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Received: 24 March 2021 | Revised: 2 July 2021 | Accepted: 10 July 2021

DOI: 10.1002/ccd.29894

ORIGINAL STUDIES

WILEY

Evaluation of a suspended radiation protection system to reduce operator exposure in cardiology interventional procedures

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Funding information
Euratom research and training programme 2014 TO 2018 under grant agreement, Grant/Award Number: 755523; GE Healthcare and Biotronik, Grant/Award Number: 058C8D97-3D39-4F21-ABEF-F3C37CCDE417

Abstract

Objectives: To investigate a novel suspended radiation shield (ZG), in reducing operator radiation exposure during cardiology interventions.

Background: Radiation exposure to the operator remains an occupational health hazard in the cardiac catheterization laboratory.

Methods: An anthropomorphic mannequin simulating an operator was placed near a phantom, simulating a patient. To measure the operator dose reduction, thermoluminescent detectors (TLDs) were inserted into the head and into the eye bulbs of the mannequin, while electronic dosimeters were positioned on the temple and at the level of the thyroid. Measurements were performed without and with the ZG system in place.

Physician exposure was subsequently prospectively measured on the torso, on the left eye and on upper arm using the same electronic dosimeters, during clinical procedures (coronary angiography (CA) and percutaneous coronary intervention (PCI)). The physicians dose reduction was assessed by comparing operator dose when using traditional radioprotection garments (Phase 0) versus using the ZG system (Phase 1).

Results: Dose reductions as measured on the mannequin ranged from 66% to the head, to 100% to the torso. No dose was detected at the level of the torso and thyroid with ZG.

When comparing CA and PCI procedures between Phase 0 and Phase 1, a significant difference ($p < 0.001$) was found for the left eye and the left wrist. Dose reduction as measured during clinical procedures for left eye/upper arm were on average 78.9%/95.6% for CA and 83.0%/93.0% for PCI, respectively ($p < 0.001$ for both).

Conclusions: The ZG systems has a great potential to significantly reduce operator dose through the creation of a nearly zero-radiation work environment.

KEYWORDS
angiography, coronary, percutaneous coronary intervention, radiation physics/dosimetry

1 | INTRODUCTION

Numerous publications have heightened the concern about the potential hazards of occupational exposure for cardiologists during fluoroscopically guided procedures. General health problems have been reported[1] and in particular the association between occupational exposure and posterior lens opacities.[2] Complications impacting life prognosis have also been suspected, as brain malignancies[3] and carotid atherosclerosis.[4]

To reduce radiation dose, all personnel are required to wear lead-equivalent radiation protection garments. Although these garments are effective at stopping radiation, a person's arms, head, and neck (without protective collar) are generally unprotected.[5] Moreover such aprons are heavy and may account for physical stress and orthopedic injuries.[6]

During the cardiovascular intervention, the person subject to the highest radiation dose is the performing physician.[7] Accessory lead shields,[8] leaded glasses[9] and lead cap[9] have been used for protection of the eye lens and the brain, but may be considerably less efficient than commonly accepted.[9,10] The Zero-Gravity (Biotronik; Berlin, Germany) suspended radiation protection system (ZG) has recently been introduced by the manufacturer as a tool to enhance radiation protection and to improve ergonomics while also eliminating physical stress for the operator. In terms of radiation protection, it is meant to replace the lead apron and thyroid shield and, in addition, to protect the head region. However, there are only few studies supporting the routine use of ZG in interventional procedures, some not specifically related to cardiology[11–13] and an another correlated to cardiology interventions but in combination with a robotic system.[14]

The aim of this study was to bring further clinical evidence on the efficiency of the ZG system in enhancing protection of physicians performing cardiac interventional procedures, especially for the cranial and upper extremities areas.

2 | MATERIALS AND METHODS

2.1 | Study design and population

This prospective, observational study, approved by our Institutional Review Board, was conducted at a single center from October 2018 to August 2020, including consecutive patients undergoing coronary procedures coronary angiography (CA) and percutaneous coronary intervention (PCI).

The study was divided into two phases: Phase 0 (from October 2018 to July 2019) and Phase 1 (from August 2019 to August 2020). In Phase 0, the traditional radiation protection garments were used, while in Phase 1 the ZG radiation protection tool was used, as described later.

2.2 | Cardiology suite and radiation dose protocol

All the study procedures were performed using an Innova IGS 5 (GE Healthcare, Chicago, IL), a floor-mounted single plane angiography system equipped with a 20 cm digital flat panel detector, installed in autumn 2018. The system is equipped with a built-in patient dose monitoring software, with tolerances as per international electro technical commission (IEC).[15]

Two different protocols have been configured for the CA and PCI procedures. The "Coronaries dose limited" protocol is used by default. It is configured with fluoroscopy at 7.5 frame per second (fps) and cine at 15fps. This protocol is set with low detail, receptor dose limited (RDL) plus automatic exposure (AutoEx) features. If the clinical task requires improved image quality, the operator can switch to normal detail in this protocol or use the "Coronaries" protocol configured with both fluoroscopy and cine at 15 fps, low detail, and IQ standard for the AutoEx.

2.3 | Phantom measurements

The efficiency of the ZG system was first evaluated by means of phantom measurements in clinical conditions. Two Rando-Alderson phantoms, representing 1.75 m tall and 73.5 kg male adults, were used as primary operator and patient, respectively. Those anthropomorphic phantoms have no arms nor legs and are composed of multiple slices of tissue-equivalent material. Impact of posteroanterior (PA), left anterior oblique (LAO) 30° and LAO 90° beam projections on the system efficiency was investigated. Those three projections were selected because they are of concern for radiation protection,[16] with PA and LAO30° being the most common projections; and LAO90, although less common, is known as the most unfavorable for exposure of the staff.

For each projection, measurements were first performed without and then with the ZG in place (Figure 1). The operator phantom was positioned to represent the use of femoral access route, i.e. on the right side of the patient and 70 cm away from the x-ray field, which was centered on the patient's heart; the phantoms' position was kept identical for all measurements. One single irradiation protocol and 20 × 20 cm detector size was used with automatic exposure control, ensuring identical exposure conditions for the measurements with and without the ZG for a specific projection.

To measure the dose to the brain and to the eyes, the phantom was filled with 33 LiF:Mg,Cu,P thermoluminescent detectors - TLDs-(MCP-N, Institute of Nuclear Physics, Krakow, Poland) inserted into the head and two detectors into the eye bulbs.

The TLDs were calibrated using ISO norms N60 reference beam[17] at the secondary standard calibration laboratory of the Belgian nuclear research centre.

A Monte Carlo simulation method[18] was used to estimate the 95% confidence interval associated with the dose efficiency of the ZG.

We also measured the dose to the torso (above the apron when no ZG was used and under the ZG when it was used) and to the left eye (temple) using Raysafe i2 dosimeters. A third dosimeter was placed on the Thyroid. A fourth dosimeter was placed at the stomach level outside the lead apron and outside the ZG to ensure that the

FIGURE 1 Experimental set-up used to assess the dose reduction TLDs were placed inside the head of the phantom and on the torso, thyroid and left temple (through Raysafe dosimeters). The picture reports the set up with the ZG in place. The same measurements were performed also with the apron instead of the ZG [Color figure can be viewed at wileyonlinelibrary.com]

incident exposures were comparable for a specific projection. The Raysafe i2 dosimeters use as operational quantity Hp(10) (i.e. the personal dose equivalent at a depth of 10 mm according to ISO 4037 [28]). The Raysafe i2 dosimeters were calibrated in ISO norms N60 reference[17] beam against personal dose equivalent Hp(10) at the secondary standard calibration laboratory of the Belgian nuclear research centre (30). The lowest detection limit (LDL) was 1 μGy. This value was used when the dosimeters reported no doses.

2.4 | Clinical measurements

2.4.1 | Technical and clinical data collection

Prior to this study, a dose management solution was installed (DoseWatch, GE Healthcare Systems, Buc, France) and connected with the cardiology interventional suite. The dose tracking system was also connected to the hospital RIS (OmniPro, Belgium).

The following information were collected: type of procedure, clinical indication, elective or emergency patient, type of access, number of vessels treated, number of segments treated, complexity index (CI),[19] patient age, gender, protocol name, body-mass index (BMI, defined as weight (kg)/ (height [m])^2), P_{KA} (Gy. cm^2), Air Kerma at the reference interventional point (AK, Gy), fluoroscopy time (FT, s), performing physician.

2.4.2 | Radiation protection tools

During Phase 0, the operator radioprotection was ensured through standard use of a lead apron (2 layers of 0.25-mm lead, equating to 0.5 mm in the front of the operator), a thyroid lead collar, low leaded flaps, an upper mobile leaded glass screen suspended from the ceiling, and leaded glasses (0.5-mm leaded equivalent for each) during all procedures.

For the second part of the project (Phase 1), the radiation protection system ZG was used. This is an entirely suspended radiation protection system (Figure 2). It provides radiation shielding from the top of the head to the calves. The ZG system is equipped with thicker and more pervasive lead shield (1.0 mm Pb equivalency for front body shield and shoulder flaps, 0.5 mm Pb equivalence for face and body shield sides). It can be used with or without ancillary shields according to operator discretion. It has sterile disposable draping systems. In our case, the leaded glass screen was used for both phases, position at the left side of the operator, between him and the collimator.

2.4.3 | Operator dose measurements

We used the same 3 Raysafe i2 dosimeters (dose reported in μSv) as for the phantom study, which were placed as follows on the principal cardiologist: one dosimeter at the level of the torso (outside the apron or outside the ZG, depending on study Phase), to test the hypothesis that both study groups are comparable in terms of input dose), one at the level of the left eye (outside glasses), one at the level of the left upper arm. There were 3 principal cardiologists involved in the study, with a range of experience varying from 5 to 20 years. The cardiologists were blinded to the RaySafe results during each case.

2.5 | Statistical analysis

For the phantom study, the measured doses were normalized to the PKA. Dose reduction at every dosimeter position was than expressed in % as the difference between the dose with the lead apron and the ZG, normalized to the dose with the apron (i.e. [Dapron-DZG]/ Dapron).

For the operator dose data, the medians with interquartile range were estimated and Mann–Whitney U test used for assessing the *p*-value ($p < 0.05$ significant). Fisher test was used to assess significant differences across binomial variables (gender, type of procedure). Box-Whiskers plots were used to represent the data graphically. Statistica for Windows (version 13.2, Statsoft, Inc) software was used for all analysis.

3 | RESULTS

3.1 | Phantom measurements

The dose reduction associated with the use of ZG is summarized in Table 1. Dose reductions ranged from 66% to the brain in PA to about 100% to the torso (all three projections).

When the ZG was used, no dose was detected at the level of the torso and thyroid. The LDL of the dosimeters was used instead (1 μGy) leading to dose reduction of at least 86% at the level of the thyroid and 100% at the level of the torso. Comparable trends were observed for the dosimeters positioned in the eyes. The brain dose with ZG was significantly lower than without, for all three projections (p-value $<10^{-8}$); statistical testing could not be performed for other anatomical locations because only one dosimeter was used.

3.2 | Patient and procedural characteristics

Data from a total of 277 procedures were collected, 105 for Phase 0 (60 CA and 45 PCI) and 172 for Phase 1 (117 CA and 55 PCI). Table 2 reports information on the demographic, clinical, and angiographic data for Phase 0 and 1, respectively.

FIGURE 2 The ZG weightless apron in the catheterization laboratory (left) and the apron as utilized during a procedure, including the full sterile draping capacity and rapid entry and exit by the operator while maintaining sterility (right) [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 1 Measured doses (μSv/Gy.cm^2) and dose reduction (%) associated without and with the use of ZG and averaged over the dosimeters inserted into the phantom, per anatomical region. Reported doses are normalized to the P_{KA} (μSv/Gy.cm^2); reduction values are reported with their 95% confidence intervals in brackets

		PA		LAO 30°		LAO 90°		All projections	
Anatomical region	Dosimeter type, nr	Apron	ZG	Apron	ZG	Apron	ZG	Apron	ZG
Brain	TLDs, 33	0.72	0.25	1.00	0.06	1.58	0.15	1.10	0.15
		66 [61, 70]%		94 [93, 95]%		89 [87, 91]%		83%	
Left eye	TLDs, 1	2.05	0.32	2.72	0.12	3.87	0.14	2.88	0.19
		84 [71, 96]%		95 [92, 99]%		96 [93, 99]%		92%	
Right eye	TLDs, 1	0.96	0.24	0.92	0.07	1.45	0.12	1.11	0.14
		75 [52, 94]%		92 [86, 98]%		92 [85, 98]%		86%	
Left temple	Raysafe i2, 1	1.09	0.03	1.75	0.04	4.57	0.13	2.47	0.07
		97 [93, 99]%		98 [95, 99]%		97 [95, 99]%		97%	
Thyroid	Raysafe i2, 1	0.09	0.01	0.13	0.01	1.48	0.01	0.57	0.01
		86 [57, 99]%		90 [69, 99]%		99 [97, 100]%		92%	
Torso	Raysafe i2, 1	3.49	0.01	5.13	0.01	4.78	0.01	4.47	0.01
		100 [99, 100]%		100 [99, 100]%		100 [99, 100]%		100%	

TABLE 2 Patient demographic, clinical and angiographic information are reported. CA = Coronary Angiography, PCI = Percutaneous Coronary Intervention. A p-values<0.05 is considered significant

	Phase 0 ($n = 105$)		Phase 1 ($n = 172$)		*p*-value
Patient demographic					
Age, y (stdev)	67 (11)		68 (11)		0.81
Female/male	41%/59%		45%/55%		0.60
BMI kg/m^2, mean (stdev)	28.1 (4.6)		28.0 (5.5)		0.80
Clinical indication					
Stable angina	45%		51%		0.72
Silent ischemia	14%		9%		
Elective PCI	10%		1%		
Ventricular arrhythmia	7%		6%		
Ntsemi/infar subaigu	4%		4%		
Instable angina	4%		5%		
Dyspnea	4%		2%		
Pre-operative	2%		5%		
Atypical pain	4%		5%		
Valvulopathy	4%		4%		
Other (cardiomyopathy, tropo+)	2%		8%		
Interventional procedure					
CA, *n*	60 (57%)		117 (68%)		0.07
PCI, *n*	45 (43%)		55 (32%)		
Access type	CA	PCI	CA	PCI	
Radial, right	85%	67%	89%	76%	0.08
Femoral, right	15%	33%	11%	24%	
Result of CA treatment					
No treatment	83%		100%		0.09
Aortic heart valve replacement	5%		0%		
Heart bypass	3%		0%		
Medical	9%		0%		
Result of PCI treatment					
No. of vessels treated					0.72
1 treated vessel	64%		65%		
2 treated vessels	27%		29%		
3 treated vessels	9%		6%		
No. of segments treated					
1 treated segment	36%		53%		
2 treated segments	44%		31%		
3 treated segments	13%		12%		
More than 3 segments treated	7%		4%		
Complexity index range for PCI treatment					
1	57%		68%		0.06
1.01–2	27%		24%		
2.01–3	10%		5%		
3.01–4	1%		3%		
4.01–5	4%		0%		

3.3 | Exposure data

In Table 3 the results for the exposure data and exam duration are reported for Phase 0 and Phase 1 and stratified per exam type.

3.4 | Operator dose

In Figure 3–4 the principal cardiologist dose levels for the different anatomical parts investigated are compared between Phase 0 and

TABLE 3 The exposure data and exam duration are reported for Phase 0 and Phase 1 and stratified per exam type

	CA			PCI		
	Phase 0	Phase 1	p-value	Phase 0	Phase 1	*p*-value
Air Kerma (Gy), median (P25, P75)	0.25 (0.15, 0.40)	0.26 (0.16, 0.41)	0.60	0.85 (0.54, 1.48)	0.52 (0.38, 1.12)	0.01*
P_{KA} (Gy.cm^2), median (P25, P75)	22.0 (13.20, 34.50)	22.50 (13.09, 5.82)	0.56	71.85 (45.18, 103.40)	45.72 (32.53, 81.88)	0.03*
X-ray time (min), median (P25, P75)	3.05 (2.06,6.03)	3.05 (0.73, 7.83)	0.69	14.70 (7.6, 26.3)	9.40 (7.05, 14.3)	0.02*
Exam Duration (min), median (P25, P75)	20.00 (20.00, 27.50)	25.00 (20.00, 30.00)	0.06	45.00 (40.0, 60.0)	40.0 (30.0, 50.0)	0.03*

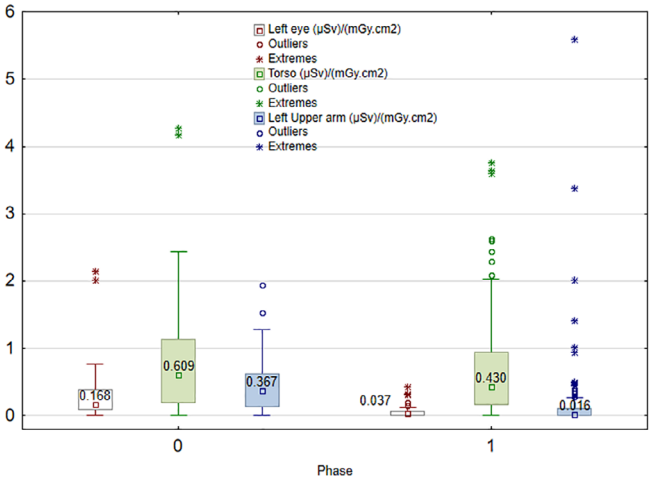

FIGURE 3 Dose to the operator during CA Dose to the left eye, torso and left upper arm of the principal cardiologist during CA procedures for Phase 0 and Phase 1 [Color figure can be viewed at wileyonlinelibrary.com]

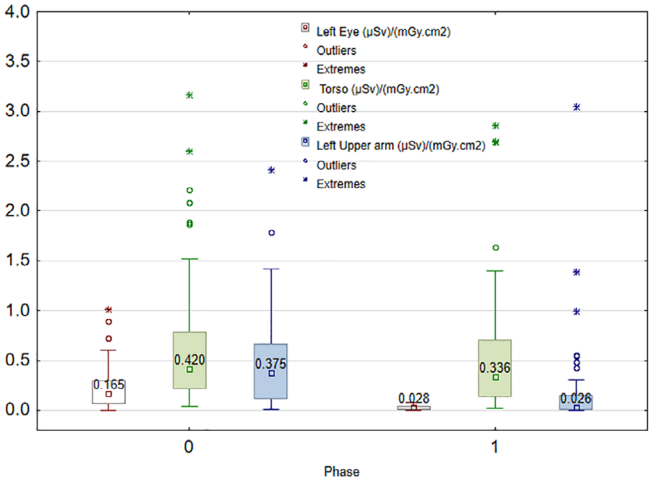

FIGURE 4 Dose to the operator during PCI Dose to the left eye, torso and left upper arm of the principal cardiologist during PCI procedures for Phase 0 and Phase 1 [Color figure can be viewed at wileyonlinelibrary.com]

Phase 1, for the CA and PCI procedures, respectively. The doses are normalized to P_{KA} to wash out difference in exam complexity and therefore total P_{KA} per exam. When comparing CA procedures from Phase 0 and Phase 1 (Figure 3), a significant difference ($p < 0.001$) was found for the left eye and the upper arm but no significant difference for the torso ($p = 0.26$). Also, for the PCI procedures (Figure 4), a significant difference was found for left eye and the upper arm ($p < 0.001$), but no significant difference for torso ($p = 0.31$). Specifically, the average median dose reduction for CA procedures was 78.9%/95.6%, while for PCI procedures it was 83.0%/93.0% for left eye/upper arm, respectively.

4 | DISCUSSION

Our experimental investigation focused on assessing the radiation dose reduction of a suspended radiation protection system (ZG) to parts of the body, which are less protected with traditional garments, for the primary operator during cardiology intervention procedures.

The present study demonstrated an average dose reduction of 83%, 92%, and 86%, respectively for the operator brain, left and right eye when using ZG in a phantom setting (Table 1). In clinical settings, the radiation dose reduction of the left eye was 79% and 83% for CA and PCI procedures, respectively. Considering the measurements uncertainty and the possible different mix of angulations in clinical practice, the phantom, and clinical results are in very good agreement.

This confirms the results of Madder et al[14] who also found that the use of ZG during PCI was associated with significantly less radiation exposure to the chest and head of operating physicians than traditional lead apparel. Our study however adds to it through organ dose measurements of brain and eyes in an anthropomorphic phantom.

The average dose reduction to the neck (thyroid) and the torso were respectively 92% and 100% in phantom settings. The average dose reduction to the upper arm was instead 96% and 93% for CA and PCI procedures respectively, in clinical settings ($p < 0.001$).

Reducing operator head and eye dose is very important[1,2,5] especially for the performing physician which is subject to the highest dose due to the relative proximity to the patient and X-ray beam.[20] Indeed,

case series of predominantly left-sided brain malignancies in interventional cardiologists or electrophysiologists have raised concern.[21] The finding of the disproportionate left-sided head malignancies is relevant because tumors should be equally distributed between right and left and because it is supported by the fact that the cardiologist stands during the procedure on the right of the patient, with the radiation source to the left. While the body can be protected with the apron, the thyroid with collar, and special glasses can protect the eyes, the head is completely exposed. Interventional cardiologists have indeed been reported to be exposed to radiation dose to the head 10-fold to 20-fold higher than the dose recorded beneath the apron.[22]

While measures to reduce dose like collimation, reducing extreme angles[16] and frame rate,[23] should be used [25]- also to reduce patient dose-, the ZG system seems to make feasible creating an almost "zero radiation exposure "work environment. As mentioned somewhere else, 'the future interventional laboratory must be designed so that radiation safety is not predicated on the voluntary cooperation, sensitivity, and education of operators, but rather is constructed into the design of the laboratory'.[24]

A possible advantage of the ZG system is its capability of providing a single barrier for radiation protection, that shields from head to lower legs. Only the forearm is unprotected. Traditional garments are separate devices and radioprotection might be limited by the discontinuity of these devices and the difficulty for the operator to maintain the ideal position for maximal protection during the procedure.[25] Moreover, lead aprons accounts for physical stress and orthopedic injuries and do not provide the best possible radiation for a person's arms, head, and neck.[26]

In terms of exposure settings, no significant difference was fund between Phase 0 and Phase 1 for CA procedure; for PCI procedures instead a significant difference between AK in Phase 0 and Phase 1 was found (0.9 Gy for Phase 0 and 0.5 Gy for Phase 1) (Table 3). A more detailed analysis of the procedures complexity index (results not reported) showed that ZG was not always used for very complex or urgent cases, during the first period of ZG utilization and the process required a learning curve. This was possibly reflected also in the longer X-ray time for procedures in Phase 0 with respect to Phase 1.

Our study has some limitations. First, data were collected in one institution, with no randomization and ZG use not blinded (for practical reasons). Second, the higher number of procedures in Phase 1 with respect to Phase zero was linked to preliminary results showing a higher protection of the operator during the procedure. Third, the dose to the patient was not directly measured. However, the exposure levels in this study are typical for the studied procedures and well below the most recent dose reference levels [29]. Fourth, organ dose – reduction – was estimated by means of phantom measurements, which might not perfectly represent real-world exposure conditions. However, this is the only approach permitting to measure actual organ doses.

5 | CONCLUSIONS

X-ray-based imaging technology is essential for all invasive diagnostic and interventional cardiology procedures, but they are associated with radiation detriment for patient and operator. The ZG systems has a great potential to drastically reduce operator dose to the head, torso, eyes and upper arms through the creation of a zero-radiation work environment.

Impact on daily practice

- Radiation exposure to the operator remains an occupational health hazard in the cardiac catheterization laboratory.
- Our data suggest that the investigated suspended radiation protection system has a great potential to significantly reduce operator dose, through the creation of a nearly zero-radiation work environment.
- Further studies are warranted to investigate the ergonomic of the ZG's ability to relive operator strain and usability.

ACKNOWLEDGEMENT

The authors disclose receipt of partial financial support for the research of this article from: GE Healthcare and Biotronik [grant number 058C8D97-3D39-4F21-ABEF-F3C37CCDE417]; Euratom research and training programme 2014 TO 2018 under grant agreement no. 755523.

CONFLICT OF INTEREST

None declared.

DATA AVAILABILITY STATEMENT

Data available on request due to privacy/ethical restrictions.

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How to cite this article: Zanca F, Dabin J, Collard C, Alexandre N, De Groote A, Salembier JP, et al. Evaluation of a suspended radiation protection system to reduce operator exposure in cardiology interventional procedures. Catheter Cardiovasc Interv. 2021;1–8. https://doi.org/10.1002/ccd.29894