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Research article

Reduction of fluoroscopy dose for cardiac electrophysiology procedures: A feasibility and safety study

F. Plank[a], B. Stowasser[b,1], D. Till[b,1], W. Schgör[a], W. Dichtl[a], F. Hintringer[a], G. Weiss[a], M. Stühlinger[a,*]

[a] Medical University of Innsbruck, University Clinic of Internal Medicine III / Cardiology and Angiology, Innsbruck, Austria
[b] Siemens Healthcare GmbH, Forchheim, Germany

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ABSTRACT

Background: Exposure to high doses of radiation during cardiac interventional procedures is associated with increased rates of cataract and cancer in patients and staff members. Thus, reduction of radiation is recommended by international medical societies. The aim of this study was to evaluate, if the lowest reasonable fluoroscopic acquisition setting for electrophysiological procedures using a novel X-ray detector operated at a minimum detector entrance dose per fluoroscopy pulse is feasible and safe.

Methods: 641 consecutive patients (407 m/234f) underwent ablation procedures at our institution between August 2015 and December 2017. All ablations were performed using an Artis Q.zen X-ray system (Siemens, Germany). The first 308 patients were treated using the conventional dose program ("fluoroscopy zen standard"), from October 2016 until December 2017 another 333 patients underwent ablations using the optimized X-ray dosing program "fluoroscopy zen ULD". For the standard program fluoroscopy dose was set to 18nGy/f, for the minimized dosing program the dose was set to 6nGy/pulse and could be increased to 10 or 15 nGy/pulse manually.

Results: A total of 213 AV-node reentry tachycardia (AVNRT), 73 accessory pathways (AP), 71 atrial flutter and 284 atrial fibrillation (AF) ablation procedures were performed. Pulmonary vein isolation was performed using an electroanatomic mapping system (CARTO, Biosense Webster, USA) in 117 or a cryoballoon (Cryocath Medtronic, USA) in 167 patients. Total area dose could be reduced in all groups by a mean of 74.7% (4201.4μGym^2 vs. 1063.7μGym^2), with a relative reduction of 73.1% for left atrial and 78.0% for right sided ablations. Total fluoroscopy time, procedure duration, acute ablation success, recurrence rate and complications remained unchanged.

Conclusion: Fluoroscopy dose could be significantly reduced using an optimized X-ray dosing program in a novel X-ray detector without increasing total fluoroscopy time and without alterations of the incidence of recurrences or complications.

1. Introduction

Medical radiation is the largest artificial source of ionizing emissions in Western countries, accounting for approximately 20% of total radiation dose. [1] The majority of medical radiation is apportioned to computed tomography imaging. However, among patients receiving the highest annual doses (> 20–50 mSv), cardiac catheterization procedures are the main contributors. [2]. Along the same lines more than 60% of medical staff with the highest annual exposure (> 6 mSv) are electrophysiologists and interventional cardiologists. [3]. Exposure to high doses of radiation is associated with DNA damage [4], as well as elevated incidence of cataract [5] and cancer [6] in radiologists and cardiologists.

Lead aprons, thyroid collars, lead glasses and appropriate shielding have been the mainstay of operator radiation protection for decades, but these measures are only partially effective. Furthermore, radiation

* Corresponding author at: University Clinic of Internal Medicine III, Cardiology and Angiology, Medical University of Innsbruck, Anichstrasse 35, 6020, Innsbruck, Austria.

E-mail addresses: fabian.plank@i-med.ac.at (F. Plank), boris.stowasser@siemens-healthineers.com (B. Stowasser), dietrich.till@siemens-healthineers.com (D. Till), wilfried.schgoer@tirol-kliniken.at (W. Schgör), wolfgang.dichtl@tirol-klinken.at (W. Dichtl), florian.hintringer@tirol-kliniken.at (F. Hintringer), guenter.weiss@tirol-kliniken.at (G. Weiss), markus.stuehlinger@tirol-kliniken.at (M. Stühlinger).

[1] employee Siemens Healthcare GmbH, Forchheim / Germany.

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exposure to patients can only be reduced by improved X-ray tubes, flat panel detectors and enhanced image processing. Thus, numerous international medical societies recognize the increased need for ionizing radiation regulation and integrated dose reduction recommendations in addition to adequate protection [7–11]. Specifically, most guidelines include the "As Low as Reasonably Achievable (ALARA)" principle when choosing equipment settings to minimize radiation time and dose.

Multiple procedural protocols have been applied to achieve reduction in periprocedural radiation exposure including a limitation of fluoroscopy time, frame rate and field size, optimizing detector positions and utilization of 3D mapping systems in complex procedures. As these factors work symbiotically, we aimed to further lower radiation dose utilizing a novel angiography system and dose-dynamic x-ray protocol during electrophysiological procedures without compromising patients' safety.

2. Methods

All consecutive patients, who underwent ablation procedures after installation of a novel biplane Artis Q.zen X-ray system (Siemens, Forchheim, Germany) in our electrophysiology laboratory in July 2015, were included. The system is equipped with a gigalix tube and novel crystalline silicon detector that reduces electronic noise and allows imaging at ultra-low-dose levels. Moreover, an established Automatic Exposure Control (AEC) automatically adopts different system parameters (tube current, pulse width, focal spot, pre-filtration and copper filtration) to ensure optimal image quality independent of angulation and patient weight. [12] Consequently, radiation can be reduced for both patients and staff, but still meeting high image requirements needed in electrophysiology procedures.

Diagnostic electrophysiology (EP) and ablation procedures were performed by 4 experienced electrophysiologists and included ablation of atrioventricular nodal reentry tachycardia (AVNRT), accessory pathways (AP), typical right atrial flutter and atrial fibrillation (AF). Because of a low case number ventricular tachycardia (VT) ablations and AV nodal ablations were excluded from the analysis. Left atrial ablations were either carried out using radiofrequency including an electroanatomic mapping system (CARTO 3, Biosense Webster, USA) or a cryoballoon (Cryocath Medtronic, USA) without a 3D mapping system. All procedures were performed according to current clinical standards.

Procedures between August 2015 and October 2016 were performed using the conventional dosing program (fluoroscopy zen standard) provided by the manufacturer when the novel system was installed. Procedures performed after October 2016 utilized the optimized X-ray dosing program fluoroscopy zen ULD. Frame rates were set to a standard of 7.5 fps and tube current to 90 kV in both programs. Cine-loops were acquired as single shots at a tube current of 81 kV. Additionally, standard ALARA principles were applied in all procedures.

The study was part of a quality management program to reduce radiation dose in electrophysiological procedures at our center in cooperation with Siemens. It was conducted in accordance with the Declaration of Helsinki and approved by the local institutional review board. All patients gave written informed consent before the procedure.

The aim of the study was to evaluate quality and duration of the EP procedures using the novel crystalline detector technology at the minimal feasible pulse dose still resulting in a sufficient and reliable image quality.

2.1. Fluoroscopy zen standard ("standard")

For the setting used at the time of installation of the X-ray system, standard fluoroscopy dose was set to 18nGy/f; added settings were FL (-) with 10nGy/pulse and FL(+) with 29nGy/pulse.

2.2. Fluoroscopy zen ULD ("ULD")

Using earlier in vitro studies [12] and results from EP studies performed with previous angiography systems [13], the minimal feasible pulse dose was determined by incrementally reducing the radiation dose. Based on this minimal level an ultra-low dose (ULD) program with an effective dose of 6 nGy/f, as well as two higher doses were implemented at 10 nGy/f (low dose, LD) and 15 nGy/f (standard dose, SD). Each procedure was started using the ULD level and LD as well as SD programs with higher doses could be selected manually during the procedure by the operator in case of transient inadequate image quality. Added settings were also continuously adapted based on the patient specifics and angulations to optimize image processing and system settings including the field of view, copper filter, tube current, potential (tube voltage), pulsing time and focus.

2.3. Data collection and statistical analysis

Information on ablation details (indication, type of procedure, primary operator, total fluoroscopy exposure (min) and total area dose (TAD in μGm^2), on patient demographics (age, gender, BMI), complications, redo procedures and arrhythmia recurrence were extracted retrospectively from the Austrian ablation registry. Additional or missing technical and clinical data were gathered by chart review. Patients were regularly followed by the referring physician after SVT ablations and at our out-patient clinic after AF ablations. The latter routinely underwent repeated follow ups up to 12 months including ECG-exams and 7-day Holter 3–6 months and 1 year after AF ablation and outcome data and complications were entered in the electronic ablation registry charts. For atrial fibrillation and atrial flutter procedures any asymptomatic or symptomatic episode lasting > 30 s in 7-day Holters or symptomatic arrhythmic episodes lasting > 30 s without ECG documentation were defined as recurrences. Symptomatic arrhythmias and / or ECG documentations of clinical arrhythmias were defined as recurrences after AVNRT or AP ablations.

Statistical analysis was performed using SSPS software (V24.0, SPSS Inc., Chicago, USA). Quantitative variables were tested for normal distribution and are expressed as means ± standard deviation or median (25th and 75th percentile), as appropriate. Categorical variables are displayed as frequencies and percentages and were tested using Chi-Square test or Fisher's exact test. Continuous variables were tested for the mean difference using independent *t*-test or one-way ANOVA. Two-tailed p-value of less than 0.05 was considered statistically significant.

2.4. Endpoints

Primary endpoint was total area dose (μGm^2) and fluoroscopy exposure (min) as reported in scanner protocols. Secondary endpoints included procedural duration, complications, arrhythmia recurrences and frequency of redo ablations.

3. Results

A total of 641 ablations, specifically 213 (33.2%) AVNRT, 73 (11.4%) AP, 71 (11.1%) right atrial flutter and 284 (44.3%) atrial fibrillation procedures were included in the study. Left atrial ablations were performed either using radiofrequency ablations including an electroanatomic mapping system in 167 (58.8%) or a cryoballoon in 117 (41.2%) patients. Patient characteristics are given in Table 1 (Fig. 1).

Total area dose (TAD; Table 2, Fig. 2) could be significantly reduced using the ULD program for both supraventricular tachycardia (429.6 ± 740.6 μGm^2 vs. 1954.0 ± 2240.3 μGm^2; $p < 0.0001$) as well as left atrial AF fibrillation ablations (1889.8 ± 1903.6 μGm^2 vs. 7027.1 ± 5917.8 μGm^2; $p < 0.0001$) compared with the standard

Table 1
Demographics of included patients (n = 641).

Parameter	Standard n = 308	ULD n = 333	p
Age	52.4 ± 15.9	52.5 ± 16.4	0.95
Female	104 (34.2)	130 (39.0)	0.21
BMI	25.4 ± 4.1	25.9 ± 4.3	0.10
BSA	1.95 ± 0.24	1.95 ± 0.22	0.62
SVT	171 (56.3)	199 (59.8)	0.88
AVNRT	100 (32.9)	113 (33.9)	
AP	38 (12.3)	35 (10.5)	
AP overt	22 (7.2)	23 (6.9)	
AP concealed	16 (5.3)	12 (3.6)	0.37
Atrial Flutter	33 (10.9)	38 (11.4)	
AF ablations	137 (45.1)	147 (44.1)	0.89
Radiofrequency	77 (25.3)	90 (27.1)	0.61
Cryoballoon	60 (19.7)	57 (17.1)	
Paroxysmal AF	109 (35.9)	101 (30.3)	0.043
Persistent AF	28 (9.1)	46 (13.8)	

Abbreviations: AF-atrial fibrillation, AP-accessory pathway, AVNRT-atrioventricular nodal reentry tachycardia, BMI-body mass index, SVT-supraventricular tachycardia.

Table 2
Total area dose of all ablation procedures (n = 641).

Ablation Procedure	Standard (μGm^2)	ULD (μGm^2)	p
Total SVT ablations	1954.0 ± 2240.3	429.6 ± 740.6	< 0.0001
AVNRT	1459.6 ± 1450.2	297.7 ± 517.4	< 0.0001
Accessory Pathway	2200.5 ± 2536.2	619.4 ± 1082.5	< 0.001
AP overt	1637.7 ± 1878.8	572.7 ± 1119.0	0.028
AP concealed	2974.3 ± 3134.0	709.1 ± 1050.9	0.024
Atrial flutter	3168.5 ± 3219.0	647.0 ± 848.1	< 0.0001
Total AF ablations	7027.1 ± 5917.8	1889.8 ± 1903.6	< 0.0001
Radiofrequency	8595.9 ± 7047.9	1520.4 ± 1368.1	< 0.0001
Cryoballoon	4979.5 ± 2981.9	2473.0 ± 2430.5	< 0.0001
Paroxysmal AF	6842.0 ± 6066.4	1973.9 ± 2061.1	< 0.0001
Persistent AF	7740.9 ± 5347.4	1705.1 ± 1505.3	< 0.0001

Abbreviations: AF-atrial fibrillation, AP-accessory pathway, AVNRT-atrioventricular nodal reentry tachycardia, SVT-supraventricular tachycardia.

protocol. Relative dose reduction was 78.0% for SVT and 73.1% for AF ablations (Table 2). Sub-group analysis showed the most significant TAD reduction among right-sided ablations in AVNRT (-79.6% relative dose reduction, $p < 0.0001$), AP (-71.9%, $p < 0.001$) and right atrial flutter (-79.6%, $p < 0.0001$). In the subgroup of more complex AF ablations TAD reduction was more pronounced in RF ablations using a 3D mapping system (-82.3%, p = 0.0001) than in left atrial cryoballoon procedures (-49.3%, p = 0.0001). Patients treated for paroxysmal AF (-71.2%, p = 0.0001) and persistent AF (-78.0%, p = 0.0001) both showed highly significant reductions (Table 2, Fig. 3).

Overall, a change of fluoroscopy dose program (from ULD to LD or SD) at some point of AF ablations due to suboptimal image quality was needed in only 21.7%. Of these, 6.7% of ablations were transiently performed in LD and utilization of SD was deemed necessary temporarily in 15% of patients by the treating electrophysiologist.

In contrast, total fluoroscopy time did not increase using the dose reduction protocol, but could even be slightly reduced in left atrial

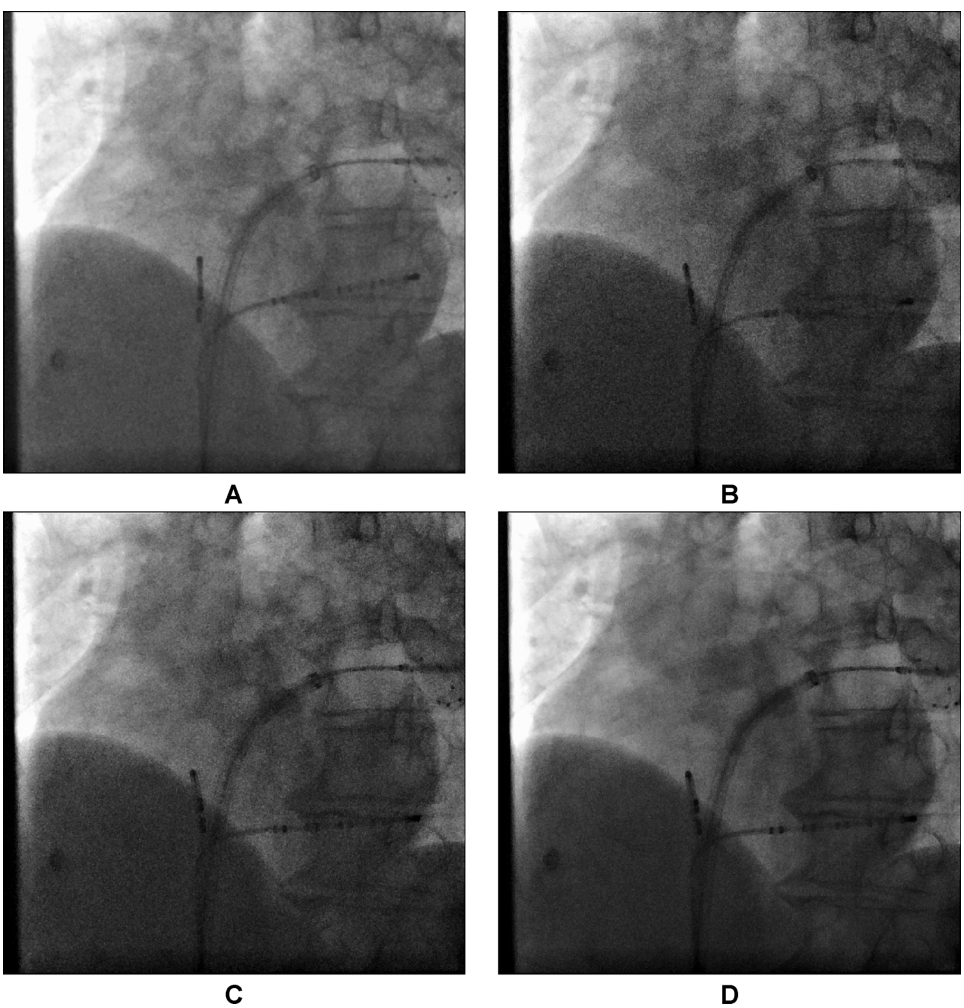

Fig. 1. Visual comparison between fluoroscopy zen standard and Fluoroscopy ULD mode (different dose programs).
Fluoroscopy shots in a LAO 45° view are shown in fluoroscopy zen standard mode and 3 different doses of fluoroscopy zen ULD mode in the same patient during left atrial cryoballoon ablation. A cryoballoon with a circular catheter at its tip was placed in the left inferior pulmonary vein and diagnostic catheters in the RV and the coronary sinus. Placement of the balloon at the antrum of the vein at the cardiac surface is visualized even with the lowest dose of ULD. A: zen standard (18ngy/f); B: zen ultra low dose with an effective dose of 6 nGy/f (ULD); C: zen low dose with 10 nGy/f (LD); D: zen standard dose with 15 nGy/f (SD)

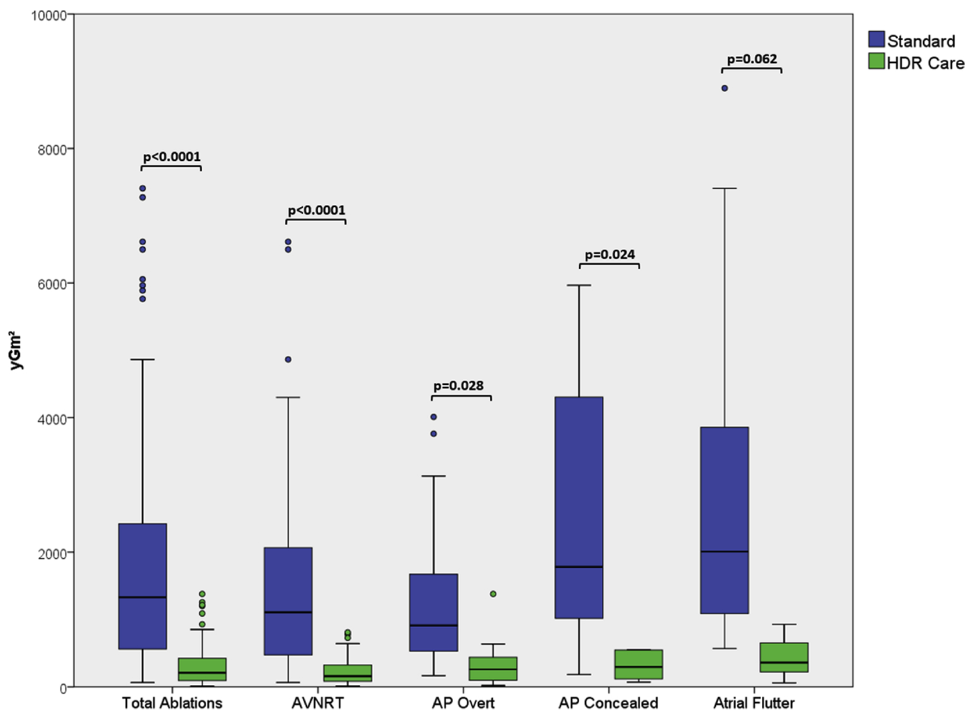

Fig. 2. Radiation dose for ablations of supraventricular tachycardia (SVT, n = 357).
Total area doses (μGm^2) for procedures using the Standard (blue) and the ULD (green) programs are shown for AVNRT (atrioventricular nodal reentry tachycardia), overt and concealed accessory pathway (AP) and atrial flutter ablations

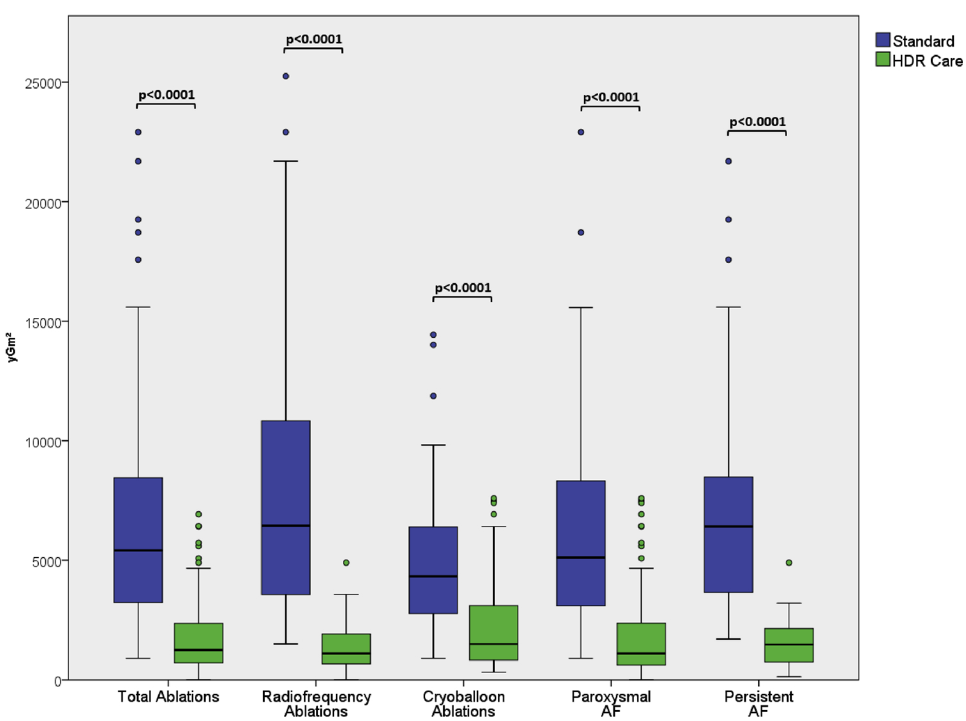

Fig. 3. Radiation dose for left atrial ablations in patients with atrial fibrillation (AF, n = 284). Total area doses (μGm^2) for procedures using the Standard (blue) and the ULD (green) programs are shown for cryoballoon and radiofrequency ablation procedures, as well as for paroxysmal and persistent atrial fibrillation (AF) ablations.

ablations: mean fluoroscopy duration for SVT (11.9 ± 9.2 min vs. 11.7 ± 7.4 min, p = 0.85) did not show any significant differences overall or between different ablations, however duration of AF (23.2 ± 10.2 vs. 26.0 ± 12.0, p = 0.035) and specifically RF ablations using a 3D mapping system could be slightly, but significantly reduced (Table 3). Overall procedure time (from puncture to sheath extraction) also remained unaffected using the new protocol with a mean 1.7 ± 0.7 h compared to 1.9 ± 0.8 h (p = 0.059) for right-sided ablation and 3.5 ± 1.2 h in the standard and 3.4 ± 1.1 h in ULD patients for AF ablations (p = 0.60).

When fluoroscopy dose and time were compared between the first 10, 20 and 30 cases and the following procedures in the ULD program no significant differences were found. These results suggest a short time to adopt to the novel system settings and a steep learning curve.

Finally, radiation dose reduction using the ULD program did not lead to a higher complication or recurrence rate, as shown in Table 4: Overall occurrence of major complications was low: 18 transient (2.8%) and 3 persistent AV blocks (0.5%), 5 pericardial tamponades (0.8%)

Table 3
Total fluoroscopy time all ablation procedures (n = 641).

Ablation Procedure	Standard (min)	ULD (min)	p
Total SVT ablations	11.7 ± 7.4	11.9 ± 9.2	0.85
AVNRT	10.4 ± 5.5	10.0 ± 5.4	0.60
Accessory pathway	15.0 ± 10.3	17.0 ± 16.4	0.53
AP overt	13.2 ± 8.9	14.3 ± 14.3	0.47
AP concealed	17.5 ± 11.7	22.4 ± 19.3	0.42
Atrial flutter	12.2 ± 7.5	13.0 ± 7.2	0.64
Total AF ablations	26.0 ± 12.0	23.2 ± 10.2	0.035
Radiofrequency	26.5 ± 13.4	20.8 ± 9.5	0.002
Cryoballoon	25.3 ± 10.0	26.8 ± 10.3	0.42
Paroxysmal AF	26.2 ± 12.8	23.8 ± 10.8	0.15
Persistent AF	25.0 ± 8.2	21.8 ± 8.7	0.11

Abbreviations: AF-atrial fibrillation, AP-accessory pathway, AVNRT-atrioventricular nodal reentry tachycardia, SVT-supraventricular tachycardia.

Table 4
Procedural complications of all ablation procedures (n = 641).

Complication	standard (n = 308)	ULD (n = 333)	total (n = 641)	p
Major complication	16	23	39	0.46
pericardial tamponade	3	2	5	0.68
stroke / TIA	0	1	1	0.57
AV-block	8	13	21	0.48
transient	7	11	18	0.58
permanent	1	2	3	0.53
phrenic nerve palsy	0	1	1	0.57
Minor complication	11	5	16	0.46
access site bleeding	7	2	5	0.1
pneumothorax	1	1	2	0.73
air embolism	2	1	3	0.61
asystole or VF during procedure	1	1	2	0.73

Abbreviations: TIA - transient ischemic attack, AV-block - atrio-ventricular block, VF - ventricular fibrillation.

and 1 case of phrenic nerve palsy (0.2%) occurred during or after the procedure without unilateral distribution between standard or ULD protocol (p = 0.43).

A total of 47 redo procedures (14.1%) were necessary in the standard and 51 (15.6%) in the ULD group due to arrhythmia recurrences. Of these 30/308 (9.0%) atrial fibrillation patients in the standard group and 33/333 (10.7%) in the ULD group underwent a first or second procedure for arrhythmia recurrences. After adjusting for different follow-up periods, no significant difference remained between the groups (p = 0.29) for total procedures and separated in the type of arrhythmia.

4. Discussion

Cardiologists and specifically cardiac electrophysiologists are among the greatest radiation exposed medical professionals. [3] Within the scope of a quality management program we already implemented a number of protective measures at our institution to reduce radiation exposure, including additional lead shielding, optimized x-ray detector angulation and protocols to reduce radiation time (e.g. single picture cineangiography). After installation of a novel fluoroscopy system including a novel crystalline silicon detector that allows imaging at ultra-low-dose levels, it was our objective to implement a dynamic user-controlled x-ray program to further decrease radiation exposure during ablation procedures. The described protocol was shown to be feasible during various ablation therapies performed by four different operators with consistent reduction of TAD up to 80% without increasing radiation or procedure time, recurrences and complications.

According to an early report in 2002, the two main determinants beside the patients' body habitus include hardware settings (tube filtration, generator voltage and current), and its utilization (fluoroscopy time, field size, overlap of fields and user experience). [14] The key message still holds true in present time and has been the underlying idea for several recent dose reduction experiments in electrophysiology laboratories: A retrospective single-center assessment of the last 12 years at the Royal Hospital in Melbourne showed reduction consequent of radiation in left atrial ablations for the treatment of AF. The authors recognized technological advances over 8 different mapping and 2 ablation systems and operator experience as main reasons for approximately cutting the absorbed dose by half [15]. An even greater dose reduction could be observed in a single-center implementation of low-dose fluoroscopy pulsing compared to a historical control group of patients from the German national PVI registry [16]. Interestingly, an initial increase in dose with later subsequent radiation reduction was found, substantiating the learning curve of cumbersome hardware handling using these protocols [17]. An initial increase of radiation dose was not observed in our study, a fact that can be potentially explained by the experience and the comfort of the operators and the simplicity of the operational protocol used.

A recent low-dose study by Rogers and colleagues reported a successful reduction of the radiation dose by 61% in over 1000 ablation simulations in an anthropomorphic phantom model. Indeed, the authors reported that up-regulation of the fluoroscopy pulse was necessary in only a handful of simulations. [19] Similarly Bourier et al. recently used a low-dose pulse method by integrating the predecessor of the X-ray system used in our study into their ablation program. The authors analyzed 140 patients, stratified half of them into low-dose and the other half into ultra-low dose to observe a decrease of 77% radiation [18]. Our data intriguingly show that TAD can be even further reduced using an innovative X-ray system equipped with a novel tube and an ultra-sensitive detector, and that the ULD settings used in our protocol lead to a further reduction radiation dose in all electrophysiological procedures analyzed.

Fluoroscopy reduction can also be achieved in cardiac interventions using other fluoroscopy manufacturers. Specifically, Phillips Allura Clarity® and Allura Xper® systems were shown to perform accurately in complex electrophysiological [30] and valvular [31] procedures as well as coronary interventions [32] with a reduction of the dose area product by app. 40–50%. Crowhurst et al. compared similar X-ray systems of 2 different manufacturers and found that fluoroscopy could indeed be significantly reduced in a modern system with dose reduction properties. [29] **S**ince our study was carried out with a unique ultra-sensitive crystalline detector and a genuine Automatic Exposure Control (AEC) software, described software settings cannot be directly applied in other X-ray machines. However, multi-vendor comparisons using the lowest achievable and reliable X-ray dose would be an essential goal to develop a gold standard in fluoroscopy systems.

Our study used a novel dynamic adaption of the field of view and tube current for alternating C-arm angulations. A previous pivotal single-center trial compared different angulation techniques in a small cohort. Asymmetric collimation of each two ipsilateral angulation was found to yield a three- to nine-fold decrease of radiation as compared to conventional all-vein encompassment. [20] Another study could decrease radiation by optimizing the x-ray system settings and avoiding highly oblique projections in patients undergoing AF, atypical atrial flutter or ventricular tachycardia ablation [21]. Beyond collimation adaption and reduction of the distance between the patient and the detector, a German group substituted ionizing radiation through intracardiac echocardiography in cryoballoon ablated AF patients. The authors achieved a dose reduction of 69% without affecting complication or procedural rates in short term follow-up. [22] According to our results additional reduction could possibly be accomplished in the procedures described above using the fluoroscopy system and ULD settings used in our study.

Reductions in fluoroscopy exposure during left atrial AF ablations were more pronounced in RF ablations using a 3D mapping system for pulmonary vein isolation and additional linear ablations compared to cryoballoon ablations. Specifically, TAD could be reduced by app. 80% in RF ablations and only 50% in cryoballoon procedures. The most plausible explanation for this finding is that a higher radiation dose is necessary for positioning guidewires or circular catheters and for the verification of pulmonary vein occlusion using a cryoballoon. Software support using 3D or non-contact mapping systems already revealed the potential of dose reduction in these applications [23–28]: According to single-center experiences with small cohorts dose reduction ranging from 25 to 90% [23–27] was reported with shortening [23–26], unaffecting [28] or prolonging the procedure time [27]. In the current study cryoballoon procedures were selectively performed in patients with paroxysmal AF with normal anatomy of the left atrium. In contrast RF-ablations using a 3D mapping system was chosen primarily in persistent AF requiring additional lesions and patients with anatomic anomalies such as common pulmonary vein ostia. The advantage of a 3D mapping system in reducing fluoroscopy using our ULD protocol was confirmed in our study and this effect might even be more pronounced in a matched patient population [26].

5. Study limitations

Radiation dose was measured by the fluoroscopy system and therefore only indirectly reflects entrance skin dose. A more accurate estimation of radiation exposure (i.e. skin entrance dose and air kerma product) may be achieved by a dose box on patients' body surface with adjustments for BMI, collimation and shielding, or by dosimeter badges worn by physicians. Furthermore, duration of follow-up was significantly longer in standard-dose patients (23 months) compared to ULD (9 months). Rate of redo ablations or late complications may therefore be underestimated in the ULD group.

6. Study strengths

Several studies compared various dose reduction techniques implementing software or hardware protocols in different clinical scenarios. The present study was conducted in routine clinical ablation procedures by four different electrophysiologists, reflecting radiation exposure during daily clinical practice in an EP lab. In addition to dose reduction clinical endpoints were analyzed in a large patient population. Whilst most studies have focused on dose reduction in AF or VT ablations, this study's results show a consistent decrease in ionizing radiation across a variety of ablation procedures without compromising the patients' safety or outcome success.

7. Conclusion

Fluoroscopy dose can be significantly reduced by optimization of a state-of-the-art fluoroscopy system without increasing the total fluoroscopy or procedure time or affecting complication or success rates.

Disclosures

None.

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