during energy delivery.

As far as an informed consent into a retrospective analysis of patient data is not feasible, patient data collection and management were approved by the local medical ethics committee.

2.2 | Technology

2.2.1 | Fluoroscopy

The biplane fluoroscopy system (Philips Allura®), x-ray filtration by 0.4 mm copper and 1 mm aluminum was set to 3.75 frames/s in the fluoroscopy mode and 7.5 frames/s in the cine mode as our standard setup for electrophysiology procedures. For storage and documentation of the ablation procedure primarily the last image hold or the last run hold option from fluoroscopy were used, whereas

What's new?

- PVI by RF ablation and ablation with the second-generation cryoballoon yield the same DAP with shorter procedure times in cryoballoon ablation.
- Awareness and low-dose fluoroscopy settings allow successful PVI at low radiation exposure in a real-life setting.
- DAP and DAP/BMI are more parameters in comparing fluoroscopy exposure than the fluoroscopy time.
- Adjusting to the BMI of the patients RF-PVI should be preferred in obese patients.
recording of short cine sequences only were performed in case of poor image quality. All operators were urged to use maximum collimation and avoid excessive zooming. For radiation protection of the operator and the staff a standard shielding with 1mm lead equivalent value was mounted at the fluoroscopy table added by a 0.5mm lead equivalent value transparent shield.

Initially, a posterior-anterior projection was used for catheter placement and turned to RAO 35° and LAO 50° without cranio-caudal angulations for transseptal puncture and ablation.

2.2.2 | Ablation procedure: Imaging and anticoagulation

Prior to the ablation all patients underwent a low-dose cardiac CT for visualization, the left atrial anatomy and enabling 3-D image integration either into the CARTO® system (Biosense Webster, Johnson&Johnson) or the EP-Navigator® (Philips).

OAK was stopped 1 day before the procedure targeting an INR of 2.5. DOAC’s were paused the morning of the procedure and were continued with half of the daily dose at the evening of the ablation procedure after bleeding complications had been ruled out.

For periprocedural anticoagulation, an initial bolus of 5000IU Heparin before transseptal puncture and 5000IU thereafter were applied with further adaptation of the heparin dosage to a target ACT of 300s (ACT-check interval 20min).

Heparin was antagonized in all patients at the end of the procedure with protamine 1:1 equivalent to the cumulative heparin dosage after exclusion of a pericardial effusion by transthoracic echocardiography.

2.2.3 | Cryoballoon ablation

All patients were awake during the cryoballoon ablation getting repetitive bol of midazolame for slight sedation and fentanyl for analgesia. A dedicated temperature probe has been introduced into the esophagus for temperature monitoring during the application of cryo-energy.

Blood pressure was monitored continuously via a 4 F femoral access sheath in the left groin.

Two 7-F-sheaths were inserted for venous access and placement of the diagnostic electrophysiology catheters.

A steerable 6 F quadrripolar catheter (Dynamic XT®, Boston Scientific) was advanced into the coronary sinus for pacing whilst isolating the left pulmonary veins (PV’s). Before treating the right PV’s this catheter was relocated into the superior caval vein for phrenic nerve stimulation.

Another 6-F quadrripolar catheter (Cournand-Curve, Supreme®, St. Jude Medical) was positioned into the right ventricular apex for ventricular pacing as far as vagal-induced AV-conduction block occurred quite frequently during the cryo-procedure.

The three-dimensional CT model was generated by the EP-navigator® after segmentation of the imported CT dataset with manually editing the left atrium and left atrial appendage if required. This 3-D-reconstruction was fused with the fluoroscopy after positioning the RV and the CS catheter and advancement of the guidewire for the transeptal sheath into the superior caval vein. After a recording of three images (last image hold) in RAO 30°, p.a. and LAO 40°, the 3D-reconstruction was integrated into real-time fluoroscopy thereby facilitating transseptal puncture as well as placement of the cryoballoon via the achieve catheter at the PV-ostia.

After advancement of the 0.032 inch guidewire into the superior caval vein, the sheath-dilator-complex (Fast Cath® SL0, 63 cm, and BRK1-needle®, 71 cm; St. Jude Medical) was carefully positioned over the wire into the superior caval vein. Transeptal puncture was performed using biplane fluoroscopy in LAO 50° and in RAO 35° including the integrated 3-D-image of the left atrium and the aorta whilst continuosly recording of pressure and the intracardiac electrograms from the sheath-dilator-complex.

The 12-F-FlexCath® or FlexCath Advance® sheath (Medtronic) was exchanged for the SL0-sheath by a long stiff wire and continuosly rinsed by saline solution. Starting with the left superior all pulmonary veins were treated with the cryoballoon (28mm diameter) artic front® (CB1) or artic front advance® (CB2). Adequate balloon occlusion was visualized by injection of contrast medium via the distal port of the cryoballoon using the “last run hold” feature of the fluoroscopy unit. The 10-polar Achieve® (Medtronic) spiral mapping catheter with 20mm loop size allowed simultaneously recording the disappearance of the PV-signals during the cryo-application except from the initial procedures with the CB1 using just a Amplatz® stiff guidewire for probing the PV’s.

2.2.4 | Radiofrequency ablation

For radiofrequency ablation with the CARTO® electroanatomical mapping system, the patients got propofol sedation plus fentanyl bol those avoiding relevant movements of the patient counteracting adequate and reliable ablation in the fused 3-D-image. A dedicated temperature probe has been introduced into the esophagus for temperature monitoring during the RF delivery in most cases.

As described above, a 4 F femoral access sheath in the left groin was inserted for continuously monitoring of blood pressure. Two 7-F-sheaths were introduced for venous access and placement of the diagnostic electrophysiology catheters. A 6 F quadripolar steerable catheter (Dynamic XT®, Boston Scientific) was advanced into the coronary sinus for pacing whilst isolating the left pulmonary veins. A 5-F quadripolar catheter (Cournand-Curve, Supreme®, St. Jude Medical) was placed into the right ventricular apex for ventricular pacing if required because of vagal-induced bradycardias.

After successful double transseptal puncture an SL1-sheath and a steerable Agilis® sheath were advanced into the left atrium and continuously rinsed by saline solution. Using the CARTO® electroanatomical
mapping system the segmented CT dataset was fused with the Map of the left atrium. All PV’s were encircled point by point with 35 Watt anterior and 25 Watt posterior by an irrigated tip catheter (Thermocool®, Biosense Webster) at an irrigation rate of 17 ml/min. Isolation of the pulmonary veins was documented via a Lasso-catheter® (Biosense Webster) inserted proximally into the pulmonary vein.

2.3 | Statistical analysis

Data are presented as mean±standard deviation. Categorical variables were expressed as number and percentage of patients. The differences between continuous values were assessed using an unpaired two-tailed Student’s t-test for normally distributed continuous variables. Multiple analysis of variance with Bonferroni correction was performed for comparison of the three ablation groups. p-values <0.05 were considered to be significant.

For investigation of the influence of different parameters on the DFP, a stratified multiple analysis of regression was applied. All statistical analyses were performed using SPSS for Windows 18.0 (SPSS Inc.).

3 | RESULTS

The aim of the present analysis was to compare radiofrequency ablation with cryoablation using first and second-generation cryoballoon (CB1 and CB2) focusing on fluoroscopy exposure and procedural parameters.

3.1 | Patients

During the 7-year period from January 2011 until August 2017, 1543 consecutive patients underwent an AF ablation in our center. Among these patients, there were 1133 identified as first ablation procedures constituting the study population. From January 2011 until April 2014, the first-generation cryoballoon (CB1) was used in 211 patients, initially with guidewire only, later on with the achieve catheter. From May 2014 exclusively the second-generation cryoballoon (CB2) in combination with the achieve catheter was applied in 587 patients for all cryoablation procedures. Three hundred and thirty-five patients received the first PVI procedure with radiofrequency point-by-point ablation in combination with a CARTO® electroanatomical mapping system.

The percentage of male patients ranged from 49% in the RF group to 57% in the CB2 group. The mean age in RF patients and CB1 patients was 62±12 years and 59±12 years, respectively, whereas CB 2 patients were slightly older at 66±10 years.

In the CB1 group, the preponderance of paroxysmal AF (PAF) was 95%. In the RF group, the proportion of PAF was much lower at about 59%. The percentage of PAF was 74% in the CB2 group.

Against the background of targeting a comparison of the fluoroscopy exposure depending on the ablation principle / energy source and balloon generation in the cryoablation patients, the mean BMI was similar in all three patient groups at about 29.

Finally, the CHA²DS²VASc-Score in the RF and CB1 Group at 2.1±0.1 and 1.9±0.1, respectively, was much lower as compared to the CB2-patient group at 2.7±0.1.

All Patient characteristics are summarized in Table 1.

Table 1.

3.2 | Ablation parameters

The point-by-point PVI using radiofrequency could be accomplished by 34.0±17.5 RF pulses per patient with a cumulative duration of the RF delivery of 35.3±14.5 min for complete isolation of all pulmonary veins. For the single-shot PVI by means of the cryoballoon 7.7±1.5
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| TABLE 2  Ablation parameters | RF |
|--------------------------------|----|
| Patients                       | 335|
| Number of RF pulses (min) mean± SD | 34.0 ±17.5|
| Duration of RF pulses (min), mean± SD | 35.3 ±14.5|
| Common Os n (%)                | CB1 | CB2 | p-value |
| Patients                       | 211 | 587 |        |
| Guidewire, n (%)               | 121 (57) | 0 (0) |        |
| Achieve, n (%)                 | 90 (43) | 586 (100) | <.001 |
| Use of EP-Navigator, n (%)     | 102 (48) | 493 (84) | <.001 |
| Common Os, n (%)               | 23 (11) | 77 (13) | n.s.  |
| Total freezes, mean± SD        | 7.7 ±1.5 | 4.8 ±2.6 | <.001 |
| LSPV                           | Number of freezes, mean± SD | 2.1 ±0.6 | 1.6 ±0.9 | <.001 |
| Minimum temperature (°C), mean± SD | −48.8 ±9.9 | −45.5 ±6.6 | <.001 |
| LIPV                           | Number of freezes, mean± SD | 2.0 ±0.6 | 1.4 ±0.8 | <.001 |
| Minimum temperature (°C), mean± SD | −44.1 ±8.8 | −42.6 ±5.7 | n.s.  |
| RSPV                           | Number of freezes, mean± SD | 1.9 ±0.5 | 1.3 ±0.7 | <.001 |
| Minimum temperature (°C), mean± SD | −46.5 ±9.7 | −46.3 ±7.4 | n.s.  |
| RIPV                           | Freeze, mean± SD | 1.7 ±0.6 | 1.3 ±0.8 | <.001 |
| Minimum temperature (°C), mean± SD | −45.5 ±7.8 | −44.5 ±4.8 | n.s.  |

Abbreviations: CB 2, cryoballoon second generation; CB1, cryoballoon first generation; LIPV, left inferior pulmonary vein; LSPV, left superior pulmonary vein; RF, radiofrequency; RIPV, right inferior pulmonary vein; RSPV, right superior pulmonary vein.

freeze were required using the CB1 und 4.8 ±2.6 freezes using the CB2. The minimum temperatures ranged from −42.6 ±5.7 °C in the left inferior pulmonary vein (LIPV) until −48.8 ±9.9 °C in the left superior pulmonary vein LSPV.

The ablation parameters are detailed in Table 2.

3.3 | Fluoroscopy exposure

3.3.1 | Dose area product (DAP)

Mean fluoroscopy dose area product (DAP) in the patients treated with RF energy was 508 ±654 cGycm² and thereby comparable to the fluoroscopy dose in the CB-2 patient group with 564 cGycm² ±489 (p =.509), whereas the fluoroscopy dose in the patients treated with CB1 was twice as much with 1077 ±683 cGycm² (p <.001, Figure 1).

3.4 | DAP/BMI—subscripted DAP

The newly introduced parameter—the fluoroscopy exposure divided by the BMI—or the subscripted DAP—was again fairly the same in the RF group with 17.5 ±22.7 cGycm²/BMI-point and the CB2 group with 18.5 ±13.8 cGycm²/BMI-point (p = 1.0). However, this value was nearly twice as much at 37.1 ±23.9 cGycm²/BMI-point (p <.01) the CB1 group (Figure 2).

The calculated regression coefficients yielded by multiple regression analysis for the parameter DAP/BMI were 26.7 (CI 95% 15.85/37.62; cor. R² 0.545) in the RF group, 53.1 (CI 95% 35.10/71.01; cor. R² 0.351) in the CB1 group and 47.2 (KI 95% 40.22/54.12, cor. R² 0.485) in the CB2 group. Whereas an increase in BMI by one point will increase the DAP only by 26.7 cGycm²/1 BMI-point using RF ablation, the same increase in BMI will elevate the DAP by 53.1 cGycm² and 47.2 cGycm², respectively, in the cryoballoon groups.

3.5 | Fluoroscopy time

The mean fluoroscopy time in the RF group was 9.6 ±5.2 min.

Using the first generation cryoballoon the mean fluoroscopy time was 17.7 ±5.9 min. The introduction of the second-generation cryoballoon led only to slightly shorter fluoroscopy durations at 16.3 ±6.8 min (Figure 3). The fluoroscopy times in both CB groups were significantly longer as compared to the RF procedures (p <.001).
Procedure duration

In contrast to the fluoroscopy time the procedure duration was longest in the RF patients (115 ± 34) and significantly shorter in both cryoablation groups: CB1 group 96 ± 17 min and CB2 group 75 ± 16 min (p < .001, Figure 4).

Fluoroscopy exposure and BMI

We analyzed the impact of the BMI on the fluoroscopy exposure differentiated by the type of ablation. Therefore, all patients were divided into three groups: BMI below 25 (non-obese patients), between 25 and 30 (moderate obese patients) and above 30 (obese patients).

3.7 | Fluoroscopy exposure and BMI

In the non-obese patients, the DAP was lowest in the CB2 group with 306 ± 620 cGycm² and 412 ± 752 cGycm² in the RF group. The highest DAP was found in the CB1 group (757 ± 620 cGycm²). As far as the difference between RF and CB2 was not significant both types of ablation have a comparable DAP with a trend to a lower DAP using cryoablation with the second-generation balloon (Figure 5).

In the moderate obese people, the DAP was similar between RF ablation and cryoablation using the second-generation cryoballoon: RF group 487 ± 509 cGycm² and CB2 group: 472 ± 584 cGycm². Again, the CB1 group has had the highest DAP with 1123 ± 791 cGycm². In these moderate obese patients, it depends from the preference of the operator whether to use RF or cryoenergy with respect of the fluoroscopy exposure.

Finally, in very obese patients with an BMI > 30 the DAP was 603 ± 267 cGycm² in the RF group, 1248 ± 275 cGycm² in the CB1 group and 794 ± 639 cGycm² in the CB2 group favoring RF ablation.
in obese patients to avoid excessive fluoroscopy exposure to the patient as far as to the cathlab staff.

### 3.8 | PVI success rate

Freedom of clinical relapse with documented atrial fibrillation within 1 and 2 years was 73.4% and 57.3% in CB1 group, 81.3% and 69.2% in the CB2 group and 81.8 and 72.2% in the RF group \((p = .012 \text{ CB1 vs. RF); } p = .057 \text{ CB1 vs. CB2 and } p = .273 \text{ CB2 and RF).}\)

### 3.9 | Complications

The overall complication rate in our study was as low as 3.6% in the CB2 group, 4.8% in the RF group, and 6.2% in the CB1 group (Table 3). We observed more pericardial effusions in the RF group (RF 3.0% vs. 0.5 and 0.7 in the CB1 and CB2 group, respectively) and more phrenic nerve palsies in CB1 group (4.7%) but not in the CB2 group (0.9%). All phrenic nerve palsies disappeared within 12 months.

![Fluoroscopy exposure and BMI](image)

**FIGURE 5** Mean fluoroscopy exposure depending on the BMI for PVI in patients with atrial fibrillation ablation by RF, CB1 and CB2 (*p < .01) BMI, body mass index; CB1, cryoballoon first generation; CB2, cryoballoon second generation; PVI, pulmonary vein isolation; RF, radiofrequency.

### 4 | DISCUSSION

At the background of the increasing awareness of the nonnegligible impact of radiation exposure associated with the growing number of interventional electrophysiological procedures, we have evaluated the fluoroscopy exposure in atrial fibrillation ablation by PVI using radiofrequency and cryo-technology in this retrospective study in 1133 patients. Hereby, we focused not only on the effect of restrictive fluoroscopy settings applying the ALARA principle (As Low As Reasonably Achievable) but also on the BMI of the patients for comparison of the different approaches in PVI. As long as many studies reported fluoroscopy times only\(^5^,23\) we think according to more recent publications\(^4\) that the resulting DAP and its relation to the BMI of the patients is the most relevant parameter for estimation of the radiation exposure both to patients and the cathlab staff.

### 4.1 | RF versus cryoballoon-based PVI for treatment of atrial fibrillation

Consistent with the current data from several studies comparing RF and CB ablation\(^5,24\) for treatment of paroxysmal atrial fibrillation both approaches yielded the same efficacy at low complication rates in our study. Freedom of clinical relapse with documented atrial fibrillation within 1 and 2 years was 73.4% and 57.3% in CB1 group, 81.3% and 69.2% in the CB2 group and 81.8 and 72.2% in the RF group in our study—comparable to the results of the Fire and Ice data published by Kuck et al.\(^5\): The primary efficacy endpoint occurred there in 34.6% of the patients in the cryoballoon group and in 35.9% in the radiofrequency group within 1-year. Later on, the same authors reported a lower rate of repeat ablations, direct-current cardioversions, all-cause rehospitalizations, and cardiovascular rehospitalizations during follow-up in patients treated by the cryo-balloon.\(^24\)

### 4.2 | DAP, fluoroscopy time, and fluoroscopy settings—What matters on evaluating the fluoroscopy exposure?

Our data, in concert with published evidence, show that offering only fluoroscopy duration without mentioning the DAP can be misleading.

### TABLE 3 | Complications

|                | RF  | CB1 | CB2 | p-value          |
|----------------|-----|-----|-----|------------------|
| Patients (n)   | 335 | 211 | 587 |                  |
| Pericardial tamponade, n (%) | 10 (3.0)* ** | 1 (0.5) | 4 (0.7) | 0.037 (* RF vs. CB1) 0.010 (** RF vs. CB2) |
| Phrenic nerve palsy, n (%) | 2 (0.6) | 10 (4.7)** | 5 (0.9) | <0.001 (* RF vs. CB1) <0.001 (** CB1 vs. CB2) |
| Hematoma, n (%) | 2 (0.6) | 2 (0.9) | 9 (1.5) | n.s.            |
| Arteriovenous fistula, n (%) | 2 (0.6) | 0 (0) | 3 (0.5) | n.s.            |
| All complications, n (%) | 16 (4.8) | 13 (6.2)* | 21 (3.6) | 0.049 (* RF vs. CB2) |

Abbreviations: CB 2, cryoballoon second generation; CB1, cryoballoon first generation; RF, radiofrequency.
to evaluate the resulting radiation exposure in interventional cardiology. In fact, fluoroscopy time alone is an overestimated factor in patient and operator radiation exposure.\textsuperscript{25}

Casella et al.\textsuperscript{4} reported data from a large high-volume center involving 6095 electrophysiological procedures including 2416 atrial fibrillation ablations. The mean DAP for PVI was 3737 (3735–13,628) cGycm\textsuperscript{2} at fluoroscopy times of 23 (15–35) min. Over the entire study period of 7 years a relevant reduction of fluoroscopy time from 45 (32–64) min to 16 (11–22) min accompanied by a reduction in radiation exposure from 16,213 (9466–26,732) cGycm\textsuperscript{2} to 3455 (1643–6365) cGycm\textsuperscript{2} could be achieved. Depending on the energy source for PVI, cryoablation was associated with higher dose area product 7820 (4195–13,853) cGycm\textsuperscript{2} versus 7178 (3668–13,423) cGycm\textsuperscript{2} (p < .001). In contrast to our data, the fluoroscopy time in this study was not different for radiofrequency catheter ablation with 24 (15–36) min in comparison to cryoablation with 22 (15–32) min.

In a multicenter study, comparing contact force (CF)-guided radiofrequency (RF) with second-generation cryoballoon (CB) ablation Squara et al.\textsuperscript{26} reported a DAP of 4853 cGycm\textsuperscript{2} at a mean fluoroscopy time off 19.3 ± 8.2 min in the CB group and a DAP of 4273 cGycm\textsuperscript{2} at mean fluoroscopy time of 17.6 ± 11 min in the RF group with comparable efficacy and complication rates in both groups. Procedure times were shorter in the CB group (109.6 ± 40 min) as compared to the RF group (122.5 ± 40.7 min). Despite slightly longer fluoroscopy durations in the RF group at versus the CB group there was no significant difference in the DAP.

Comparing these data with the results of our center 508 ± 654 cGycm\textsuperscript{2} at a mean fluoroscopy time of 9.6 ± 5.2 min in RF-PVI and 564 cGycm\textsuperscript{2} ± 489 at a mean fluoroscopy time of 16.3 ± 6.8 min in cryoballoon-PVI using the second generation of CB we got significant shorter fluoroscopy times in RF-PVI using the CARTO-Mapping system as compared to the cryoballoon ablation. This finding seems consistent with the advantage of the guidance of the PVI relying on the non-fluoroscopic mapping system in the RF patients. Even if the fluoroscopy times were at least about half of those reported by Casella et al.\textsuperscript{4} the resulting DAP-values in our study are much lower by the factor 7 when comparing to the values at the end of this study. Both studies were retrospectively without changes in the fluoroscopy technology illustrating that “real life” can be very different just facing a substantial reduction of DAP over the study period. There is a large discrepancy between a tow fold difference in the fluoroscopy time and the at least sevenfold difference in the DAP comparing to the data from Casella et al.\textsuperscript{4} from a large high volume-electrophysiology center with experienced operators with the results of our study. The possible reason for this remarkable difference in the resulting DAP for PVI could be both: different awareness of the operators\textsuperscript{27,28} and the technical settings of the fluoroscopy (7.5 pulses per min for fluoroscopy, FOV by 20 cm, no collimation in the Casella study).

This was highlighted in a small study of 180 patients by Wieczorek et al.\textsuperscript{29} investigating the effect of different modifications in the fluoroscopy protocol to minimize the radiation exposure in cryoablation procedures. Interestingly they focused on the same issues being standard in our cath-lab for more than 10 years: a general reduction of fluoroscopy frame rate to 3/s (3.75/s in our center), avoidance of cine runs and selective PV angiograms (cardiac CT in advance of all PVI-procedures in our center), and enhanced radiation awareness.\textsuperscript{19} By these changes a substantial reduction of the DAP from initially 3334 ± 2271 cGycm\textsuperscript{2} (same as reported by Casella et al.\textsuperscript{4} discussed previously) to 426 ± 433 cGycm\textsuperscript{2} despite only a slightly reduction of the fluoroscopy time from 16.7 ± 5.6 min to 13.8 ± 6.3 min could be achieved, highlighting the misleading issue of fluoroscopy duration being the most important factor in evaluating the procedure-associated radiation exposition.

It compares to our data supporting our approach adapting the setup of the fluoroscopy unit to the lowest dosage required for adequate image quality. The mean fluoroscopy doses in our study were comparable low: 508 ± 654 cGycm\textsuperscript{2} at a mean fluoroscopy time of 9.6 ± 5.2 min in the patients treated with RF energy and 564 cGycm\textsuperscript{2} ± 489 at a mean fluoroscopy time of 16.3 ± 6.8 min in the CB-2 patient group with (p = .461). In the CB1 group—at the beginning of our “learning curve” in cryoablation—DAP was twice as much with 1077 ± 683 cGycm\textsuperscript{2} (p < .01) even if the mean fluoroscopy duration of 17.7 ± 5.9 min was only slightly longer—may be also an effect of the increasing awareness of the operators.

### 4.3 Procedural safety using low fluoroscopy settings

As nicely shown by Sommer et al.\textsuperscript{10} low to near zero fluoroscopy atrial fibrillation ablation will not lead to safety issues. Furthermore, Huang et al.\textsuperscript{30} could demonstrate by a meta-analysis that the application of low- and zero-fluoroscopy approaches in PVI will not increase the risk of AF-recurrence, necessity of redo-ablation procedures and procedural complications.

The overall complication rate of AF-ablation procedures in our study was low at 3.6% in the CB2 group, 4.8% in the RF group, and 6.2% in the CB1 group. We observed more pericardial effusions in the RF group (3.0% vs. 0.5 and 0.7 in the CB1 and CB2 group, respectively) and more phrenic nerve palsies in CB 1 group (4.7%) but not in the CB2 group (0.9%). These observations are consistent with the current data from other studies\textsuperscript{10} and a meta-analysis of PVI-ablation procedures by Cardoso et al.\textsuperscript{31} showing a lower rate of pericardial effusions or tamponades in cryoablation as compared to radiofrequency ablation but a higher rate of mostly transient phrenic nerve palsies. The lower rate of transient phrenic nerve alterations in the CB-2 group may be a result of an increased awareness of this potential complication and the consistent use of phrenic nerve stimulation\textsuperscript{12} whilst treating the right pulmonary veins. Additionally, the introduction of electromyography monitoring using standard surface electrodes placed in the subxiphoidal region (compound motor action potential; CMAP)\textsuperscript{13} and termination of
cryoablation (quick Stop) in case of a decrease in the amplitude of this continuously registered signal more than one-third of the initial signal may have contributed to the comparable very low incidence of phrenic nerve palsies in the CB2 group. These data are in contrast to the study of Fürnkranz et al.\textsuperscript{14} who reported a much higher rate of phrenic nerve palsies using the second-generation cryoballoon as compared to first-generation cryoballoon. However, this group observed a trend to reduction of the phrenic nerve palsies over the time, what is again consistent with our own experience.

However, the type and incidence of complications in PVI is more dependent from the ablation principle and not from the excessive or restrictive use of fluoroscopy. The comparable low complication rate in our center despite the limitation to the absolutely necessary fluoroscopy disproves the argument that high fluoroscopic image quality is essential to avoid complications in ep-procedures.

4.4 | BMI and DAP

An increasing BMI is associated with an increase in radiation exposure both for the patient and the exposed cathlab staff\textsuperscript{31–33} as far as higher output of the fluoroscopy unit is required to obtain a reliable image quality leading to a higher amount of scatter radiation.

As expected, the mean DAP was lowest in the non-obese patients and highest in the obese patients irrespective from the ablation principle. Interestingly, the increase in DPA according to the obesity stage was lower in the RF ablation group as compared to the cryoablation group: whereas in the cryoballoon procedures the DAP was twice as high in obese versus non-obese patients, the DAP arose only at about 50\% in the RF ablation group.

This issue was supported by the introduction of the parameter DAP/BMI-point or “subscripted DAP” and the analysis of the impact of this parameter on the resulting radiation exposure. In general, the DAP indexed to the BMI allows a more objective comparison of different ablation procedures and study data: By excluding the BMI on the resulting DAP the influence of other factors—mainly fluoroscopy settings and the behavior of the operator depending of their awareness with respect to use as low fluoroscopy as reasonable required for sufficient image quality—can be focused on.

Regression analysis of this parameter supports the findings mentioned about concerning the different influence of the BMI depending of the ablation principle:

Whereas an increase in BMI by one point will increase the DAP only by 26.7 cGycm\textsuperscript{2}/1 BMI-point using RF ablation, the same increase in BMI will elevate the DAP by 53.1 cGycm\textsuperscript{2} and 47.2 cGycm\textsuperscript{2}, respectively, in the cryoballoon groups.

From the point of view of radiation exposure therefore RF ablation should be favored in obese patients to avoid excessive fluoroscopy exposure to the patient as far as to the cathlab-staff.

On the other hand, in non-obese patients, cryoablation has advantages over RF ablation concerning a lower DAP could be achieved.

4.5 | Limitations

This is a single-center study with a retrospective analysis. However, the data represent a “real-life” scenario without any study-related exclusion criteria for patients. Even if all operators used the same fluoroscopy unit with the low-dose EP-setup we could not check for the use of different angulations and preferences using more RAO or LAO projections during the procedure which could represent a certain bias on the DAP. A 10° increase in angulations contributes substantially to the fluoroscopy dose\textsuperscript{14} and LAO projections require in general more output of the fluoroscopy unit than RAO projections.\textsuperscript{35}

Finally, success rate depending on the ablation approach was not the primary intention of this analysis so far not all patients got the complete follow-up (including repetitive Holter-monitoring or perfectly by implantable loop reorders) as would be required for a detailed analysis focusing on this issue.

5 | CONCLUSIONS

Despite longer fluoroscopy durations in the CB technique, the introduction of CB2 resulted in a comparable low radiation exposure in PVI as compared to RF accompanied by shorter procedure durations. The relative increase in DAP in according to the BMI was higher in CB as compared to RF procedures favoring the latter technique in obese patients. The subscripted DAP (DAP/BMI) could become a useful index for comparison of different ablation approaches, especially in studies performed in countries with a high prevalence of obesity.

PVI for the treatment of AF can be performed with a radiation exposure that is about 60\% to 80\% lower than the reference DAP of 2800 cGycm\textsuperscript{2} which is recommended for standard coronary angiographies in Germany. This demonstrates that it is worthwhile adapting the fluoroscopy settings to the minimum as reasonable in order to limit radiation exposure in interventional electrophysiology.

Further reduction of radiation exposure even with conventional fluoroscopy by evolving technological advances (i.e., clarity view, Philips) should become achievable and endorsed by the ep community parallel to the application of non-fluoroscopic techniques.

AUTHOR CONTRIBUTIONS

Konstantin Heinroth: concept/design, data analysis/interpretation, drafting article. Tilman Blum: data collection, data analysis/interpretation, statistics. Max Drexler: data collection, data analysis/interpretation, statistics. Alexander Plehn: concept/design, data collection, statistics. Thomas Hartkopf: concept/design, data
CONFLICT OF INTEREST

All authors declared no conflict of interest. None of the authors has received any funding’s from Medtronic (Cryoballoon), Biosense Webster (CARTO) or Philips (fluoroscopy unit).

DISCLOSURE STATEMENT

The undersigned author transfers all copyright ownership of the manuscript entitled "X-ray exposure in cryoballoon vs. radiofrequency ablation for atrial fibrillation over seven years: A single-center study" to Wiley in the event the work is published. The author warrants that the article is original, is not under consideration by another journal, and has not been previously published.

I sign for and accept responsibility for releasing this material on behalf of any and all co-authors.

ETHICS APPROVAL STATEMENT

As far as an informed consent into a retrospective analysis of patient data is not feasible, patient data collection and management were approved by the local medical ethics committee.

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