Frame-rate reduction to reduce radiation dose for cardiac device implantation is safe

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BACKGROUND Radiation exposure to patient and surgeon during cardiac implantable electrical device (CIED) procedures remains a substantial health hazard to date. Advanced technical options for radiation dose reduction often pose considerable financial hurdles. We propose a near-zero cost, low-effort modification to a clinical x-ray system significantly reducing radiation dose during CIED implantation.

OBJECTIVE We aim to evaluate a reduced frame rate protocol in CIED implantation for complication rates and reduction in radiation exposure.

METHODS Starting May 2019, the frame rate during CIED implantations at our hospital was halved from 7.5 frames/s to 3.8 frames/s, and no further technical changes were made. During the following year, 264 patients were operated using this protocol and retrospectively compared with 231 cases implanted in the year before the protocol change, totaling 495 cases. Of these, 17%, 63%, and 19% were single-chamber, dual-chamber, or resynchronization devices, respectively. Incidence of complication prior to hospital discharge was considered the primary endpoint of the analysis. Radiation dose and procedural parameters were secondary endpoints.

RESULTS There was no increase in complications with the reduced frame rate protocol. Regression analysis further supported that the reduced frame rate radiation protocol was not associated with complication rates. Radiation exposure measured as dose area product was significantly reduced by ∼62% (median 369 [interquartile range 154–1207] cGy·cm^2 via the reduced frame rate protocol vs median 970 [interquartile range 400–1906] cGy·cm^2 with the standard frame rate; $P < 0.01$).

CONCLUSION A reduction of frame rate during CIED implantation is safe in terms of complication incidence and effective in terms of reducing radiation exposure.

KEYWORDS Pacemaker; Defibrillator; X-ray; CIED; Complication

(Heart Rhythm O^2 2023;4:427–432)

Introduction

Procedures in interventional cardiology are increasing and x-ray usage is an integral part of these. Radiation-related morbidity, including cataract and brain malignancy, are concerns of occupational radiation exposure among interventional cardiologists.[1] Patients may similarly experience x-ray–related morbidity. Several measures are in place to protect both staff and patients from these hazards of medically indicated procedures. In particular, lead-weighted protective gear for physicians or application of principles such as the ALARA (as low as reasonably achievable) principle to minimize radiation exposure are used for this purpose. Nevertheless, the risk still remains, and cardiac implantable electrical device (CIED) procedures are particularly known for their relatively high radiation exposure.[2]

In other fields of electrophysiology, alternative means of anatomical orientation during procedures have emerged. These include 3-dimensional mapping systems in electrophysiological ablations.[3] Echocardiography-guided lead implantation has been attempted, yet such approaches are not widely used in CIED procedures.[4,5] Advanced radiation shielding technologies suitable for these procedures include, among others, suspended protective gear (termed "zero gravity") and robot-assisted implantation for complex procedures but come at high cost.[6,7]

In addition to traditional methods of radiation reduction, such as the use of lead aprons, thyroid protectors, lead glasses, lead shielding, and adherence to the ALARA principle, our hospital has further implemented a reduction in the fluoroscopic frame rate to 3.8 frames/s.

Other groups followed a similar approach,[8] or employed modifications of x-ray settings, such as pulse width reduction, physical filter spacing, automatic exposure control, and advanced digital image filters. While such measures are effective, they require in-depth technical support from the manufacturer of the x-ray system and a contemporary system for the most modern digital filters.[9]

Considering economic limitations and optimal resource utilization, we evaluated a simple reduced frame rate protocol

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2666-5018/ https://doi.org/10.1016/j.hroo.2023.05.003

KEY FINDINGS

- A reduction of the fluoroscopy frame rate in cardiac implantable electronic device implantation effectively reduces the radiation dose.
- This approach is safe in terms of complication incidence.
- Compared with previously published, more complex approaches, this method achieves a comparable dose reduction.

for CIED procedures regarding reduction of radiation exposure and complication rates.

Methods

Study design

The study is based on retrospective data evaluation of our center's CIED operations between April 2018 and July 2020. Complication rates as well as fluoroscopy and radiation parameters before and after a change in fluoroscopy protocol were compared. Because the study was retrospective, no written consent of patients to the study was obtained. Local ethics committee approval to conduct the study was obtained (ethics committee vote 2022-3109-evBO) and we conducted our research in compliance with the ethical principles outlined in the Declaration of Helsinki for human research.

We compared procedures performed with a conventional frame rate protocol of 7.5 frames/s for x-ray image acquisition prior to April 2019 with a reduced frame rate protocol of 3.8 frames/s. No further modifications were made. A 3-month period from April to June 2019 was excluded to account for potential variations in use of the reduced frame rate protocol. Implantations were performed by 4 different operators. For venous access, the cephalic vein was primarily targeted. If unsuccessful, the axillary and subclavian veins were sequentially attempted, employing a tiered strategy with anatomical landmarks, fluoroscopy, and contrast-enhanced fluoroscopy as needed.

The aim of this study was to analyze if the reduction in frame rate—along with reduced image resolution—was safe for CIED implantation while reducing x-ray exposure. Accordingly, patients were grouped by fluoroscopy protocol (reduced frame rate vs standard) and stratified according to the kind of procedure performed (single/dual-chamber or resynchronization device).

The primary endpoint was the incidence of CIED-related complications until discharge. Complications were extracted from a structured report and are defined as occurrence of pneumothorax, hemothorax, resuscitation, pericardial effusion, wound infection, lead dislodgement, lead dysfunction, pocket hematoma, or other necessitating intervention in the time until discharge. Secondary endpoints were procedural data. Procedural data were assessed measuring intraoperative fluoroscopy time, x-ray dose area product, and procedure duration as recorded in the surgical report.

Data acquisition, processing, and statistical software

German legislation mandates a structured report on CIED operations (§ 137a, 1 SGB V). This information was extracted and amalgamated with in-hospital documentation, namely surgical report, reports on prior echocardiography, International Classification of Diseases–Tenth Revision–German Modification,[10] and procedure codes (Operationen und Prozedurenschlüssel).[11]

Clinical characteristics of the population were collected: age; sex; weight; height; body mass index; body surface area; preoperative left ventricular ejection fraction; preexistence of arterial hypertension, diabetes mellitus, or coronary artery disease; and prior prescription of acetylsalicylic acid, $P2Y_{12}$ inhibitors, or oral anticoagulants.

All data were anonymously stored, prepared in a SQLite database and subsequently analyzed using the pandas package of the python programming language (version 3.9, Python Software Foundation, Beaverton, OR). Visualization was performed using python's matplotlib and seaborn packages.[12–17] Additionally, SPSS Statistics 28 (IBM Corporation, Armonk, NY) and Microsoft Excel 16 (Microsoft Corporation, Redmond, WA) were used.

Statistical analysis

Groups of patients were analyzed according to fluoroscopy protocol used and type of procedure performed. Basic statistics were calculated for all variables, outliers, and missing values identified and were manually corrected when more reliable data were available. Assessment of normal distribution was performed using linear and logarithmic probability plotting and the Shapiro-Wilk test. For nonparametric, continuous variables, statistical significance was assessed using a 2-sided Mann-Whitney *U* test, and for categorical data the Fisher exact test was used. A logistic regression model was used to examine the relation between radiation protocol, fluoroscopy time (independent variables), and complication rate (dependent variable).

Unless otherwise indicated, all reported values follow the format mean ± SD, median (interquartile range [IQR]) for skewed distributions, or number and percentage for categorical data. P values $\leq$.05 were considered significant.

Results

Complete data were acquired on all 495 cases treated within the observation period. Of these, 231 (47%) were operated using the standard protocol between April 2018 to March 2019 and 264 (53%) using the reduced frame rate protocol between July 2019 and June 2020. Table 1 illustrates case numbers and types of procedures performed. To compensate for inconsistent use of the reduced frame rate protocol at the beginning of April 2019, a 3-month period was blanked and excluded from evaluation. No intraprocedural changes to the

Table 1 Types of CIED implantation procedures

	All	Standard protocol	Reduced frame rate protocol
Single chamber	86 (17.3)	35 (40.7)	51 (59.3)
Dual chamber	314 (63.4)	146 (46.5)	168 (53.5)
CRT	95 (19.2)	50 (52.6)	45 (47.4)
All	495 (100)	231(46.6)	264 (53.3)

Values are n (%).
CIED = cardiac implantable electronic device; CRT = cardiac resynchronization therapy.

protocol were necessary after implementation, indicating that all procedures were successfully conducted at a reduced frame rate of 3.8 frames/s.

The mean patient age was 79 (IQR 73–84) years, 185 (37.4%) were female, and the body mass index was 25.6 (IQR 23.4–29.1) kg/m^2. Median time from surgery to discharge was 3 (IQR 1.0–4.0) days. A more detailed representation of the population characteristics can be found in Table 2. Statistically significant differences between the groups were found in prescription of acetylsalicylic acid and $P2Y_{12}$ receptor inhibitors, which were less common in the reduced frame rate group, while oral anticoagulation was more commonly used in the reduced frame rate group. Ejection fraction was slightly lower in the standard protocol group.

Regarding the incidence of the primary endpoint, analysis of complications showed no statistically significant differences between protocol groups (Table 3). Linear regression analysis revealed complication rate to be associated with fluoroscopy time [Exp(B) 1.864, 95% confidence interval (CI) 1.098–3.165, $P = .021$] but not with the radiation protocol [Exp(B) 0.821, 95% CI 0.276–2.443, $P = .723$].

Analysis of secondary endpoints showed that dose area products were significantly lower overall (∼62% reduction) with reduced frame rate protocol as well as for individual subgroups of device types (Figure 1). Fluoroscopy time was significantly reduced in dual-chamber pacemaker implantations (∼26% reduction), while other procedure types were similar (single-chamber and cardiac resynchronization therapy implantation: $P = .21$ and .17, respectively), showing no statistically significant differences. Overall procedure duration was significantly reduced by ∼43% during reduced frame rate use, including subgroups ($P < .01$) (Table 4).

Discussion

Primary endpoint: complications

Overall complication rates for CIED operations range between 5% and 10% within the first year.[18,19] A cohort study from Denmark reported complication rates on all Danish patients undergoing CIED operations between May 2010 to April 2011, including a total of 5918 patients. Considering only complications requiring intervention, complication rates in our study were similar to those reported by Kirkfeldt and colleagues.[19] Notable differences included no reported infections requiring intervention in this study compared with 0.8% in the Danish registry. A probable cause is the short follow-up in this study, as for instance, device infections usually occur after a period of 30 to 90 days.[20]

The observation that incidence of complications did not vary between groups in our study is of key importance. No statistically significant difference in lead dislocation rates occurred in the reduced frame rate protocol group (1.5%) compared with standard protocol (0.4%) (P = NS), despite potentially reduced visual resolution during implantation.

In their recent publication concerning best practices in electrophysiological device implantation, the European Society of Cardiology highlighted the increased risk of infection in pocket hematoma, recommending periprocedural interruption of antiplatelet therapy where justifiable.[4] For instance in a recent large, retrospective study with 1388 implantations, Tompkins and colleagues[21] found a significant increase in pocket hematoma risk through antiplatelet therapy and oral

Table 2 Clinical characteristics

	All (N = 495)	Standard protocol (n = 231)	Reduced frame rate protocol (n = 264)	P value
Age, y	79.0 (73.0–84.0)	79.0 (74.0–83.0)	79.0 (72.0–84.0)	.649
Female	185 (37.4)	87 (37.7)	98 (37.1)	.902
Weight, kg	76.0 (68.0–85.5)	75.0 (68.5–85.0)	77.0 (67.8–86.2)	.722
Height, m	170.0 (165.0–178.0)	170.0 (165.0–178.0)	170.0 (165.0–177.2)	.958
Body mass index, kg/m^2	25.6 (23.4–29.1)	25.5 (23.2–28.8)	25.7 (23.4–29.1)	.638
Body surface area, m^2	1.9 (1.8–2.0)	1.9 (1.8–2.0)	1.9 (1.8–2.1)	.324
Surgery to discharge, d	3 (1.0–4.0)	3 (1.5–5.0)	3 (1.0–4.0)	.055
Arterial hypertension	416 (84.0)	198 (85.7)	218 (82.6)	.342
Coronary artery disease	332 (67.1)	157 (68.0)	175 (66.3)	.693
Diabetes mellitus	138 (27.9)	60 (26.0)	78 (29.5)	.377
Ejection fraction, %	55.0 (35.0–55.0)	50.0 (30.0–55.0)	55.0 (35.0–55.0)	.032
Oral anticoagulation	175 (35.4)	70 (30.3)	105 (39.8)	.028
ASA	153 (30.9)	88 (38.1)	65 (24.6)	.001
$P2Y_{12}$ inhibitor*	55 (11.1)	37 (16.0)	18 (6.8)	.001

Values are median (interquartile range) or n (%).
ASA = acetylsalicylic acid.
*Ticagrelor, prasugrel, or clopidogrel.

Table 3 Procedural complications

	All (N = 495)	Standard protocol (n = 231)	Reduced frame rate protocol (n = 264)	*P* value
Pneumothorax	5 (1.0)	3 (1.3)	2 (0.8)	.67
Pericardial effusion	1 (0.2)	1 (0.4)	0 (0.0)	.47
Lead dislocation	5 (1.0)	1 (0.4)	4 (1.5)	.38
Lead dysfunction	2 (0.4)	2 (0.9)	0 (0.0)	.22
Lead revision due to PNS (CRT)	1 (0.2)	1 (0.4)	0 (0.0)	.47
All	14 (2.8)	8 (3.5)	6 (2.3)	.4

Values are n (%). Absolute and relative frequency of complications are listed. *P* values were determined using Fisher's exact test.
CRT = cardiac resynchronization therapy; PNS = phrenic nerve stimulation.

anticoagulation. Consequently, a significantly higher rate of antiplatelet therapy in the standard protocol group of our study might imply a higher risk for pocket hematoma; however, this might have been set off by a higher rate of oral anticoagulation use in the reduced frame rate group. No such complications could be demonstrated in our study, which might be ascribed to perioperative management of antiplatelet therapy or an insufficient population size.

To address the potential confounding effect of operator experience, we performed an exploratory analysis adjusting for fluoroscopy time (as a proxy for operator experience and procedure complexity). We constructed a logistic regression model with occurrence of complication as the dependent variable and fluoroscopy time (*ln*-transformed for normality) and radiation protocol as independent variables. In this model, fluoroscopy time was directly associated with complication rate, whereas radiation protocol was not. This supports our hypothesis that a reduced frame rate protocol does not lead to increased complication rates.

Radiation dose

Most importantly, dose area product was effectively reduced by ∼62% overall. A similar study presented distinctly lower radiation doses in conventional protocol and low-dose protocol alike compared with our results. In comparison with our institution, the achieved dose reduction was similar (Eichenlaub and colleagues: ∼60% overall reduction compared with ∼62% overall reduction in this study).[9] While Eichenlaub and colleagues additionally changed specific filter settings and advanced parameters, our reduction was achieved simply by reducing the frames per second, a simple, cost- and time-efficient measure, as opposed to the application of additional, possibly proprietary digital filters, analog filter adjustments, and adjustments in exposure control.[9]

In our study, we found that all procedures showed a significant reduction in intraoperative radiation dose. Interestingly, we also observed that implantations were significantly faster during the reduced frame rate protocol period. This finding may seem contradictory, as one would expect poorer image quality to lead to longer exposure times and potentially longer procedure duration. Alternatively, if image quality was not noticeably impacted by the intervention, one would expect no change in overall procedure duration. We propose that a Hawthorne-like effect may have played a role in these results, in which the operators were motivated to perform more efficiently due to increased emphasis on fluoroscopy times as a contributor to overall radiation exposure. Specif-

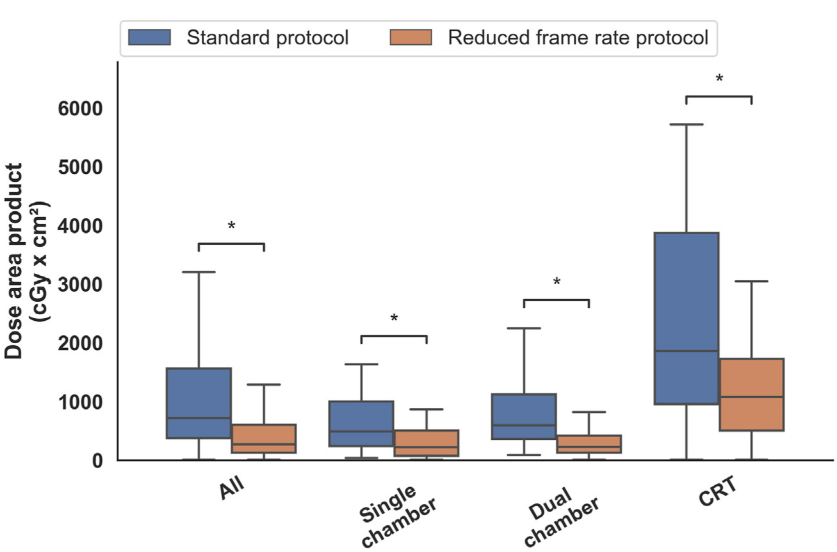

Figure 1 Dose area product of patients treated with different fluoroscopy protocols. The boxplots show median and first and third quartiles for the different procedures (on the x-axis) and protocols (by color). The asterisk indicates the significant $P < .05$. CRT = cardiac resynchronization therapy.

Table 4 Procedural characteristics

	All (N = 495)	Standard protocol (n = 231)	Reduced frame rate protocol (n = 264)	*P* value
Dose area product, cGy·cm^2				
Single chamber	290.5 (111.8–675.8)	484 (235.5–994.5)	214 (65.0–499.0)	<.001
Dual chamber	359 (183.3–692.5)	589 (353.5–1116.8)	220 (123.3–409.0)	<.001
CRT	1365 (728.5–2506.0)	1856.5 (949.5–3862.3)	1072 (498.0–1722.0)	.003
Cumulative	610 (241–1285.5)	970 (400.3–1905.8)	369 (154–1206.8)	<.001
Fluoroscopy time, min				
Single chamber	2.3 (1.3–4.3)	2.6 (1.3–5.5)	2.3 (1.3–3.5)	.207
Dual chamber	3.8 (2.5–6.0)	4.5 (3.2–7.2)	3.3 (2.3–4.3)	<.001
CRT	13.9 (8.6–22.6)	14.9 (9.0–26.4)	13.6 (8.1–17.8)	.169
Procedure duration, min*				
Single chamber	27 (18.25–39.0)	40 (26.0–53.5)	21 (16.0–31.5)	<.001
Dual chamber	37 (26.25–53.0)	50 (39.3–60.0)	28 (20.0–37.0)	<.001
CRT	70 (52.0–103.0)	90.5 (70.0–123.8)	54 (44.0–70.0)	<.001

Values are median (interquartile range). *P* values were calculated using the Mann-Whitney *U* test for nonparametric sample groups.
CRT = cardiac resynchronization therapy.
*From skin incision to cutaneous suture.

ically, the change in fluoroscopy protocol may have prompted the operators to be more mindful of both radiation usage and surgical metrics in general, such as procedure duration, leading to reductions in both. The Hawthorne effect refers to the phenomenon in which subjects modify their behavior in response to being observed, and might be expected when comparing data obtained in routine clinical practice and after an intervention.

Limitations

This study was retrospective, and the protocols were compared longitudinally, rather than by cross-section, limiting the validity of results by design. Nonetheless, both groups were sufficiently similar to allow comparison. There was a confounding reduction in fluoroscopy time for dual-chamber device implantation potentially associated with reduced procedure durations during the reduced frame rate protocol period.

Furthermore, the procedure duration decreased significantly for all types of implantations. A possible explanation for this reduction in time may also be the increased attention given to procedure and fluoroscopy durations following the protocol change. This heightened awareness could impact not only fluoroscopy times, but also other aspects of the surgical procedure. Anecdotally, we found that preparing all required steps (such as stylet formation and sheath preparation among others) prior to skin incision had the most significant impact. This approach is also applicable to cardiac resynchronization therapy implantations and is even more crucial, given that the materials required for coronary sinus intubation and lead placement are more extensive than those needed for conventional pacemaker implantation.

As discussed previously, increased operator awareness to radiation dosage and procedure time in general may contribute, though it most likely does not account for the entirety of the observed dose reduction. Additionally, while increasing operator experience cannot be completely ruled out as a reason for reduced fluoroscopy times or complications, we consider this influence minimal, as all operators had several years of experience in CIED implantation.

The reduction in procedure duration is likely due to multiple factors. A complete explanation remains elusive at this moment but is subject of further investigation.

Conclusion

This study demonstrates a significant reduction of approximately 62% overall in radiation dose for electrophysiological device operations by simply halving the frames per second for fluoroscopy during procedures. This was accomplished without an increase in complication rates. Furthermore, linear regression analysis showed radiation protocol not to be a predictor of complication rate.

Funding Sources: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Disclosures: The authors have no conflicts to disclose.

Authorship: All authors attest they meet the current ICMJE criteria for authorship.

Patient Consent: Patient consent was not required, as the data analyzed were retrospective and de-identified.

Ethics Statement: Local ethics committee approval to conduct the study was obtained (ethics committee vote 2022-3109-evBO) and we conducted our research in compliance with the ethical principles outlined in the Declaration of Helsinki for human research.

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