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Safe procedures despite ultra low radiation doses during catheter ablations of atrial and ventricular arrhythmias—A multicenter experience

Philipp Attanasio MD^{1,6} Martin Huemer MD^{1,6} Nora Kaehler^{1,6} Theresa Keller² Tobias Schreiber MD^{1,6} Reinhard Niehues MD³ Dimitra Katsani-Potempa MD³ Rolf Michael Klein MD^{3,5} Ulf Landmesser MD^{1,6} Isabel Deisenhofer MD⁴ Osman Tutdibi MD³ Felix Bourier MD⁴

¹ Department of Cardiology, Charité–Universitätsmedizin Berlin, Campus Benjamin Franklin, Berlin, Germany

² Institute for Biometry and Clinical Epidemiology, Charité - Universitätsmedizin Berlin, Berlin, Germany

³ Augusta Krankenhaus Düsseldorf, Department of Cardiology, Academic Teaching Hospital of the University Faculty of Health, Düsseldorf, Germany

⁴ Department of Electrophysiology, German Heart Center Munich, Munich, Germany

⁵ Department of Cardiology, University Hospital Witten/Herdecke, Witten, Germany

⁶ DZHK (German Centre for Cardiovascular Research), Partner Site Berlin, Berlin, Germany

Correspondence

Philipp Attanasio, MD, Department of Cardiology, Charité–Universitätsmedizin Berlin, Campus Benjamin Franklin, Hindenburgdamm 30, Berlin 12203, Germany. Email: philipp.attanasio@charite.de

Philipp Attanasio and Martin Huemer authors contributed equally and thus share first authorship.

Osman Tutdibi and Felix Bourier authors contributed equally and thus share last authorship.

Abstract

Introduction: Despite the development of non-fluoroscopic catheter visualization options, fluoroscopy is still used in most ablation procedures. The aim of this multi-center study was to evaluate the safety and efficacy of a new ultra-low dose radiation protocol for EP procedures in a large number of patients.

Methods and results: A total of 3462 consecutive patients (male 1926 (55.6%), age 64.4 \pm 14.0 years, BMI 26.65 \pm 4.70) undergoing radiofrequency ablation (left atrial (n = 2316 [66.9%], right atrial (n = 675 [19.5%], or ventricular (n = 471 [13.6%]) in three German centers were included in the analysis. Procedures were performed using a new ultra-low dose protocol operating at 8nGy for fluoroscopy and 36nGy for cine-loops. Additionally a very low framerate (2-3FPS) was used. Using the new protocol very low Air kerma-area product (KAP) values were achieved for left atrial ablations (104.25 \pm 84.22 μ Gym²), right atrial ablations (70.98 \pm 94.79 μ Gym²) and ablations for ventricular tachycardias or PVCs (78.62 \pm 66.59 μ Gym²). Acute procedural success was achieved in 3289/3388 (97.1%) while the rate of major complications was very low compared to previously published studies not using low dose settings (n = 20, 0.6%).

Conclusion: The ultra-low dose, low framerate protocol leads to very low radiation doses for all EP procedures while neither procedural time, fluoroscopy time nor success or complication rates were compromised. When compared to current real-world Air KAP data the new ultra-low dose fluoroscopy protocol reduces radiation exposure by more than 90%.

KEYWORDS

ablation therapy, antiscatter grid, framerate reduction, radiation dose

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1 | INTRODUCTION

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While non-fluoroscopic catheter visualization options are increasingly used during most ablation procedures, fluoroscopy is still necessary at least to some degree to visualize catheter or wire location. Even if experienced operators already minimize fluoroscopy time, the lowest dose used per minute of fluoroscopy has to be achieved to reduce the risk of potentially fatal radiation induced complications for patients and operators.

For this purpose apart from standard measures to reduce radiation dose like using maximum collimation or keeping the detector close to the patient, so called "ultra-low dose" programs with optimized image processing and exposure system settings have been developed by EP physicians in cooperation with the X-ray system manufacturer.^{1,2}

These ultra-low dose programs may lead to very low contrast images that still serve the purpose, as image quality demands are usually modest, even during complex ablation procedures. Nevertheless, even experienced users need to get used to these low dose settings, especially in combination with very low framerates of down to 2–3 FPS. Apart from difficulties adapting to these low quality images, operators might also refrain to use the low dose settings because they expect an increase risk of complications caused by insufficient visibility of the catheters and surrounding anatomical structures. Previous trials evaluating the use of ultra-low dose programs for various EP procedures have not shown increased complication rates,^{1,2,3} although due to the comparatively low patients numbers some types of rarer complications might have been missed.

This multicenter trial aimed at showing the efficacy and safety of using an ultra-low dose radiation protocol in a large number of various EP procedures.

2 | METHODS

2.1 | Study design

This study represents a retrospective multicenter analysis of 3462 consecutive patients undergoing various EP-procedures. The procedures were performed between 2015 and 2018.

All procedures were performed with the same type of X-ray Angiography systems (Siemens Healthineers Artis systems; Siemens Healthcare AG, Erlangen, Germany) in order to avoid potential system-based differences.

For each patient demographic parameters such as age, sex, Body Mass Index (BMI), comorbidities and drug treatment were documented. As procedural parameters fluoroscopy time, total procedure time, total radiation dose (measured as DAP), acute procedural success and major periprocedural complications potentially associated with the dose reduction protocol were recorded. These included periprocedural death/cardiopulmonary resuscitation, relevant pericardial effusion (requiring elective or urgent pericardiocentesis or prolonged surveillance), periprocedural stroke/transient ischemic attack, air embolism, cardiac valve injury, new conduction disturbance/sinus node dysfunction requiring permanent pacing or phrenic nerve palsy.

In case of repeat procedures in the same patient only the index procedures was included in the analysis.

2.2 | Fluoroscopy protocol

The ultra-low dose program with optimized image processing and exposure system settings is based on the integrated automatic adjustment of five system parameters of the applied Siemens X-ray systems, including change of copper filtration, exposure time and focal spot.^{1,2,3} For the presented EP procedures a very low entrance dose at the detector for fluoroscopy (down to 8nGy) and cine loop acquisition (36nGy) was programmed.

The design of the X-ray Tube with anode track speeds up to 75 m/s and flat emitter-technology allows high tube currents up to 250 mA in fluoroscopy, which is the pre-requisite to maximize the copper beam filtration. Framerates of 2–3 FPS were used for all procedures.

The reduction of the Kerma-area product (KAP) was used to evaluate the effect of the above-mentioned changes, as KAP strongly correlates with skin dose and can be used for objective comparisons between x-ray systems. The expression "KAP" was used instead of "Dose Area Product" (DAP) according to the ICRP recommendation.⁴

2.3 | Ablation procedures

All EP procedures included in this study were performed in three different centers (German Heart Center Munich; Charité Berlin, Campus Benjamin Franklin, Department of Cardiology; Augusta Hospital Düsseldorf) by a total of seven different operators.

Procedures were grouped into left atrial (atrial fibrillation, left atrial tachycardia), right atrial (AVNRT, atrial flutter, right atrial tachycardia) and ventricular ablations (ventricular tachycardia and PVC-ablation). The procedures were performed according to current clinical standards as described before.² As 3D Mapping Systems CARTO three (Biosense Webster, Diamond Bar, CA, USA) EnSite Velocity (St Jude Medical, St Paul, MN, USA) as well as the Rhythmia mapping system (Boston Scientific, Marlborough, MS, USA) were used.

None of the included cases were performed using additional imaging modalities like intracardiac ultrasound or transesophageal echocardiography during the ablation procedure.

2.4 | Real time dosimetry measurements

In a substudy real time dosimetry (RaySafe i3 [RaySafe, Unfors, Hopkinton, Mass]) was used to measure operator radiation exposure during left atrial ablations. For this purpose real time dosimetry badges were placed outside of the lead apron at the left side of the chest. The

TABLE 1 Baseline characteristics and procedural data (all procedures)

Procedure	Left atrial	Right atrial	Ventricular	All
	n = 2316	n = 675	n = 471	n = 3462
Age, median (25-75%)	69.0 (59.5-75.6)	62.9 (48.5-74.4)	62.1 (49.6-72.8)	67.5 (56.2-75.1)
Male, n (%)	1261 (54.4)	371 (55.0)	294 (62.4)	1926 (55.6)
BMI, mean (±SD)	26.90 (±4.51)	25.94 (±5.07)	26.54 (±4.91)	26.65 (±4.70)
Use of 3D mapping system, n (%)	2308 (99.7)	559 (82.8)	463 (98.3)	3330 (96.2)
KAP, median (25-75%) (μGym2)	92.1 (51.8-142.5)	71.0 (20.0-97.0)	62.6 (30.0-113.9)	80.1 (39.8-132.4)
Procedural duration, mean (\pm SD) (min)	133.7 (±47.1)	85.6 (±37.0)	126.6 (±57.2)	123.3 (±50.5)
Fluoroscopy time, median (25-75%) (min)	6.3 (4.1-9.5)	4.5 (2.7-7.8)	3.0 (1.4-5.3)	5.5 (3.3-9.0)
KAP per minute fluoroscopy, median (25-75%) (μ Gym2)	14.1 (8.8-21.2)	9.8 (4.6-21.9)	20.6 (10.5-38.0)	14.0 (8.0-22.8)
Acute procedural success, n (%)	2289 (98.8)	665 (98.5)	334/397 (84.1) ^a	3288/3388 (97.9)ª
Major complications, n (%)	16 (0.7)	2 (0.3)	2 (0.4)	20 (0.6)

Abbreviations: BMI, Body mass index; KAP, Air kerma-area product; SD, Standard deviation.

^aPVC procedures with only sporadic PVCs (74 procedures) were excluded from the success calculation.

operators were blinded to the measured doses. Optimized shielding was used with table suspended lead curtains, ceiling suspended leaded plastic shields and radiation absorbing shields placed on the patient to minimize scattered radiation that reaches the operator.

2.5 | Definition of acute success

Acute procedural success was considered as efficacy endpoint. For PVI acute procedural success was defined as exit- and entry block for all pulmonary veins. If additional linear ablation was performed bidirectional block of the line was defined as acute success. For atrial flutter ablations bidirectional block over the cavotricuspid isthmus was considered as acute success. Noninducibility of the clinical arrhythmia was considered as acute success for AVNRT, AT, PVC, and VT ablations. If VT induction was not performed at the end of the procedure these procedures were not counted as acute success. PVC ablation procedures with only sporadic PVCs at the beginning of the procedure were excluded from the success rate calculation.

2.6 Statistical analysis

Mean values were calculated as the arithmetic average \pm standard deviation. A χ 2 test was used to compare categorical variables. For continuous variables Mann-Whitney *U* test was used in case of skewed data to evaluate group differences. An independent sample *t*-test was used if data were normally distributed. Distribution of variables was evaluated by checking histograms and using the Kolmogorow-Smirnow-Test. Data are presented as absolute numbers and percentages for categorical variables or mean \pm standard deviation (SD) for continuous variables. As this study is explorative, no adjusting for multiple testing was performed. All analyses were explorative, *p*-values are interpreted as such. Statistical analysis was performed with SPSS version 25 (IBM, Armonk, USA).

3 | RESULTS

A total of 2316 left atrial, 675 right atrial, and 471 ventricular procedures were included in the analysis. All operators were able to perform the procedures using the ultra-low dose protocol without switching to higher dose levels.

By using the ultra-low dose program very low Air KAP values were achieved for the various EP procedures (see Table 1). Table 2 shows detailed information for left atrial procedures. Results for comparison between different procedural types are included in the supplement section (see Table S1, S2, S3).

Table 3 and 4 show detailed data for right atrial and ventricular procedures. Table 5 shows detailed information on the recorded major periprocedural complications. Results for comparison between different procedural types are included in the supplement section. (see Table S4, S5, S6, S7, S8, S9, S10)

3.1 | Real time dosimetry results

A total of 145 left atrial ablation procedures were included in this substudy (97 pulmonary vein isolations (PVIs) and 48 PVI + Linear ablation/substrate based ablation). Mean radiation dose measured as KAP for the included procedures was 150.38 \pm 285.76 μ Gy/m² with a mean fluoroscopy duration of 9.9 \pm 9.9 min. Real time dose measurement showed very low average operator doses of 0.73 \pm 4.83 μ Sv. For comparison Figure 1 shows previously published radiation dose exposure for different cardiovascular interventions as well annual background radiation and radiation during an intercontinental flight.

4 DISCUSSION

Interventional cardiologists still experience high doses of cumulative radiation throughout their professional lives.⁴ This may lead to

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TABLE 2 Baseline characteristics and procedural data (left atrial procedures)

Procedure	PVI	PVI + Linear ablation/substrate based ablation	Ablation of left atrial micro- or macro-reentry tachycardia
	n = 1742	n = 128	n = 446
Age, median (25-75%)	68.0 (58.4-75.0)	70.1 (62.0-75.9)	72.5 (63.8-77.2)
Male, n (%)	991 (56.9)	64 (50.0)	206 (46.2)
BMI, mean (\pm SD)	26.91 (±4.55)	27.66 (±4.45)	26.60 (±4.38)
Use of 3D mapping system, n (%)	1741 (99.9)	128 (100)	439 (98.4)
KAP, median (25-75%) (μGym2)	90.7 (51.5-143.1)	97.9 (53.8-149.0)	95.0 (52.3-139.0)
Procedural duration, mean (\pm SD) (min)	133.6 (±46.1)	149.11 (±46.5)	129.67 (±50.3)
Fluoroscopy time, median (25-75%) (min)	6.2 (4.1-9.3)	8.0 (4.4-70.5)	6.4 (4.0-9.5)
KAP per minute fluoroscopy, median (25-75%) (μ Gym2)	14.4 (8.7-21.8)	13.0 (8.8-20.1)	13.1 (8.9-20.3)
Acute procedural success, n (%)	1724 (99.0)	124 (96.9)	441 (98.9)
Major complications, n (%)	14 (0.8)	2 (1.6)	0 (0.0)

Abbreviations: BMI, Body mass index; KAP, Air kerma-area product; SD, Standard deviation.

TABLE 3 Baseline characteristics and procedural data (right atrial procedures)

Procedure	Atrial flutter	AVNRT	AT
	n = 277	n = 343	n = 55
Age, median (25-75%)	73.0 (61.3-77.3)	53.3 (37.2-67.7)	57.1 (36.0-68.2)
Male, n (%)	203 (73.3)	138 (40.2)	30 (54.5)
BMI, mean (±SD)	26.84 (±5.10)	25.45 (±5.03)	23.84 (±3.98)
Use of 3D mapping system, n (%)	263 (94.9)	244 (71.1)	52 (94.5)
KAP, median (25-75%) (μGym2)	54.0 (23.0-118.0)	35.0 (17.0-75.0)	69.0 (34.0-127.0)
Procedural duration, mean (\pm SD) (min)	83.6 (±35.0)	80.3 (±31.4)	128.3 (±50.4)
Fluoroscopy time, median (25-75%) (min)	5.6 (3.3-9.4)	4.83 (±4.24)	4.2 (1.5-7.5)
KAP per minute fluoroscopy, median (25-75%) (μ Gym2)	9.2 (4.7-15.6)	9.4 (4.2-24.7)	16.7 (11.3-35.2)
Acute procedural success, n (%)	274 (98.9)	337 (98.3)	54 (98.2)
Major complications, n (%)	0 (0.0)	2 (0.6)	0 (0.0)

Abbreviations: BMI, Body mass index; KAP, Air kerma-area product; SD, Standard deviation.

radiation related disease like cataracts, but also an increased risk for malignancies with published reports showing a tendency to left sided brain or breast tumors in interventional cardiologists, whose left side is closer to the radiation source during most procedures^{5,6} It is therefore of utmost importance to reduce radiation exposure as much as possible.

The interventional electrophysiologist is fortunate as image quality demands for EP procedures are usually modest and, due to their size and diameter, ablation and diagnostic catheters as well as pacemaker leads are sufficiently visible even when low radiation doses are applied.

This is why modifications in the X-ray system settings like very low detector doses or a very short pulsewidth, tailored to the operators' needs, can be implemented to reach the lowest acceptable image quality. Multiple publications using different low dose protocols in combination with non-fluoroscopic catheter visualization tools have already been published and show impressive results with radiation doses of <200 $\mu \rm Gym^2$ for AF ablations.^1,7,8,9

Despite the available data, most EP labs still use "standard" settings, the same used for coronary interventions and therefore unnecessarily experience higher doses. The same is true for reducing frame rates, one of the simplest ways to reduce radiation dose. According to a European Heart Rhythm Association Survey, only 15% of the participating centers used a frame rate of less than six FPS for EP procedures.¹⁰

One of the reasons for this finding may be that in most countries radiation doses do not have to be reported for EP procedures and recommended maximum doses are not well defined.^{1.11}Another reason may be concerns about the safety of using such low dose settings. The aforementioned publications did not show any effect on procedural of RF-times, clinical outcomes or complication rates after the low dose

TABLE 4 Baseline characteristics and procedural data (ventricular procedures)

Procedure	VT	PVC
	n = 139	n = 332
Age, median (25-75%)	64.2 (55.2-73.7)	60.1 (47.9-72.5)
Male, n (%)	113 (81.3)	181 (54.5)
BMI, mean (±SD)	27.62 (<u>+</u> 5.46)	26.16 (±4.64)
Use of 3D mapping system, n (%)	138 (99.3)	325 (97.9)
KAP, median (25-75%) (µGym2)	93.0 (52.2-145.0)	51.1 (23.7-103.5)
Procedural duration, mean (\pm SD) (min)	157.2 (±56.5)	113.7 (±52.5)
Fluoroscopy time, median (25-75%) (min)	4.3 (2.2-7.9)	2.4 (1.2-5.0)
KAP per minute fluoroscopy, median (25-75%) (µGym2)	21.5 (13.6-32.0)	20.2 (8.5-42.1)
Acute procedural success, n (%)	91 (65.5) ^a	243/258 (94.2) ^b
Major complications, n (%)	1 (0.7)	1 (0.3)

Abbreviations: BMI, Body mass index; KAP, Air kerma-area product; SD, Standard deviation.

^aOnly VT ablations where VT inducibility was tested at the end of the procedure were considered as acute successful.

^bPVC procedures with only sporadic PVCs (74 procedures) were excluded from the success calculation.



FIGURE 1 Comparison between annual background radiation and different interventions.¹⁵ FRA, Frankfurt airport, Frankfurt, Germany; JFK, John F. Kennedy International Airport in New York City, USA; PVI, pulmonary vein isolation [Color figure can be viewed at wileyonlinelibrary.com]

setups had been implemented. Although, due to their size some of the rarer complications may have been missed.

To our knowledge the presented data is the first multicenter evaluation of a commercially available dose reduction protocol specifically designed for EP procedures. After a total of 3462 performed procedures, the resulting radiation doses measured as Air KAP were 104.25 (\pm 84.22) μ Gym² for left atrial, 70.98 (\pm 94.79) μ Gym² for right atrial and 78.62 (\pm 66.59) μ Gym² for ventricular procedures. Again procedural durations and clinical outcomes were not compromised. The recorded periprocedural complications were not increased when compared to data from larger registries.^{12,13} When compared to real-world Air-kerma area product data, as presented in a European Heart Rhythm Association survey,¹² or larger registries^{14,15} the new ultra-low dose fluoroscopy protocol reduces radiation exposure by more than 90%.

The resulting operator doses of combining the low dose settings with optimized shielding are extremely low. Measured by using real time dosimetry, the average radiation dose hitting the operator outside of the lead apron during left atrial ablations was about 1% of the dose that travelers are exposed to during a transatlantic flight (Frankfurt-New York). This data provides more evidence in support of a widespread use of similar approaches and sets a target for low radiation doses during these procedures.

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Major Complications	n = 3462
Periprocedural death/cardiopulmonary resuscitation, n (%)	O (O)
Relevant pericardial effusion, n (%)	12 (0.4)
Periprocedural stroke/TIA, n (%)	2 (0.06)
Air embolism, n (%)	3 (0.09)
Cardiac valve injury, n (%)	O (O)
AV-Block/Sinus node dysfunction, n (%)	1 (0.03)
Phrenic nerve palsy, n (%)	1 (0.03)

Abbreviation: TIA, transient ischemic attack.

5 | CONCLUSION

In this multicenter study the use of a new ultra-low dose, low framerate protocol lead to very low radiation exposure for patients and operators for all kinds of EP procedures without compromising safety and acute efficacy endpoints.

6 | LIMITATIONS

All procedures included in this study were performed by operators that have long term experience in working with low dose radiation programs. Complication rates may be increased in the phase of getting accustomed to low quality images.

Moreover, measures to minimize radiation dose always lead to increased radiation awareness which reduces radiation dose on top of the effects caused by ultra-low dose settings of the X-ray systems (e.g., by improvements in collimation or angulation). This is especially true as operators who are used to working with low dose setups use collimation and less steep angulations to enhance contrast.

While most electrophysiologist use 3D mapping systems for left atrial and ventricular procedures, the use these systems for right atrial procedures is less common. In this study the percentage of procedures using 3D Mapping systems for right atrial procedures was very high (82.8%). This has to be taken into consideration when these results are compared to low dose procedures in the right atrium without the use of 3D Mapping systems.

Although effects of using low dose programs on long term success seem unlikely the results of this trial only provide information on acute outcome. Additionally effects on complications with delayed onset (e.g., atrioesophageal fistulas) may have been missed.

Due to national radiological protection laws, this study is based on a retrospective analysis of consecutive patients with the inherent methodological limitations.

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CONFLICTS OF INTEREST

The authors report no conflicts of interest.

DATA AVAILABILITY STATEMENT

Data is available on request from the authors.

ORCID

Philipp Attanasio MD [®] https://orcid.org/0000-0002-6559-7499 Martin Huemer MD [®] https://orcid.org/0000-0002-3068-6109 Tobias Schreiber MD [®] https://orcid.org/0000-0001-7511-3809 Felix Bourier MD [®] https://orcid.org/0000-0003-4861-6595

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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