Circulation: Cardiovascular Interventions

ORIGINAL ARTICLE

Efficacy and User Experience of a Novel X-Ray Shield on Operator Radiation Exposure During Cardiac Catheterization: A Randomized Controlled Trial

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BACKGROUND: Radiation shielding is mandatory during cardiac catheterization, but there is a need to improve efficacy and ease of use.

METHODS: The aim of the study was to assess the shielding effect and user feedback for a novel flexible multiconfiguration x-ray shield (FMX). The 0.5-mm Pb equivalent FMX can be selectively configured to accommodate for variations in patient morphology, access site, and type of procedure with maintained visualization, vascular access, and shielding. To evaluate efficacy, relative operator dose (operator dose indexed for given dose) was measured during 103 consecutive procedures randomized in a 1:1 proportion to the current routine setup or FMX+routine. User feedback was collected on function, relevance, and likelihood of adoption into clinical practice.

RESULTS: Median relative operator dose was 3.63 μSv/μGy·m^2×10^{-3} (IQR, 2.62–6.37) with routine setup and 0.57 μSv/μGy·m^2×10^{-3} (IQR, 0.27–1.06) with FMX+routine, which amounts to an 84.4% reduction (P<0.001). For 500 procedures/year, this corresponds to an estimated yearly dose reduction from 3.6 to 0.7 mSv. User feedback regarding size, functionality, ease of use, likely to use, critical issues, shielding, draping, procedure time, vascular access, patient discomfort, and risk was 99% positive. No critical issues were identified. There was no significant difference in patient radiation exposure.

CONCLUSIONS: The FMX reduces radiation exposure considerably. The FMX represents an effective and attractive solution for radiation protection that can easily be implemented in existing workflow. FMX has potential for general use with maintained visualization, vascular access, and shielding in routine cardiac catheterization.

GRAPHIC ABSTRACT: A graphic abstract is available for this article.

Key Words: cardiac catheterization ■ fluoroscopy ■ patient ■ radiation exposure ■ radiation protection

See Editorial by Khambhati and Leopold

During x-ray-guided cardiac catheterization, the operator is exposed to scatter radiation. Although operator dose for a given procedure is low compared with patient dose, interventional cardiologists may perform hundreds of procedures each year over a career spanning multiple decades. There are concerns over the potential negative health effects of radiation exposure.[1–3] Mandatory personal protective equipment is heavy,

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WHAT IS KNOWN

- Cardiac catheterization exposes operators to significant radiation with current x-ray shielding

WHAT THE STUDY ADDS

- The flexible multiconfiguration x-ray shield has the potential to lower relative operator dose by 84.4%.
- Allows for optimized protection with maintained access and visualization.
- Simple, low-cost solution without negative effects on procedural quality or logistics.

Nonstandard Abbreviations and Acronyms

CA	coronary angiography
DAP	dose area product
FMX	flexible multiconfiguration x-ray shield
PCI	percutaneous coronary intervention
ROD	relative operator dose (operator dose indexed to patient dose area product)

uncomfortable, and may cause orthopedic strain injuries. Fear of radiation exposure during childbearing age is often cited as a reason for choosing a different career path, which contributes to gender inequality.[4] Shielding solutions that lower operator exposure to levels that alleviate operator concerns are therefore needed. Lighter protective clothing or even avoiding personal protective equipment altogether is desirable. A routine setup, with a table- and ceiling-mounted shield, leaves unshielded scatter from the patient (Figure 1A). A range of shielding devices have been introduced to optimize operator protection.[5–9] Recent solutions have shown potential but both clinical efficacy and widespread use may still be suboptimal due to positioning, cost, and complexity.[10–13] Aiming to achieve an effective, user-friendly, low-cost solution, a novel flexible multiconfiguration x-ray shield (FMX) was designed. A model based on real-world cardiac catheterization radiation data indicated that an FMX could dramatically reduce operator dose.[14] To further validate the concept, a pilot randomized controlled trial was conducted to evaluate clinical relevance based on shielding efficacy and user feedback in routine use.

METHODS

Study Design

The study was a prospective, single-center randomized controlled trial evaluating the protective effect of a novel FMX on operator radiation dose. Over a 2-week period, all diagnostic coronary angiographies (CAs) and percutaneous coronary interventions (PCIs) were prospectively randomized in a 1:1 proportion to routine protection or routine+FMX. Inclusion criteria were patients aged 18 years or above and scheduled for elective or urgent CA or PCI. Exclusion criteria were extreme patient height or weight (<50 or >120 kg, <150 or >200 cm), pregnancy, or hemodynamically unstable patient. The FMX is a one-size-fits-all for general use. However, patients of extreme weight and height were excluded because the optimal placement was considered to possibly be impractical. A change of operator during the procedure was also an exclusion criterion, as the operator dose could not be reliably assessed. Both urgent and elective procedures were included to have a representative sample of everyday practice. The primary end point was the difference in relative operator dose (ROD, received operator dose in micro-Sievert [μSv] indexed for given patient dose). Additional registrations included user experience, procedure duration, irradiation time, dose area product (DAP), Air Kerma, and operator dose.

Cardiac Catheterization Facility

The study was conducted at Haukeland University Hospital, Norway, with 3 cath laboratories dedicated to coronary procedures and an annual caseload of ≈3600 procedures. All cath laboratories were equipped with a 78 cm×90 cm ceiling-mounted lead acrylic x-ray shields with a lead curtain on the lower side (0.5-mm lead equivalent OT54001; MAVIG, Munich, Germany). A 137-cm wide and 75-cm tall table-mounted shield with 3 27-cm top shields extending 25 cm above the tableside rail was used during all procedures, stretching from the floor to the operators' waist (0.5-mm Pb, 312/DS-039/5; KENEX, Essex, England—Figure 1A and 1B). The STARSystem for patient positioning (0.5-mm lead equivalent; Adept Medical, Auckland, New Zealand) was available in all cath labs and used at the operator's discretion in most procedures. The C-arms systems consisted of a Philips Azurion7-B12/12 biplane from 2018, a Philips Allura Xper FD10C from 2009 and a Siemens Artis Q from 2016.

Measurement of Patient and Operator Dose

The operator dose was measured with Raysafe I3 dosimeters (Unfors, Sweden) attached to the thyroid collar. It offers high-resolution individual procedure data and measures Hp(10) dose in microsievert with 2 additional digits, detection limit <30 μSv/h, and dose uncertainty of 10% for doses below 150 mSv/h. The dosimeters come calibrated from the vendor. To ensure correct functioning, we performed a measurement performance verification according to the manufacturer manual. DAP and Air Kerma were recorded from the fluoroscopy system. To normalize for differences in patient dose between procedures, we calculated the ROD, which is the received operator radiation dose indexed by given patient DAP.[5,15] Ten operators participated in the study, 6 men and 4 women. The mean operator height was 175 cm (range, 163–184 cm; SD, 6.6 cm), and mean dosimeter height at thyroid collar was 131.5 cm (range, 121–141 cm; SD, 6.3 cm). Individual data per operator are available in Table S1.

The FMX

Based on clinical experience and extensive bench testing with an anthropomorphic phantom in the cath laboratory,[14,16] we developed the reusable FMX to be placed on the patient to shield the operator from scatter radiation (Figure 1B). Pilot investigations indicated the importance of optimal positioning

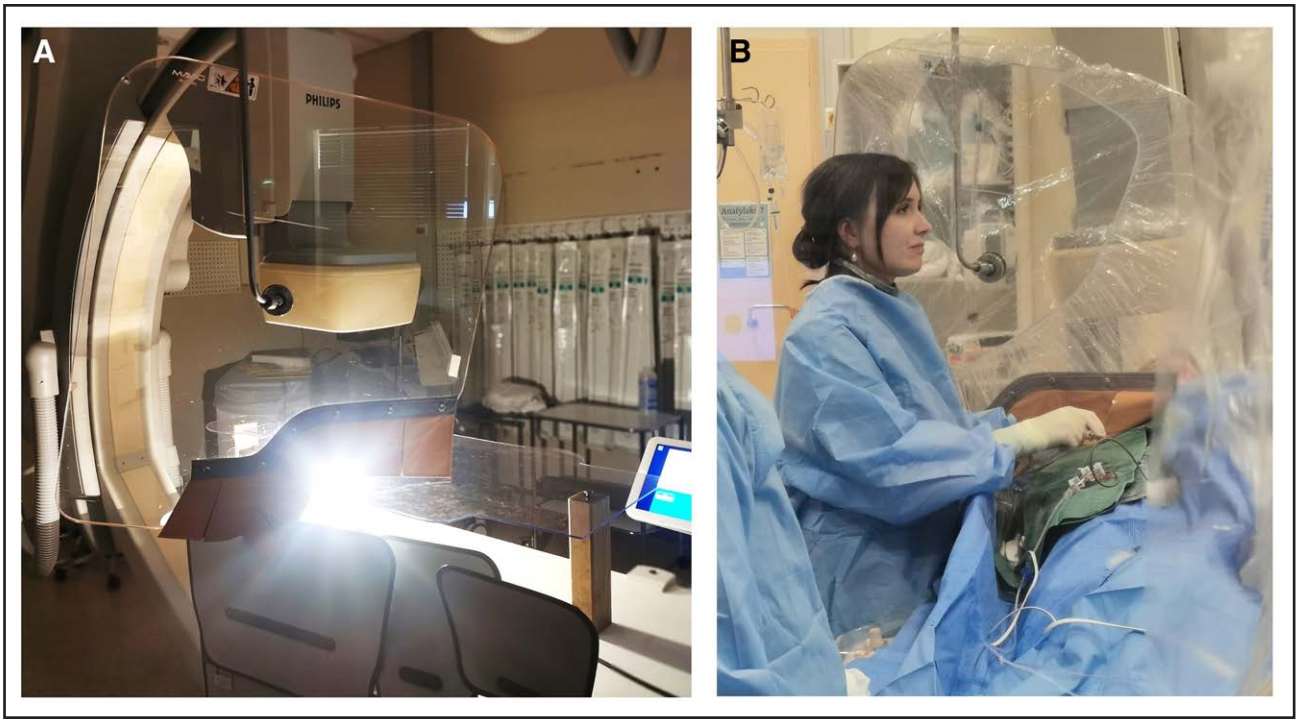

Figure 1. Scatter radiation and mechanism of action of the flexible x-ray shield.
A, Illustration of unshielded scatter radiation from the patient in a routine shielding setup using photons from the visible part of the electromagnetic spectrum. **B**, The flexible x-ray shield seals the gaps between the ceiling- and table-mounted shield thus enhancing operator protection.

with a shield covering both cranially and caudally to the vascular access site and laterally to make contact with the table-mounted shield. The FMX was designed to maintain protection and ease of use across a variety of patients, access sites, and procedure types (Figure 2). The system can be immediately and fully removed or repositioned in seconds according to clinical need. The FMX was fitted inside single-use polyethylene drapes sterilized with vaporized hydrogen peroxide at the hospital's central sterile services department. A commercially available x-ray protection material (Scanflex Medical AB, lead equivalency of 0.5 mm according to IEC 61331 Standard) was used to manufacture 3 identical FMX prototypes.

Ethical Approval

The Regional Committee for Medical and Health Research Ethics of Western Norway (REK Vest, application number 395777) and the local data protection officer approved the study. Operators were required to sign an informed consent. Written patient consent was not required but oral information was given before the procedure. Data were recorded simultaneously on article and in an electronic case report form securely stored on the hospital's research server. Patient information was deidentified before being entered in the case report form. The data that support the findings of this study are available from the corresponding author upon reasonable request.

User Feedback

After the study operators were asked to complete a survey with 11 questions regarding design and user experience (size, functionality, ease of use, likely to use, critical issues, shielding, draping, procedure time, vascular access, patient discomfort, and risk), each with 3 grading options (optimal, adequate, and should be improved). Additional spontaneous feedback received during the inclusion process was registered.

Statistics and Power Analysis

Data analysis was done in RStudio: integrated development for R Version 1.1.456 (RStudio Inc, Boston, MA). To estimate sample size, ROD was recorded during the prestudy pilot investigation of 44 routine cardiac catheterizations in a comparable setup at the University Hospital in Liege, Belgium. In 23/44, an additional generic nonsterile pelvic shield was used. Mean ROD was 7.02 $\mu Sv/\mu Gy \cdot m^2 \times 10^{-3}$ (SE, 0.93) without the pelvic shield and 3.53 $\mu Sv/\mu Gy \cdot m2 \times 10^{-3}$ (SE, 0.48) with the pelvic shield. The mean difference between groups was 49.7% ($P<0.01$) supporting the rationale to target a 50% difference. Pooled SD was 3.39 $\mu Sv/\mu Gy \cdot m^2 \times 10^{-3}$. Based on ROD and SD from the prestudy pilot, we calculated a sample size of a minimum of 21 procedures in each group was needed to detect a 50% difference with a 2-sided alpha-level of 0.05 and a power of 90%. To ensure procedure diversity, we aimed to include 100 procedures randomized in a 1:1 proportion. Procedures were randomized into blocks of 10 with 5 routine and 5 routine+FMX in a random blinded sequence. Continuous variables with 2 levels were evaluated using *t* test or Mann-Whitney *U* test depending on normal distribution. Continuous variables with more than 2 levels were analyzed with ANOVA or Kruskal-Wallis test. Categorical variables were analyzed with χ^2 test/Fisher exact test. A 2-sided alpha-level of 0.05 was used. Multiple linear regression was performed to check for confounding factors.

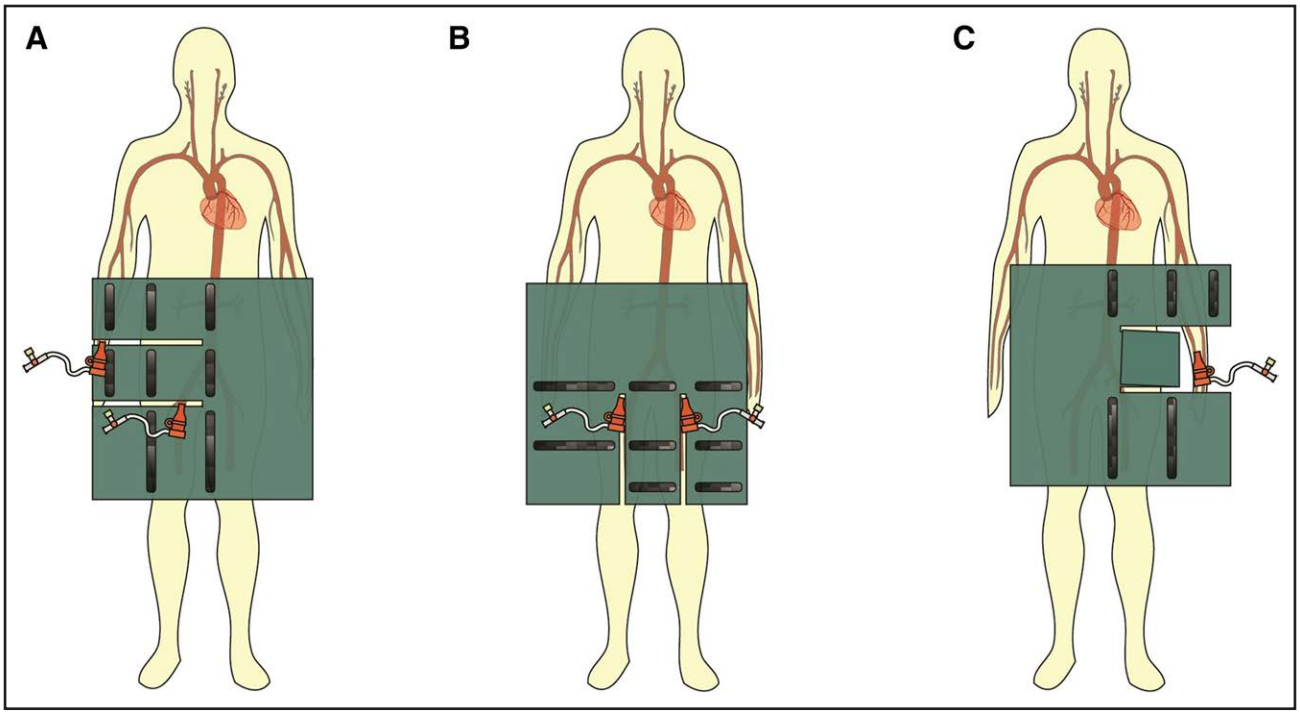

Figure 2. Illustration of the novel flexible multiconfiguration x-ray shield.
The versatile design can adopt multiple configurations to accommodate variations in patient morphology, access site, and type of procedure. **A**, Combined radial and femoral access. **B**, Double femoral access. **C**, Left radial vascular access with the flap in open position.

RESULTS

Patient Characteristics

One hundred five consecutive daytime procedures were screened and met the inclusion criteria. A dosimeter detached during 1 procedure and 1 operator malpositioned the FMX on his first patient. Thus, 103 were included in the final analysis. Routine protection was used in 51 procedures (49.5%) and FMX in 52 procedures (50.5%). Men represented 72.8% of patients. Reduced kidney function defined as estimated glomerular filtration rate <60 mL/min per 1.73 m^2 was present in 20% of patients, diabetes in 18%, and previous coronary artery bypass graft surgery in 4.9%. There were no statistically significant differences between groups for the recorded parameters. Table 1 compares patient characteristics according to shielding.

Procedural Characteristics

Planned procedures accounted for 51% of all cases, semi-urgent for 46% (unstable angina or non–ST-segment–elevation myocardial infarction), and urgent for 3%. Urgent procedures were defined as either ST-segment–elevation myocardial infarction or non–ST-segment–elevation myocardial infarction with additional signs of severity requiring immediate CA. Diagnostic angiography represented 49% of procedures, whereas 51% were intracoronary procedures defined as PCI, intracoronary pressure measurement or intracoronary imaging. PCI of chronic total occlusion represented 6.8% of procedures, and 3.9% were bifurcation PCI requiring 2-stent techniques. Radial approach was used in 97% of procedures (86% right radial, 7% left radial, 4% biradial) whereas femoral access was used in 3%. Table 2 lists procedural characteristics according to shielding. Groups were similar regarding access site, urgency of the procedure, number of stents of PCI, chronic total occlusion, and contrast use. Numerically, there were more intracoronary procedures in FMX group (55.8%) versus the routine protection group (43.1%), but this did not reach statistical significance (*P*=0.288).

Radiation Data According to Procedure Type and Protection

Table 3 shows radiation data according to procedure type and protection. Compared with CA, intracoronary

Table 1. Patient characteristics

	Routine (n=51)	FMX (n=52)	*P* value
Age (mean±SD)	68.8±12.5	65±11.5	0.12
BMI, kg/m^2	27±4.2	27±4	0.97
Height, cm	175.1±7.6	174.2±10	0.59
Weight, kg	82.8±14.4	82.2±15.1	0.83
Men	76.5% (39/51)	69.2% (36/52)	0.55
eGFR<60	21.6% (11/51)	19.2% (10/52)	0.96
Diabetes	13.7% (7/51)	23.1% (12/52)	0.33
Prior CABG	5.9% (3/51)	3.8% (2/52)	0.98

BMI indicates body mass index; CABG, coronary artery bypass graft; eGFR, estimated glomerular filtration rate; and FMX, flexible multiconfiguration x-ray shield.

Table 2. Procedural Characteristics

	Routine (n=51)	FMX (n=52)	*P* value
Planned procedure	52.9% (27/51)	50% (26/52)	0.83
Semiurgent procedure	45.1% (23/51)	46.2% (24/52)	
Urgent procedure	2.0% (1/51)	3.8% (2/52)	
Intracoronary procedure	43.1% (22/51)	55.8% (29/52)	0.288
Right radial access	90.2% (46/51)	82.7% (43/52)	0.24
Left radial access	7.84% (4/51)	5.77% (3/52)	
Left and right access	1.96% (1/51)	5.77% (3/52)	
Right femoral access	0% (0/51)	5.8% (3/52)	
Right heart catheterization	0% (0/51)	0% (0/52)	…
Mean number of stents if PCI	1.5±0.8	1.6±0.96	0.82
Mean stented length, mm	37.7±18.7	32.5±26.4	0.75
CTO	5.9% (3/51)	7.8% (4/52)	1
Bifurcation PCI	0% (0/51)	5.8% (3/52)	0.248
Artery treated			
LMS	5.3% (1/19)	4% (1/25)	0.80
LAD	36.8% (7/19)	20% (5/25)	
CX	10.5% (2/19)	16% (4/25)	
RCA	36.8% (7/19)	44% (11/25)	
LAD+CX	10.5% (2/19)	12% (3/25)	
CX+RCA	0% (0/19)	4% (1/25)	
Contrast in mL; median (P25–P75)	55 (36.5–90)	67.5 (37.75–122.75)	0.288

CTO indicates chronic total occlusion; CX, circumflex artery; FMX, flexible multiconfiguration x-ray shield; LAD, left anterior descending artery; LMS, left main stem; PCI, percutaneous coronary intervention; and RCA, right coronary artery.

procedures were associated with longer procedure duration (median, 53 versus 18 minutes; $P<0.001$), longer irradiation duration (median, 1224 versus 218 seconds; $P<0.001$), and higher patient dose assessed by DAP (median, 4493 versus 1083 μGy·m^2; $P<0.001$) and Air Kerma (median, 703 versus 147 mGy; <0.001). Procedure duration was defined as the start of local anesthesia to arterial closure. There were no significant differences between routine protection and routine+FMX regarding procedure duration, irradiation duration, or patient dose.

Operator Dose and Shielding Effect

Adding the FMX to a routine protection setup resulted in an 84.4% reduction ($P<0.001$; Figure 3A) of median (mean) ROD from 3.63 (4.3) to 0.57 (0.9) μSv/μGy·m^2×10^{-3} and a 79.6% reduction in median operator dose (7.14 versus 1.46 μSv; $P<0.001$). Similar shielding effects were observed both in intracoronary procedures (81.6% reduction of median ROD, $P<0.001$; Figure 3B) and CA (86.4% reduction; $P<0.001$; Figure 3C). Operator sex did not significantly influence ROD ($P=0.63$). In multiple linear regression analysis including patient weight, access site, operator, procedure type, cath laboratory, and urgency of procedure, the FMX was the only predictor variable significantly associated with lower ROD ($P<0.001$). To assess the potential impact of FMX on annual operator dose for a high-volume operator, median operator dose per procedure was multiplied by an annual caseload of 500 procedures giving an estimated annual operator dose of 3.6 mSv with routine protection and 0.7 mSv with the FMX.

In the routine protection group, there was a large variation in ROD and several outliers. The highest ROD was 16.45 μSv/μGy·m^2×10^{-3} and was recorded during complex PCI of the right coronary artery where most of the fluoroscopy was done in left cranial projection. The lowest observed dose of 0.31 μSv/μGy·m^2×10^{-3}

Table 3. Radiation Data According to Procedure Type and Protection

Coronary angiography (n=52)	Routine (n=29)	FMX (n=23)	*P* value
%	55.8%	44.2% (23/51)	
Irradiation duration, s	235 (296, 181–390)	189 (274, 138–352)	0.29
Air kerma, mGy	144 (185, 100–261)	150 (150, 80–201)	0.28
DAP, μGy·m^2	1093 (1393, 689–1741)	1007 (1182, 531–1535)	0.40
Operator dose, μSv	4.07 (6.59, 2.41–9.09)	0.51 (0.77, 0.27–0.96)	<0.001
Procedure duration, min	18 (19, 15–22)	18 (20, 12–23)	0.49
Intracoronary procedure (n=51)	**Routine (n=22)**	**FMX (n=29)**	
%	43.1%	56.9%	
Irradiation duration, s	1278 (1520, 879–1713)	1152 (1502, 798–1732)	0.85
Air kerma, mGy	672 (962, 368–1354)	846 (912, 444–1234)	0.82
DAP, μGy·m^2	4187 (5857, 2566–7934)	4719 (5488, 2548–7657)	0.76
Operator dose, μSv	14.04 (26.38, 7.54–27.04)	2.59 (4.78, 1.53–5.73)	<0.001
Procedure duration, min	56.5 (65.6, 40–66.5)	51 (65, 44–80)	0.72

Data presented as median (mean, P25–P75). DAP indicates dose area product; and FMX, flexible multiconfiguration x-ray shield.

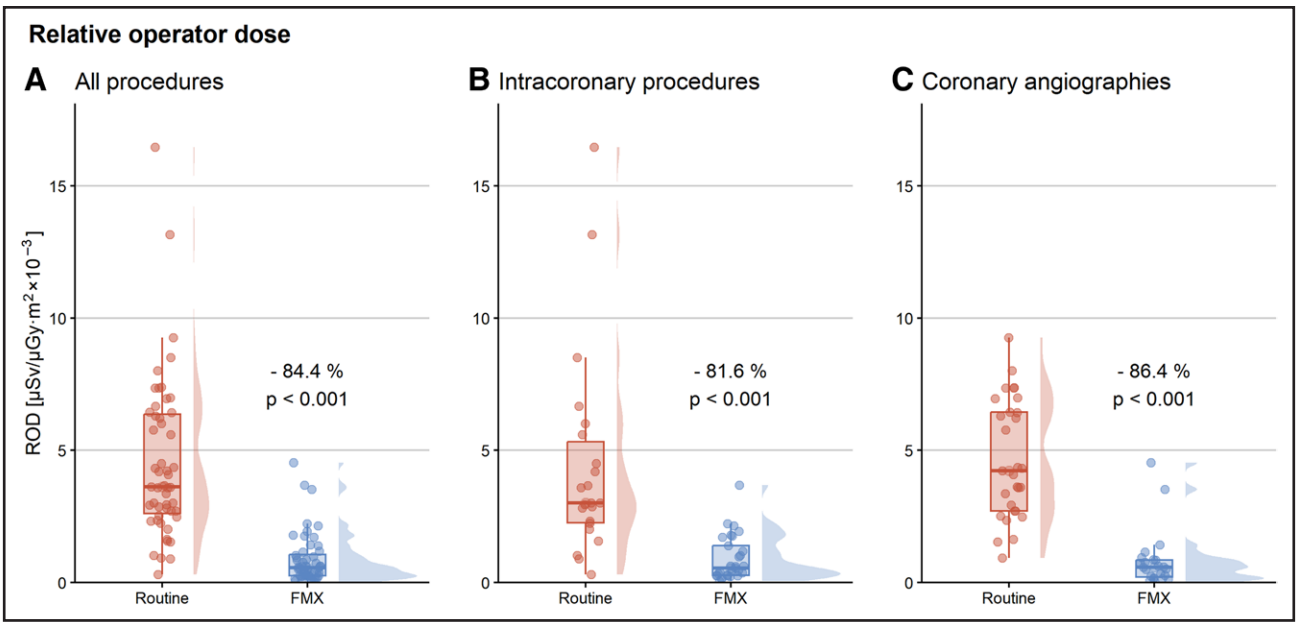

Figure 3. Relative operator dose (ROD) according to shielding setup.
Adding the flexible multiconfiguration x-ray shield (FMX) resulted in a median reduction of 84.4% of ROD ($P<0.001$) across all procedures (**A**). It was similarly effective in both intracoronary procedures (**B**) and during coronary angiographies (**C**).

was recorded in a planned PCI of the LAD. In the FMX group, ROD was generally low with less variation between procedures with all but 3 below the interquartile range of the routine protection group (Figure 3A). In the FMX group, the highest recorded ROD was 4.53 µSv/µGy·m^2×10^{-3}, which is close to the median of the routine setup.

User Feedback

Figure 4 illustrates answers to the survey from the different operators. Ten operators replied to 11 questions on size, functionality, ease of use, likely to use, critical issues, shielding, draping, procedure time, vascular access, patient discomfort, and risk. In general, user feedback was highly positive, suggesting the FMX concept may represent an attractive novel approach likely to be implemented by clinicians. 86% of feedback was optimal, 13% adequate, 1% should be improved. Seven operators found the size optimal, 2 thought it could be slightly larger and one slightly smaller. All found the new functionality (size and flexibility) of the FMX to be beneficial to improve shielding. Six found the process of inserting the FMX into the sterile drape easy, 2 found it fair, and one

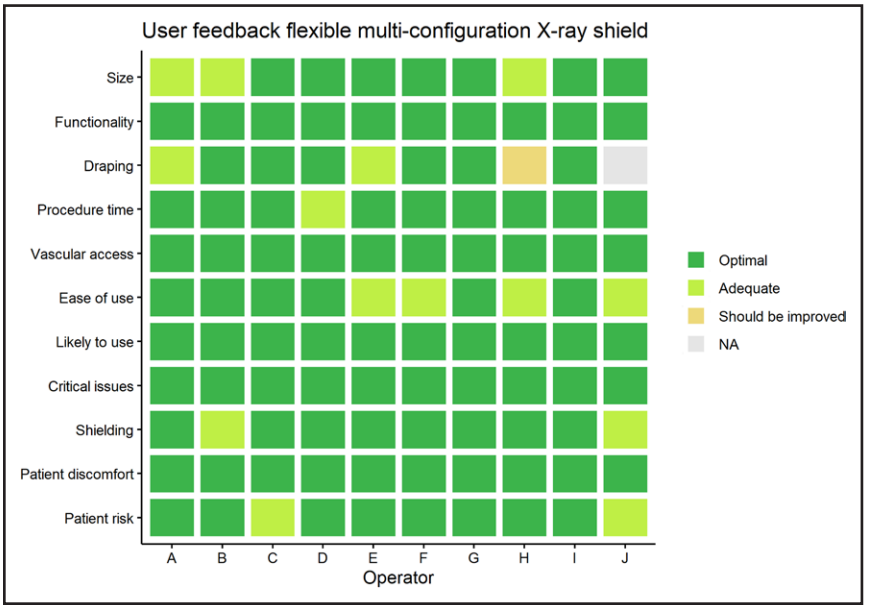

Figure 4. User feedback on functionality and user-friendliness.
Participating operators answered a feedback form with 11 questions and 3 grading options (optimal, adequate, and should be improved). About 86% of feedback was optimal, 13% adequate, 1% should be improved. No critical issues were identified.

found it difficult. One operator could not answer as he had delegated the task. Nine answered that the FMX did not increase procedure time, whereas one responded that it increased procedure time slightly, but acceptably. None found it to hamper vascular access. All found the FMX easy to use, 6 stated no need for extra attention to the FMX during use and the remaining 4 reported it needed some, but acceptable attention. Eight answered that they considered the x-ray mat in its current form to offer better shielding than existing approaches and the remaining 2 answered that it was comparable to existing solutions. No patient discomfort was reported. Potential for patient risk was considered negligible by 8 and minimal by 2. No critical problems were noted. All operators would use the FMX in their daily clinical routine if available.

DISCUSSION

Table and ceiling-mounted shields are effective at stopping scatter radiation, but the routinely encountered shielding setup leaves unshielded areas where scatter from the patient may increase operator exposure. Although new approaches have been developed, there is a need to further optimize x-ray protection to minimize operator exposure. Positioning of the shielding elements is crucial as cardiac catheterization is a dynamic procedure where access and visualization needs may differ and change both during a procedure and between procedures. Thus, even with perfect positioning at the start of the procedure, shielding elements often need to be moved which reduces effectiveness and attractiveness. Several solutions have been proposed.[5–13,17] In its simplest form, a nonsterile drape is placed on the patient under the surgical drape.[8] The obvious limitation of this approach is that the shield is not repositionable during the procedure and may conflict with the imaging area. Compared with single-use, nonlead, sterile blankets, the reusable FMX has the advantage of significantly reducing cost as well as waste per procedure. Reusable shields have are in use but have to date only shown far only shown moderate efficacy ranging from 20% to 72%.[5,15,18,19] More recently, comprehensive ceiling table- or floor-mounted systems[10–13] have entered the market. These have gained traction, but to date, have not reached general uptake among interventional cardiologists. Limited implementation of existing radiation shields into the daily routine is likely due to cost, complexity, and scarceness of data. Flexibility, ease of use, in addition to acceptable cost are important factors in achieving widespread use. For this reason, this study had a strong emphasis on user feedback to identify features that could impact the efficacy and clinical uptake of the FMX.

Patient and Procedural Characteristics

In this study, a wide range of procedures was included to mirror everyday practice. The data show a homogenous repartition between groups regarding patient baseline characteristics as well as procedural characteristics. No patients were excluded due to extreme height or weight. In routine use, it is unlikely that stringent height and weight limits are needed. As in most modern PCI centers, radial access was used in the majority of cases.

Operator Dose and Shielding Effect

Adding the FMX led to a highly significant (84.4%) reduction in the median ROD measured at the thyroid collar. In clinical practice, dosimeter at thyroid collar level is commonly used as a standard clinical, legal, and regulatory reference for the assessment of operator radiation exposure. However, supplementary dosimetry may add further highly relevant information. Previous studies evaluating different x-ray shields placed on the patient have demonstrated highly variable reduction in ROD ranging from 20% to 72%.[5–8,15,18,19] In these studies, x-ray shield size, lead equivalency, and functionality were highly variable. There was, however, a trend toward larger shields yielding better operator protection, and the largest reduction in ROD being observed with a 2-piece shield in sterile draping.[19] We have previously shown that openings between the shielding elements may cause a large increase in operator exposure.[14] The FMX was specifically designed to offer a more continuous shielding solution independently of different access and visualization needs. Our results indicate promising shielding effect. It should also be noted that in our study, median ROD in the control group with standard shielding was relatively low with median (mean) ROD 3.6 (4.3) $\mu Sv/\mu Gy{\cdot}m^2{\times}10^{-3}$ compared with 4.9 and 8.1 $\mu Sv/\mu Gy{\cdot}m^2{\times}10^{-3}$ in recent similar trials.[5,15] Compared with the published data from 21 499 cardiac catheterizations between 2013 and 2019,[16] mean ROD in the routine group was similar to mean ROD before 2018 (4.3 versus 4.6 $uSv/\mu Gy{\cdot}m^{2\times}10^{-3}$). From 2018, most operators used a commercially available pelvic shield in addition to routine setup, and the mean historic ROD for 2018 to 2019 was 2.4 compared with 0.9 $uSv/\mu Gy\ m^{2\times}10^{-3}$ in the FMX group. In our study, the variation in both absolute and ROD was much larger in the routine protection group than in the FMX group, and the outliers with the highest ROD were all recorded without the FMX. This suggests that these high operator dose exposures could largely be eliminated using an FMX. Based on the extrapolation of our data, an annual caseload of 500 procedures would result in an estimated annual operator dose of 0.7 mSv/y with the FMX setup.

User Feedback

Although it is widely known that shielding can reduce operator exposure, available measures are not sufficiently used.[20] Cardiac catheterization labs are high-paced

environments with many constraints and requirements. Therefore, to ensure uptake among operators, it is vital that any new measure does not add significant logistic and ergonomic issues and has minimal impact on procedure time and cost. User-friendliness and patient safety should be high and well-documented. Thus, user feedback is key for optimizing x-ray protection. In this study, all operators appreciated the new design and functionality. Most operators found the process of inserting the FMX in the sterile cover immediately to be easy and the remaining operators reported a short learning curve and little hassle once mastered. Despite being larger and with more complex features than comparable devices the FMX added minimal preparation time and did not hamper vascular access or visualization. Several operators commented informally that after positioning the FMX at the start of the procedure they forgot it was there. Operators reported no limitations in accommodating any angle of exposure during the study. All operators answered they would wish to implement the FMX as part of their clinical routine. There was no negative feedback from the patients. Regarding patient safety, no concerns were raised. The FMX was easily kept from entering the primary field and no increase in DAP observed. Altogether, user feedbacks provided in this study suggest the low threshold, general-use FMX may be an attractive approach for optimizing radiation protection during interventional procedures.

Limitations

Findings from this single-center study would benefit from further validation in a larger multicenter trial. In most cases, the FMX can be repositioned according to the need for access and visualization without removing the system. However, if an emergency situation occurs where the FMX must be removed, any operators not wearing personal protective equipment would need to use additional shielding including PPE.

Conclusions

Adding the FMX reduces exposure to radiation considerably. The FMX represents an effective and attractive solution for operator radiation protection that can easily be implemented in existing workflow. The FMX for general routine use has potential to optimize radiation protection in the cath laboratory with minimal logistic and practical constraints and offers flexible visualization, access, and shielding.

ARTICLE INFORMATION

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Disclosures

Drs Tuseth and Davidsen are co-inventors in a patent pending on x-ray shield design. The other authors report no conflicts.

Supplemental Material

Table S1

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