Operator radiation exposure in cardiac catheterization

Cedric Davidsen

Thesis for the degree of Philosophiae Doctor (PhD)
University of Bergen, Norway
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Abbreviations and acronyms

AP	Anteroposterior (projection)
CAUD	Caudal (projection)
CRAN	Cranial (projection)
DAP	Dose Area Product
FMX	Flexible Multi-configuration X-ray shield
FPS	Frames Per Second
Gy	Gray
kVp	kilovoltage peak
LAO	Left Anterior Oblique (projection)
LAO90	Left Anterior Oblique 90º (projection)
NORIC	The Norwegian Registry for Invasive Cardiology
PCI	Percutaneous Coronary Intervention
PPE	Personal Protective Equipment
RAO	Right Anterior Oblique (projection)
RDSR	Radiation Dose Structured Report
ROD	Relative Operator Dose (operator dose indexed to patient DAP)
TAVI	Transcatheter Aortic Valve Implantation
XRB	X-Ray Blanket
cath lab	cardiac catheterization laboratory
mGy	milliGray
µGy	microGray
mSv	milliSievert
Pb	Lead
µSv	microSievert

Scientific environment

The PhD program was performed at the University of Bergen. The research was conducted at the Department of Heart Disease, Haukeland University Hospital which is the teaching hospital for the faculty of Medicine at the University of Bergen. It was performed under the auspices of the Interventional Cardiology Research Group with a strong collaboration with the Medical Physics Department at Haukeland University Hospital and the Department of Physics and Technology at the University of Bergen. The work was also supported by the Department of Cardiology at the University Hospital of Liège, Belgium.

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Life is notoriously unpredictable and who could have foreseen that what started out as a concern for ionizing radiation at the start of my career in the cath lab in 2013 would evolve into a research project and a PhD ten years later. During this time life events unfolded, with the addition of two wonderful daughters to the family, change of workplace and country of residence. To be able to conduct a research project of this magnitude through such changes while pursuing clinical work as an interventional cardiologist required a strong supportive team with a high level of flexibility both in the research group, at work, and at home.

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Finally, I would like to thank my family, and my dad who passed on the interest of building and repairing things rather than just buying something new. Spending a lot of time on the aging family sailboat taught me that much can be repaired or built with some creativity and what you already have at hand.

List of Publications

Paper I

Davidsen C, Bolstad K, Nygaard E, Vikenes K, Rotevatn S, Tuseth V. Temporal Trends in X-Ray Exposure during Coronary Angiography and Percutaneous Coronary Intervention. J Interv Cardiol. 2020 Aug 31; 2020:9602942. doi: 10.1155/2020/9602942. PMID: 32934609; PMCID: PMC7481933.

Paper II

Davidsen C, Bolstad K, Ytre-Hauge K, Samnøy AT, Vikenes K, Tuseth V. Effect of an optimized X-ray blanket design on operator radiation dose in cardiac catheterization based on real-world angiography. PLoS One. 2022 Nov 10;17(11):e0277436. doi: 10.1371/journal.pone.0277436. PMID: 36356038

Paper III

Davidsen C, Ytre-Hauge K, Samnøy AT, Vikenes K, Lancellotti P, Tuseth V. Efficacy and User Experience of a Novel X-Ray Shield on Operator Radiation Exposure During Cardiac Catheterization: A Randomized Controlled Trial. Circ Cardiovasc Interv. 2023 Nov 13:e013199. doi: 10.1161/CIRCINTERVENTIONS.123.013199. Epub ahead of print. PMID: 37955163.

Abstract

Introduction

During X-ray guided cardiac catheterization, both the patient and operator are exposed to ionizing radiation. Whereas the patient is exposed to the primary beam, the main source of operator exposure is scatter radiation from the patient. Operator dose is only a small fraction of patient dose, but an operator may perform thousands of procedures during a career spanning multiple decades. Radiation protection is mandatory and important to reduce the occupational health risk of working in the cardiac catheterization laboratory. Although lead and lead-equivalent devices are effective at stopping radiation in the energetic spectrum encountered in the cath lab, there are important challenges and constraints to the seemingly simple task of improving operator shielding. During cardiac catheterization, the operator needs to be close to the patient and have sterile access to vascular puncture sites to steer the catheters, wires, balloons, and stents under fluoroscopic guidance. The C-arm must be able to move freely, and table height and position will often change throughout the procedure. A routine setup with table- and ceiling-mounted shield leaves unshielded areas which tend to increase during the procedure due to progressively suboptimal positioning of shielding devices related to table- and C-arm movement.

As a first step, registry analysis was done to evaluate temporal trends in patient and operator X-ray exposure between 2013 and mid 2019 at Haukeland University Hospital and the impact of upgrades in X-ray equipment and shielding, as well as operator awareness measures.

We then developed a novel Flexible Multi-configuration X-ray shield (FMX) to address shortcomings of existing shielding devices. The shielding effect was evaluated in an experimental setup mirroring everyday practice.

Finally, a fully functional prototype of the FMX was tested in a clinical trial to evaluate efficacy and user feedback during routine cardiac catheterization.

Materials and methods

Data on 21499 coronary angiographies and percutaneous coronary angiographies performed at our institution between the start of 2013 and June 2019 was extracted from the Norwegian Registry for Invasive Cardiology (NORIC). Personal operator dosimetry records for the same period were provided by the Norwegian Radiation and Nuclear Safety Authority. Patient and operator X-ray exposure was analyzed in relation to patient and procedural characteristics, upgraded X-ray equipment, improved shielding, and enhanced operator awareness.

To create an experimental setup mirroring everyday practice, Radiation Dose Structured Report (RDSR) data from 7681 routine procedures was used to establish a reference for a typical cardiac catheterization procedure and which C-arm angulations are used. Using this data, we assessed the shielding potential of the FMX.

To evaluate effect in clinical practice, relative operator dose (operator dose indexed for patient dose) was measured during 103 consecutive cardiac catheterizations randomized in a 1:1 proportion to current routine shielding or FMX + routine shielding. User feedback was collected on perceived function, relevance, and likelihood of adoption into clinical practice.

Results

Registry analysis showed that, between 2013 and 2019, mean patient dose per procedure (assessed by Dose Area Product) decreased by 37% in coronary angiography (from 2981 µGy·m2 in 2013 to 1891 µGy·m^2 in 201, $p < 0.001$) and 39% in percutaneous coronary intervention (from 8358 to 5055 µGy·m^2, $p<0.001$). During the same period annual operator dose decreased 70% with a marked drop in 2018 which coincided with the implementation of improved radiation protection measures.

In a bench testing setup mirroring everyday practice, adding an FMX to a standard shielding setup comprising a table- and ceiling-mounted shield resulted in a 94.9% reduction in estimated operator dose. With a standard shielding setup, the operator receives most of the X-ray exposure (86%) when imaging in cranial and left anterior oblique projections where the ceiling-mounted shield offers less protection. The FMX was particularly effective in these projections.

In the clinical trial, adding the FMX to routine shielding setup resulted in an 84.4% reduction in median relative operator dose (from 3.63 to 0.57 $\mu Sv/\mu Gy \cdot m^2 \cdot 10^{-3}$). The FMX received highly positive user feedback regarding size, functionality, ease of use, likely to use, critical issues, shielding, draping, procedure time, vascular access, patient discomfort, and risk.

Conclusions

Registry analysis showed a temporal trend towards considerable reduction in X-ray doses received by the patient and operator during cardiac catheterization. Upgraded X-ray equipment, improved shielding, and enhanced operator awareness are likely contributors to this development.

In a bench model, the FMX is a simple shielding measure that has the potential to reduce operator dose.

In clinical use, FMX reduces operator radiation exposure considerably. The FMX represents an effective and attractive device 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.

Abstract in Norwegian

Introduksjon

Røntgenveiledete hjerteprosedyrer utsetter både pasient og operatør for ioniserende stråling. Selv om operatørdosen er en brøkdel av pasientdosen, kan en operatør utføre tusenvis av prosedyrer i løpet av en yrkeskarriere. Strålevern er viktig og obligatorisk. Utfordringen med strålevern ved hjertekateterisering er at operatøren må stå tett inntil pasienten og ha steril vaskulær tilgang for å manipulere utstyr inni blodbanen under røntgengjennomlysning. I tillegg er både C-buen og pasientbordet bevegelig.

Bedre bruk og oppgradering til moderne røntgenutstyr kan redusere gitt dose til pasient, noe som også vil redusere operatørdose. Skjerming reduserer operatørdosen ytterligere, men konvensjonelle bord- og takmontert beskyttelse etterlater uskjermede områder som har tendens til å øke i størrelse underveis i prosedyren. Det er derfor et behov for nye skjermingsløsninger som er bedre tilpasset arbeidssituasjonen til invasive kardiologer.

Materiale og metode

For å se på pasient- og operatørdoser og evaluere effekten av oppgraderinger i røntgenutstyr og skjerming, analyserte vi 21499 koronare angiografier og perkutan koronar intervensjon (PCI) utført ved Haukeland Universitetssykehus mellom 2013 og juni 2019. Prosedyredata ble hentet fra Norsk register for invasiv kardiologi (NORIC), og operatørdoser ble innhentet fra Direktoratet for strålevern og atomsikkerhet.

Vi utviklet deretter et nytt fleksibelt multikonfigurasjons røntgenskjold (FMX) og testet skjermingseffekt i et eksperimentelt oppsett som speiler hverdagspraksis. Ettersom røntgenprojeksjoner i stor grad påvirker dose til operatør, analyserte vi data fra 7681 prosedyrer for å kartlegge hvilke projeksjoner blir brukt og i hvilken proporsjon.

FMX ble så utprøvd i en randomisert klinisk studie med 103 hjertekateteriseringer der halvparten av prosedyrene ble utført med rutinemessig skjerming med bord- og takmontert røntgenbeskyttelse, og halvparten med rutinemessig skjerming + FMX.

Resultater

Mellom 2013 og 2019 sank gjennomsnittlig pasientdose per prosedyre med 37 % ved koronar angiografi (fra 2981 til 1891 $\mu Gy \cdot m^2$, $p < 0,001$) og 39 % ved PCI (fra 8358 til 5055 $\mu Gy \cdot m^2$, $p<0,001$). I samme periode gikk operatørdosen ned 70%. Den mest markante nedgang i operatørdose ble observert i 2018 noe som sammenfaller med innføringen av forbedrede stråleverntiltak.

I et eksperimentelt oppsett reduserte FMX relativ operatørdose med 94.9% sammenlignet med et standard skjermingsoppsett bestående av et bord- og takmontert beskyttelse. FMX var spesielt effektiv i venstre kranial og venstre skrå projeksjoner.

I en klinisk randomisert studie reduserte FMX median relativ operatørdose med 84.4% (fra 3,63 til 0,57 $\mu Sv/\mu Gy \cdot m^2 \cdot 10^{-3}$) og mottok svært positive tilbakemeldinger fra brukerne vedrørende funksjonalitet og brukervennlighet.

Konklusjoner

Registerstudien viser en tydelig reduksjon i stråledoser til pasient og operatør ved Haukeland Universitetssykehus mellom 2013-2019. Oppgradert røntgenutstyr, forbedret skjerming og økt operatørbevissthet er sannsynlige bidragsytere til denne utviklingen.

I en benkmodell er FMX et enkelt skjermingstiltak som kompletterer eksisterende røntgenbeskyttelse og fører til markant reduksjon i relativ operatørdose.

Klinisk testing bekrefter at FMX er effektiv, brukervennlig og attraktiv, og kan enkelt implementeres i eksisterende arbeidsflyt.

Contents

1. Introduction

1.1 X-rays and their deleterious health effects

The imaging properties of X-rays were discovered in 1895 by William Roentgen, but already in 1896, several reports emerged of radiation related hair loss, skin burns and swelling. The first cancer death linked to X-ray exposure occurred in 1904[1]. In the following decades, the need to protect the population and workers from the harmful effects of ionizing radiation became increasingly apparent and led to the establishment of the International Commission on Radiation protection (ICRP) in 1928.

Ionizing radiation effects can broadly be divided into two categories, deterministic and stochastic effects. Deterministic effects occur at a certain dose, such as erythema, cataract, and hair loss. Stochastic (or random effects) are biological effects that may occur at any given dose such as DNA damage which can result in malignancy many years after the initial exposure. Whereas deterministic effects can easily be appreciated, stochastic effects are more difficult to evaluate. Although the probability of stochastic effects generally increases with dose, they do not systematically occur, and there may be a substantial time delay between exposure and observed effect.

Much of the knowledge on stochastic effects is based on events where subjects were exposed to high amount of radiation in a relative short period of time such as the Hiroshima bomb and Chernobyl disaster[2, 3]. The effect of repeated exposure to low-dose radiation is less well established [4, 5], although an association with increased cancer risk have been suggested for doses as low as 10-15milliSievert (mSv) in children and young adults[6]. The ICRP [7] supports a Linear-no-threshold model where all radiation exposure is considered harmful and the risk of cancer for lower doses can be linearly extrapolated from higher radiation doses where cancer risk can more easily be quantified. As a consequence the ICRP recommends that exposure should be kept as low as reasonably achievable, also known as the ALARA-principle[8].

1.1.1 Recommendations, laws, and regulations

Legislation is a key step to improve the protection of workers and the public. International guidelines are established by the ICRP based on available scientific evidence, then implemented in national laws and regulations, and enforced through national radiation protection authorities.

In Europe, radiation protection principles and dose limits proposed in the *2007 Recommendations of the International Commission on Radiological Protection*[9] was largely adopted in EU directive *2013/59/EURATOM of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionizing radiation*[10]. A European Directive sets out a goal the EU countries must achieve but leaves it up to member states to decide how to reach the goals through national legislation[11].

Although Norway is not a member of EU, it is part of the European Economic Area (EØS) and thus legally bound to implement EU directives. Whereas the majority of ICRP recommendations from 2007 were adopted in the 2010 *Regulations on Radiation Protection and Use of Radiation* (Strålevernforskriften), it was updated in 2016 to better conform to EU directives[12]. Additionally, the *Working Environment Act*[13] (Arbeidsmiljøloven) and *Regulations concerning the Performance of Work*[14] states that it is the employer's responsibility to ensure a safe work environment, keep radiation exposure to the lowest possible level and provide personal protection equipment and a personal dosimeter. The workers should be informed about dose readings, and annual dose readings should be reported to the Norwegian Radiation and Nuclear Safety Authority.

For occupational exposure in adults, the ICRP[9] recommends effective annual dose limit <20mSv, with specific organ dose limits of <500 mSv for the skin, hands, and feet. Recommended annual dose limit to the lens of the eye was 150mSv in the initial 2007 version but was lowered to 20mSv in 2011 following evidence of lower threshold for cataract development[15, 16]. Monitoring of operator dose should be done with at least one dosimeter and ideally two, where one is worn below the protective apron, and one outside the apron attached to the thyroid collar [8]. It is worth noting that the ICRP and EU does not ban pregnant women from working with radiation as long as adequate precautionary measures are taken and the additional dose to the fetus does not exceed 1mSv during pregnancy.

The ICRP also emphasizes the importance of basic radiation protections principles namely justification (avoiding unnecessary exams), optimization (limiting dose per procedure by optimizing imaging techniques) and application of dose limits.

1.1.2 Background radiation

It is important to remember that ionizing radiation is omnipresent in nature and all humans are exposed to some degree of natural background radiation. According to the United Nations Scientific Committee on the Effects of Atomic Radiation, the global average of natural background radiation exposure is 2.4mSv/year [17], and is due to inhaled radon (1.26mSv/year), cosmic radiation (0.39mSv/year), ingestion of radioactive products (0.29mSv/year) and external terrestrial irradiation (0.48mSv).

1.1.3 Medical exposure

Medical imaging is an important source of radiation to the general population, especially in developed countries. A CT-scan typically exposes a patient to effective doses in the magnitude of 1-10mSv, and a coronary angiogram 7mSv [18]. According to the National Council on Radiation Protection and Measurements [19], U.S. citizens receive on average 3mSv/year due to medical exposure, which roughly corresponds to a doubling of background radiation. Medical exposure can be further divided in Computed Tomography (50% of medical exposure), nuclear medicine (25%), interventional fluoroscopy (7%), and conventional radiography (10%). In the European Union, yearly medical exposure is lower and has been estimated to 1.2mSv/year[20].

1.1.4 Cardiac cath in the modern era

Since the first percutaneous coronary angioplasty in 1977[21] and transcatheter aortic valve implantation (TAVI) in 2002[22], X-ray guided percutaneous catheter based procedures are increasingly used to diagnose and treat ischemic, rhythmic and structural heart disease. Today, an estimated 450 000 percutaneous coronary interventions (PCI)[23] and 78 000 TAVI procedures[24] are performed annually in the United States. The corresponding numbers in Norway in 2022 were 26 656 PCI and 1146 TAVI procedures[25]. Techniques and equipment continue to evolve both in interventional cardiology and radiology and allow to tackle increasingly complex diseases such as chronic total occlusions and percutaneous mitral valve repair and replacement. These new advanced techniques may lead to longer procedures and irradiation time.

1.1.5 Operator health concerns

During X-ray guided procedures operators are not exposed to the primary beam but scatter radiation. Although the dose to the operator is only a small fraction of the patient's dose, interventional cardiologists may perform hundreds of procedures per year.

Cancer has been linked to radiation, but individual risk for repeated low-dose irradiation is not easy to determine. It is a stochastic effect, and there can be many years of latency between exposure and development of cancer. Since the lifetime risk of cancer in the general population have been estimated to 50%[26], it can be difficult to distinguish between cancer linked to radiation exposure and natural occurrence. Venneri estimated that cardiac catheterization staff had a 1/192 lifetime risk for developing fatal or non-fatal cancer due to occupational exposure[27]. Roguin published a series of case reports of brain and neck tumors among physicians performing interventional procedures where 85% of tumors were located on the left side which closest to the radiation source[28]. More recently, evidence has emerged of an increase in markers of DNA damage repair in circulating lymphocytes of operators performing endovascular aortic repair[29].

Cataract is considered as a deterministic effect and estimated to occur for a cumulative dose of 500 mGy[15]. Several studies have reported an increased incidence of cataract amongst interventional cardiologist [30-33] and a meta-analysis estimated the relative risk to be 3.2 compared to an unexposed population [34].

Although acute *skin lesions* that were observed during the first years following X-ray discovery are nowadays rare[1], hands may still be exposed to considerable amounts of radiation if they accidentally or purposely enter the imaging area. If table- attached shields do not extend far enough towards the floor, lower extremities are also exposed to a significant amount of scatter. Chronic occupational radiodermatitis on the lower extremities have been reported in interventional cardiologists [35]. In more systematic reviews, skin lesions were found in 8.2% of interventional cardiologists compared to 2.0% in a control group[31].

Radioprotective garments contain lead- or lead-equivalent elements and are heavy, typically weighing between 5-10kg. Prolonged and repeated use may lead to *orthopedic problems*, and a high prevalence of spine, hip and knee problems amongst interventional cardiologists have been reported and tends to increase with annual caseload and years of practice in the cath lab[31, 36]. This aspect has an important impact on the quality of life of the operator but can also lead to an increase in sick leave, which has a financial impact and creates operational challenges in the cath lab. The physically demanding nature of interventional cardiology have also been cited as an obstacle for recruitment[37].

1.2 Operator dose

The operator is exposed to scatter radiation that originates from interactions of the primary beam with patient tissue. Operator dose is proportional to the given dose but can be reduced by shielding or by increasing the distance from the X-ray source.

1.2.1 Given dose

The given dose is assessed by Dose Area Product (DAP), which is the product of dose expressed in Gray (Gy) multiplied by the irradiated area. DAP is typically measured with a built-in ionizing chamber mounted on the collimator of the X-ray tube. Documentation of given doses is important as it enables comparison of PCI centers and changes over time, as well as evaluate cumulative dose in patients with repeated procedures.

Diagnostic Reference Levels (DRL) are seen as an important step to improve radiation protection to provide a benchmark to which a center can compare[10]. At present, each country establishes its own national DRL. The highest DRL for coronary angiography is in the Netherlands (8000 µGy*m2), Poland and Belgium (6000 µGy*m2) and the lowest in Norway (2000 µGy*m2) [38, 39]. A European DRL for coronary angiography (3500µGy*m2) and PCI (8500µGy*m2) has been proposed[40], but has so far not been universally adopted.

1.2.2 Temporal trends and registry data

Registry data can give valuable insights into temporal trends and current practice. Since 2013 all cardiac catheterization procedures in Norway are documented in NORIC (The Norwegian Registry for Invasive Cardiology) with patient, procedural, and basic radiation data. The considerable number of cardiac catheterizations documented in NORIC is a unique source for in-depth data analysis of factors influencing patient and operator dose.

In addition, a *radiation dose structured report (RDSR)* is generated at the end of each procedure and contains detailed information on each exposure regarding C-arm angulations, irradiation time, voltage, current and filter setting. This allows for more in-depth analysis than the aggregated procedure parameters stored in NORIC. At Haukeland University Hospital, starting in 2017, RDSR was stored in an OpenREM database. This is an opensource database which is easy to interrogate via Structured Query Language and allows for detailed analysis of large number of real-life procedures in regard to C-arm angulations, lab settings and imaging protocols.

1.2.3 Assessment of operator dose

Occupational exposure is assessed with one or several dosimeters from a dosimetry service accredited by the relevant national radiation protection authority. The ICRP recommends dosimetry at thyroid collar level outside the lead apron, with an additional dosimeter below the apron on the trunk to more easily estimate effective dose[8]. Dosimeters measure the personal dose equivalent Hp (10) which corresponds to the dose 10mm below the skin. Effective dose is then extrapolated under the assumption of a uniform whole-body exposure, which is a simplification as radiation to the operator is not uniform. Traditional dosimeters are read periodically (typically every month or two months) and are effective to assess occupational exposure over time. However, they do not give feedback on individual procedures.

Live dosimeters are increasingly popular as a supplementary measure to the mandatory dosimeters. They are digital devices which give the operator instant feedback during procedures and enable the operator to assess radiation exposure in relation to shielding and behavior.

As given doses vary between procedures, to compare the efficacy of shielding devices, it is common to calculate the *relative operator dose* (ROD), which is operator dose divided by patient DAP. This corrects for differences in patient dose between procedures due to procedure length, patient morphology, and differences in X-ray equipment [36].

1.3 Shielding

1.3.1 Effect of lead and lead-equivalent shielding

Lead (Pb) is highly effective at stopping X-rays in the energetic spectrum encountered in the cath lab but it's efficacy depends on photon energy. At 120kilovoltage peak (kVp) 0.5mm Pb will attenuate 93.7% of the radiation, at 80kVp 97.5%, and at 60kVp 99.6%[41]. According to our RDSR data from 7681 procedure, only 2.3% percent of exposures are above 120kVP (figure 1). Thus, in theory, it should be possible to reduce operator dose by at least 90% with continuous 0.5mm Pb shielding between the operator and patient.

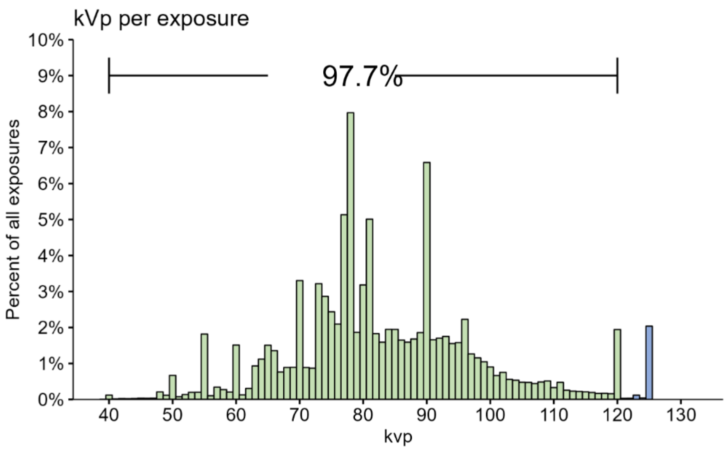


Figure 1. X-ray energies encountered in the cath lab during routine practice. Data on peak kilovoltage (kVp) for each exposure was extracted from OpenREM from 7681 routine procedures. The graphic represents the percentage of exposures according to kVp. 97.7% of all exposures were comprised between 40-120 kVp.

To reduce the weight of protective aprons, composite materials have been developed which provides similar attenuation properties as lead. Attenuation depends on photon energy. For a given element attenuation is stronger at and directly above K-edge which is the energy necessary to knock an electron out of the atom's innermost shell, the K-shell.

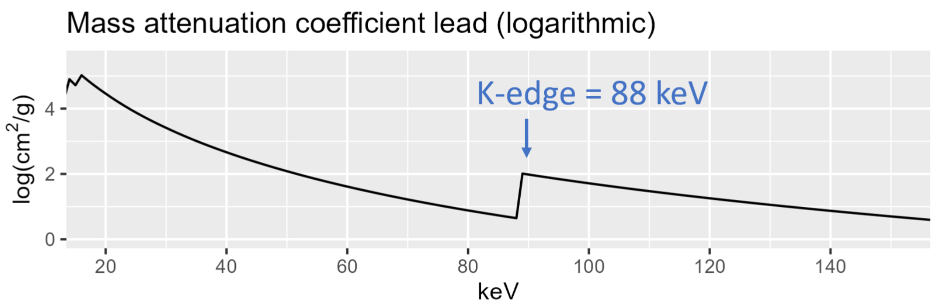


Figure 2. Mass attenuation coefficient of lead. *Attenuation depends on photon energy. The K-edge (88keV) is the energy necessary to knock an electron out of the K-shell. Attenuation is stronger at and right above the K-edge, but less below (data from the National Institute of Standards and Technology, https://physics.nist.gov/PhysRefData/Xcom/html/xcom1.html)*

Lead has a K-edge of 88 keV which means that it is highly effective at stopping photons at or directly above 88keV but is relatively poorer at stopping photons between 50 and 88 keV (figure 2). Combining lead with lighter elements such as antimony (K-edge 30.5keV), bismuth (37.4keV) or tungsten (69.5 keV) that are more effective in the lower energy ranges may offer equivalent protection with less weight[42]. Since lead is considered toxic, a popular lead-free composite in modern aprons is antimony-bismuth. In this composite, bismuth (K-edge 90.5 keV) has similar properties to lead and effectively attenuates higher energy photons, whereas antimony is more effective at lower energy range[43]. The term lead-equivalent (LE) refers to the ability to attenuate X-rays in a similar way to lead in the energy range encountered in diagnostic X-rays, and is defined in the IEC Standard 61331-1:2014[44].

1.3.2 Shielding devices

The objective of operator shielding is to create continuous shielding between the patient and the X-ray tube on one side and the operator on the other side. This is in theory possible to achieve with a combined use of a wheel-mounted side screen (figure 3, device A), a large ceiling-mounted shield (CMS) with flaps on the lower side (device B), a large X-ray blanket covering the patient and extending to the feet (device C), and a table-mounted shield with additional top shields (device D).

However, during cardiac catheterization, the operator needs sterile access to the patient to be able to manipulate catheters, wires, balloons, and stents. Therefore, this exact shielding setup is impractical during real-life procedures, especially at patient level.

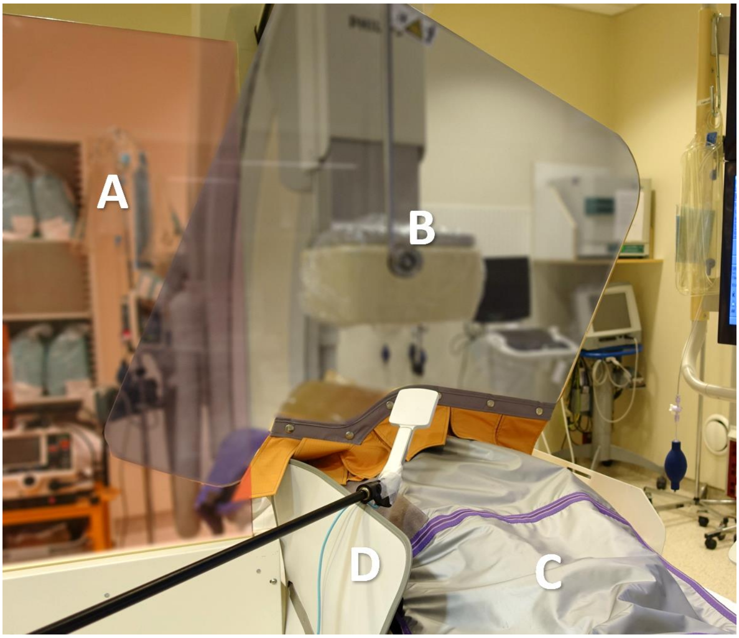


***Figure 3. Shielding devices encountered in the cath lab**. Device A is a wheel-mounted side screen, B a ceiling-suspended shield, C an X-ray blanket and D a table-mounted shield. The illustration shows it is possible to create continuous shielding with conventional shielding devices, but this configuration is bulky and leaves no access to the patient.*

Table- and ceiling-mounted shields

The most commonly encountered shielding setup consists of a table-mounted shield and a transparent lead-acrylic ceiling-suspended shield. Although these two devices are present in almost all cath labs, there are significant variations in size and design. Ceiling-mounted shields range from a small rectangle to large screens with patient cut-out and flaps on the lower side. Table-mounted shields also have large variations in width and length, and most have some sort of additional top shields that can either be flipped up or completely removed (figure 4). It should be noted that some operators find the top shield cumbersome and omit using them which leaves an unshielded area below the table (figure 4, middle panel).

Figure 4. Table-mounted shield designs*. In the left panel a smaller model is shown. Width and length are limited and there is a single top shield. In the middle panel, the top shield has been flipped down, which leaves a large unshielded area. To the right is a newer model with three top shields, and a wider under-table shield that extends protection to the second operator or nurse.*

Sterile and non-sterile X-ray blankets

In addition to the table- and ceiling-mounted shield, there has been increased focus on adding an X-ray blanket on top of the patient, as this is an area that is partially left unshielded by table- and ceiling-mounted shields (figure 5).

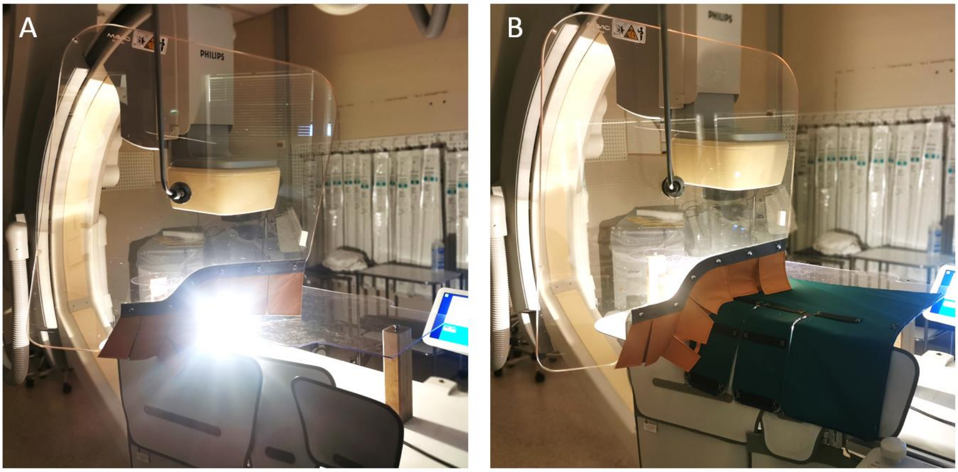


Figure 5. Mode of action of an X-ray blanket positioned above the patient. *In panel A, photons exit the patient between shielding devices and reach the operator. In panel B the X-ray blanket covers the unshielded area between the ceiling- and table-mounted shield thus enhancing operator protection.*

Different devices have been proposed. In its simplest form, a non-sterile lead apron is placed on the patient[45]. This is a straightforward and low-cost device. The drawback is that it is not repositionable during the procedure.

Single-use X-ray blankets are commercially available[46]. However, since they are discarded after use, they increase waste and adds procedure cost.

Reusable shields that are inserted into a sterile single-use plastic cover also exist on the market[47]. Compared to non-sterile X-ray blankets, they have the advantage of being repositionable, and reduce waste and cost compared to single-use devices. However, existing devices have simple designs with limited features for vascular access. They are commonly positioned cranially to the vascular access site and therefore provide no cover distally.

Personal Protective Equipment (PPE)

In addition to table- and ceiling-suspended shielding, there is a variety of wearable protection that are grouped under the term personal protective equipment (PPE, figure 6)

Figure 6. Illustration of personal protective equipment worn in the cath lab. *The operator wears a two-piece apron, lead hat, and lead glasses.*

The basic equipment is an apron which is available with various degrees of protection (0.25, 0.35, 0.5mm LE). Initially, they were simple aprons resting on the operators' shoulders. Newer designs are two-pieces with a vest and kilt that better distribute weight on the operator with an overlap in the front. This creates a double protection layer on the front and a thinner, one layer protection on the back, where there is less scatter.

Use of additional lead glasses for eye protection is strongly recommended[8] as the eye lens is a radio-sensitive organ. It is important that they fit tightly with lateral protection since scatter radiation tends to come from below and the left.

Lead hats have gained some traction following promising publications which showed reduction in radiation inside the hat at skin level on the left temporal side [48, 49]. Enthusiasm has however been tempered after evidence that most of the scatter radiation come from below, against which the hat provides little protection[50].

All PPEs are made of heavy, non-breathable material. They are uncomfortable, damp, reduce operator comfort and lead to increased orthopedic stress in prolonged procedures.

New shielding devices

In recent years new comprehensive shielding devices have entered the market. Some can be characterized as improvements of existing shielding designs such as the Eggnest®[51] (Figure 7, panel A), Rampart®[52] (panel B), and Protego®[53] (panel C). The Zero-gravity®[54] (panel D) proposes a different approach where the operator wears a ceiling-suspended suit. Robotic PCI, where the operator controls the robot from outside the cath lab has also been proposed[55].

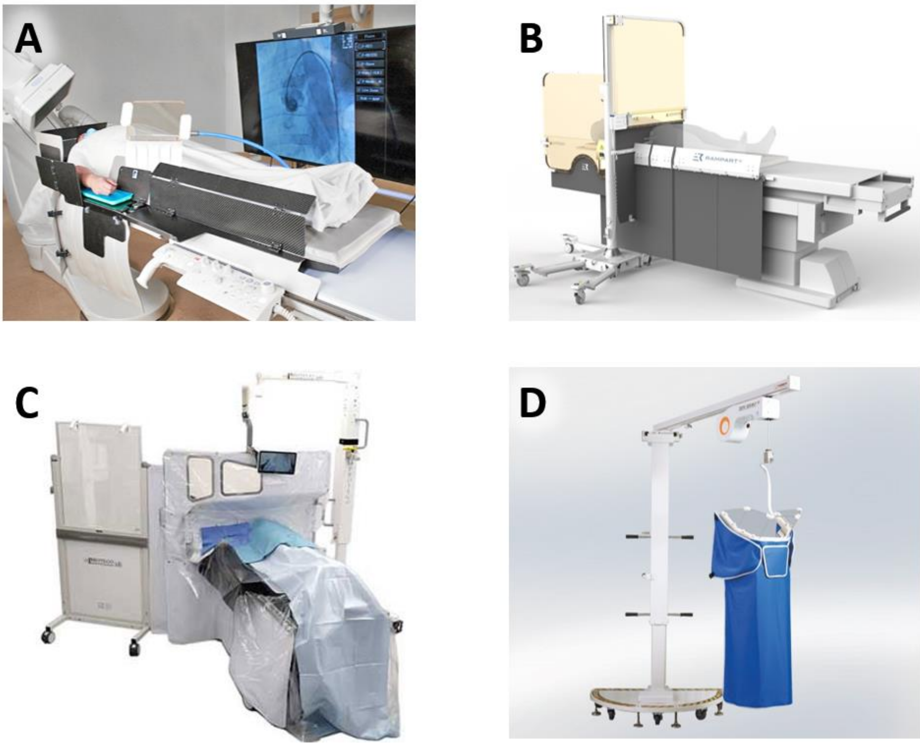


***Figure 7. Shielding systems that have recently entered the market**. In panel A the Eggnest® radiation protection system, panel B the Rampart 1128 ®, Panel C the Protego® and panel D the Zero-Gravity® suit. All pictures are promotional pictures from the respective companies' website.*

1.3.3 Clinical and patient considerations

A major consideration in improving operator radiation protection is that cardiac catheterization is a dynamic procedure. To properly visualize anatomic structures, table height, position and C-arm angulation will change during the procedure. Arterial access sites may be radial or femoral, or multiple such as bi-radial or radial and femoral and change throughout the procedure. Some procedures may encounter unstable patients with cardiogenic shock with the need for cardiopulmonary resuscitation or mechanical circulatory support.

Thus, a highly effective device in bench testing may prove useless in real-life procedures if it cannot accommodate for the dynamic nature of cardiac cath. It is important that it allows for vascular access with maintained shielding, is effective through all C-arm angulations, does not accidentally enter the imaging area, and is stable enough to not need constant attention and repositioning. Yet, it should be repositionable and even easily removable to allow for full access to the patient in an emergency situation.

All these aspects cannot be explored in an experimental setup, and thus it is very important to validate shielding effect and user-friendliness during routine cardiac catheterization. Collection of user feedback in routine general use is also crucial to assess user-friendliness and identify shortcomings that could limit general uptake. Shielding should ideally be used in all procedures, and operator acceptance and awareness is key to implement any new shielding measure and reduce operator dose. Reliable data on efficacy should optimally be available for all devices. X-ray protection should be easy and attractive to implement, and it is important that shielding is viewed as important, necessary, and attractive. Operators should not dread the hassle of using yet another device with little perceived benefit. Education and key opinion leaders have an important role to play in this regard.

Another important aspect is that improving operator protection should not negatively impact the patient. Theoretically there are two mechanisms by which an X-ray shield may increase patient dose. If a radio-opaque structure enters the imaging area, the X-ray system will try to compensate by increasing tube voltage and current which will result in an increase in patient dose. The second mechanism is that scatter that exits the patient may be backscattered towards the patient by the X-ray shield.

1.3.4 Limitations of current shielding devices

The most encountered shielding setup with a ceiling- and table-mounted shield leaves unshielded areas between the patient and operator. In addition, rigorous positioning of the shielding devices is imperative to optimize operator protection. The ceiling-suspended shield is a source of special attention as it needs to constantly be repositioned during the procedure. This is not always feasible in a high-paced interventional cardiology environment.

Adding an X-ray blanket on the patient has shown promise, but existing designs have limitations. Non-sterile blankets are not repositionable. Single-use sterile blankets add waste and cost, and reusable devices in sterile draping lacks features for vascular access with maintained shielding. So far, in clinical studies, these devices have only shown varying efficacy ranging from 20-72% % [47, 49, 56-60]. New comprehensive devices have been proposed but they are typically in the price range of 50-100k USD, which limits widespread use and general uptake. Also, some of the new systems are bulky, which may hamper access to the patient, as well as table- and C-arm movement. The importance of ease of use should not be underestimated. Studies have shown that available shielding equipment is not always used despite being available[61], and from clinical experience, some operators already find current routine shielding setups cumbersome. Thus, adding more complex and bulky protective measures are unlikely to achieve general uptake.

Operator awareness, education, training, and culture are important determinants of how existing shielding is used and its efficacy. Protection should be used at all times and in all procedures to maximize operator protection.

PPE that are worn by the operator is heavy and only protects areas covered by PPE. From an operator's point of view, reducing weight or even avoiding PPE altogether is desirable.

There is a need for improved easy to use shielding devices that would address shortcomings of routinely encountered setup with a table- and ceiling-mounted shield.

2. Pilot investigations

The work presented in this thesis is based on a number of hypothesis-generating preliminary investigations conducted during live procedures and in a controlled bench testing setup. As they are important to understand the rationale and methods underpinning the three scientific articles, they are presented in this section.

2.1 Live dosimeter measurement

Historically, operators were limited to receive a monthly or bi-monthly assessment of occupational exposure. Live dosimeters changed this and allowed for instant and continuous information on operator exposure via a monitor inside the cath lab (figure 8). Operators now had access to an instant feedback loop that allowed them to assess how their behavior, usage of shielding and C-arm setting, and angulation influenced received dose rate.

Figure 8. Live dosimeters. *To the left is a Live dosimeter (Raysafe I3® licensed to Philips), and to the right the DoseAware® screen in the cardiac catheterization lab which shows instant dose rate for all dosimeters located in the room.*

In addition, live dosimeters have a built-in memory which stores dose rate throughout the procedure with a resolution of one measure per second. This makes it possible to retrospectively analyze in detail dose rates as well as the cumulative dose. (Figure 9).

Using live dosimetry in clinical practice since 2016, we soon recognized the importance of optimal positioning of shielding devices and that small unshielded areas resulted in large increases in operator dose rate. The influence of C-arm angulation on operator dose was equally evident where left and cranial projections led to higher operator exposure.

We also noticed that in longer procedures dose rate tended to increase as time went by due to increasingly suboptimal positioning of shielding devices. This was particularly evident in acute or complicated procedures where the operator was intensely focused on the patient and had less attention paid to checking and adjusting shield positions.

The most difficult region to achieve shielding continuity was directly above the patient, even with large table- and ceiling-mounted shield, and this area seemed to be the source of most residual scatter to the operator. The addition of an X-ray blanket reduced the size of this unshielded area but if not optimally positioned, had limited effect. With available designs, it proved difficult to maintain an optimal positioning throughout the procedure and led us to the conclusion that there was a need for better X-ray blanket design. The novel shield should be large enough to minimize unshielded areas, require less attention and repositioning, adapt to different patient morphologies, and allow for vascular access with maintained shielding.

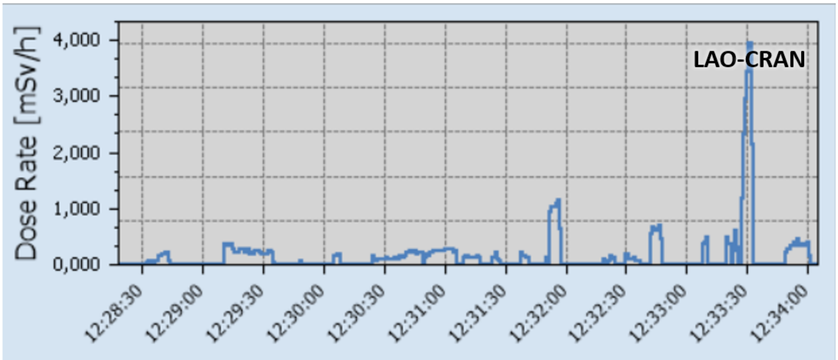


Figure 9. Dose rate analysis*. In addition to instant feedback, live dosimeters have a built-in memory which stores detailed information on dose rate and cumulative dose throughout a procedure. The image shows operator exposure during a diagnostic coronary angiogram. The highest dose rate (12:33:30) was registered during acquisition of the left coronary artery in left cranial projection.*

2.2 Visualizing importance of unshielded areas with a simple model using visible light photons

X-rays are photons albeit with a higher energy level than visible light. To help in new shield design and communicate the importance of unshielded areas, we developed a simple visible light model which aimed to demonstrate scatter radiation from the patient. A light bulb at heart level simulates the scatter source, and a transparent styrene acrylonitrile plastic was cut out to the silhouette of a patient and placed above the light bulb.

Figure 10. A simple visible light model to illustrate scatter radiation. *To the left the X-ray blanket is positioned too far towards the patient's legs. In the right picture the operator is protected in the shade of the X-ray blanket.*

In the left panel of figure 10 it is easy to appreciate that if positioned too caudally, the X-ray blanket provides no protection between the scatter source and the operator. In the right panel, the X-ray blanket is moved more cranially, and the shade cast on the operator demonstrates better shielding effect.

2.3 Bench testing with an anthropomorphic phantom

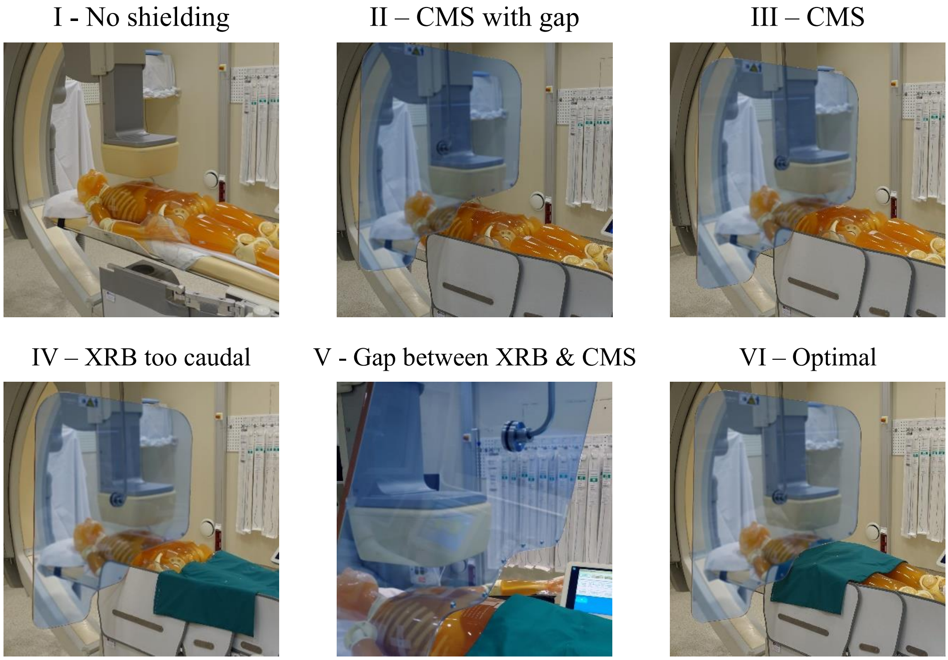
To evaluate the effect and limitations of current and new shielding devices it was necessary to create a realistic bench testing setup for controlled reproducible measurements of patient and operator dose. To simulate the patient, we used a Kyoto Kagaku Whole Body Phantom PBU-50. Measurements were done in a cath lab equipped with Philips Allura Xper FD10C C-arm from 2009. For scatter radiation measurements we used the Raysafe X2® (Unfors Raysafe AB, Sweden) with the X2 Survey sensor (figure 11).

Figure 11: Bench testing setup. *An anthropomorphic X-ray phantom is used to simulate the patient in the cath lab. Scatter radiation is measured with the X2 survey sensor (Unfors Raysafe AB, Sweden)*

2.3.1 Positioning of shielding devices and impact on operator dose.

After live dosimetry established the importance of covering unshielded areas, the next step was to measure and quantify the impact of shielding device positioning on operator exposure (figure 12).

Dose rate measurements were done with the X2 Survey Sensor, positioned 65cm caudally and 45 cm laterally to the center of the primary beam 140cm above the floor which is a typical position for the first operator thyroid attached dosimeter. Three measurements were done for each setup and the average was used. Table height was 90cm, source-to-image distance (SID) 100cm, field of view 20cm x 20cm, and we used a 15 frames per second (FPS) acquisition protocol with anteroposterior angulation of the C-arm. The shielding setup and dose rates are listed in figure 12.



Setup	Description	Table flaps	CMS	XRB	Dose rate nGy/s	Norm dose rate
I	No shielding	no	none	none	221.9	100.0 %
II	CMS with gap	yes	15cm above patient	none	204.5	92.2 %
III	CMS	yes	5cm above patient	none	123.6	55.7 %
IV	XRB too caudal	yes	5cm above patient	15cm caudally to CMS	113.6	51.2 %
V	Gap between XRB and CMS	yes	15cm above patient	well positioned	76.5	34.5 %
VI	Optimal	yes	5cm above patient	well positioned	7.3	3.3 %

Figure 12: Operator dose rate according to shielding setup. *Pictures I to VI show the tested shielding setups with increasingly better shielding. The corresponding dose rates are listed in the table. Adding an XRB reduces operator shielding, but positioning of shielding elements is also important to avoid unshielded areas. CMS = ceiling-mounted shield, XRB = X-ray blanket.*

Compared to no shielding (100% - setup I), operator dose rate with a ceiling-mounted shield positioned 15 cm above the patient (setup II) decreased to 92.2% compared to setup I. Lowering the CMS to 5cm above the patient (setup III) significantly improved shielding and the dose rate to the operator fell to 55.7%.

Adding an XRB with a 15 cm vertical opening between the XRB and the CMS (setup IV) yielded a similar dose rate at 51.2%. When the CMS was lowered toward the patient, and the XRB moved 15cm caudally to create a horizontal unshielded area between the two (setup V), dose rate was 34.5%

In an optimal shielding setup with an XRB optimally positioned extending slightly cranial to the edge of the CMS and a CMS lowered on to the patient, dose rate was reduced to 3.3% compared to no shielding.

These preliminary investigations confirmed the importance of continuous shielding above the patient. Small horizontal or vertical unshielded areas between shielding devices increase operator exposure significantly.

2.3.2 Impact of an X-ray blanket on patient dose

To assess the potential increase in patient dose of adding an X-ray blanket on top of the patient it was necessary to measure both scatter radiation exiting the patient, and backscatter from the X-ray blanket. As the X2 survey sensor is directional, it could not be used. Instead, we attached a bi-directional DAP meter (Doseguard Kerma Area Product Meter model 100) to the abdomen of the anthropomorphic X-ray phantom and measured dose rate with and without a pelvic blanket (Figure 13). With the X-ray blanket, we found a small, non-significant 1.2% increase DAP rate compared to no blanket.

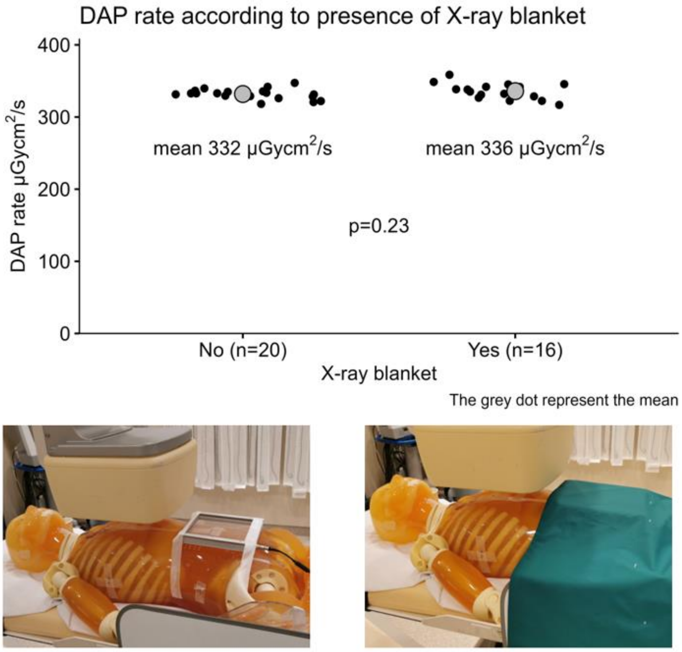


Figure 13: Impact of an X-ray blanket on patient dose. *To assess the increase in dose rate below the X-ray blanket, a bi-directional DAP meter was attached to the abdomen of the X-ray phantom. Measurements were repeated with and without and X-ray blanket. The upper panel illustrates dose rate according to presence of X-ray blanket and the lower panels show the experimental setup.*

It is however important to remember that what is measured under the X-ray blanket is not the effective dose to the patient, but the intensity of scatter radiation at this specific point. Only a small fraction of the primary beam is scattered towards the XRB, and a 1% increase in dose rate below the X-ray blanket due to backscatter is unlikely to have a clinical meaningful impact on patient effective dose.

2.4 Computer simulations

Radiation is not uniformly distributed during fluoroscopic procedures. Although it is possible to increase the number of measuring points to gain a better understanding of dose distribution, there is a limit to what is practically feasible. Monte-Carlo simulations circumvent these limitations and are a useful supplement to dosimetry measurements in the cath lab.

Although it was beyond the scope of the current work to develop and utilize a framework for Monte-Carlo simulations in the cath lab, we collaborated with the Department of physics and technology, University of Bergen (Prof Kristian S. Ytre-Hauge and MSc Jon S. Dyrkolbotn) to simulate operator dose with different shielding setups to increase the understanding on how radiation is distributed on the operator and patient.

Figure 14 shows a simulation of relative dose to the patient and operator with no shielding. For the operator, the relative dose is higher on the left side which is closer to the radiation source and below the table.

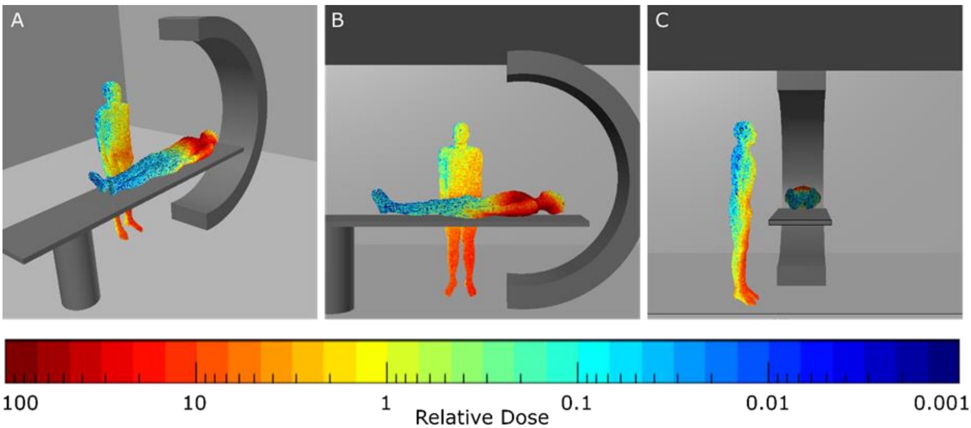


Figure 14: Monte-Carlo simulations of relative dose during cardiac catheterization. *Monte-Carlo simulations are useful to visualize dose distribution on the operator and patients and can also be used to assess dose to individual organs. (courtesy of prof. Kristian S. Ytre-Hauge).*

Adding shielding to the simulation changes dose distribution. Figure 15 shows the relative fluence with no shielding (red line) and with a table- and ceiling mounted shield (blue line)

With no shielding the maximum relative fluence is measured 42cm above the floor. Adding a table and ceiling-mounted shield is highly effective for under-table scatter but leaves residual scatter above the table. In this simulated setup fluence to the operator is highest 147 cm above the floor which is close to where the mandatory thyroid dosimeter is worn.

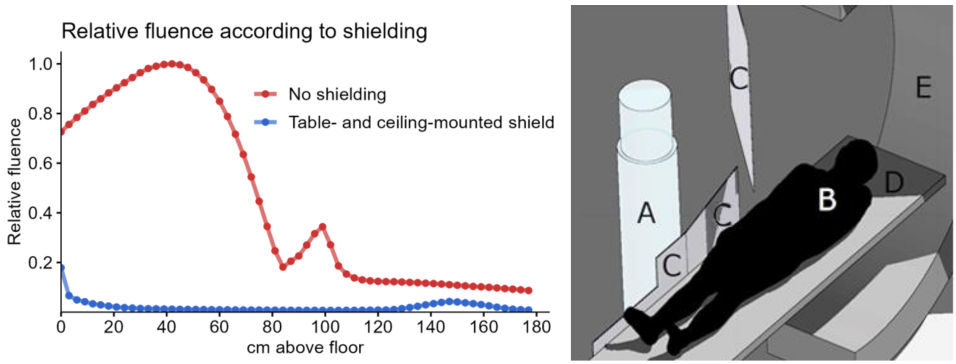


Figure 15 Monte-Carlo simulations of relative fluence on operator according to shielding. *In the left panel is the relative fluence on the operator according to height above floor for two shielding setups. In the right panel is the 3d model used for Monte-Carlo simulation with the operator (A), the patient (B), the table- and ceiling-mounted shield (C), table (D) and C-arm (E). Figure adapted with permission from the Master Thesis of J.S Dyrkolbotn : Occupational Radiation Exposure During X-ray Guided Interventional Cardiology Procedures, University of Bergen, 2021*[62]*.*

2.5 Importance of cat lab settings

2.5.1 Framerates

During exploratory analysis we compared DAP per unit of time for each of the cath labs both for *acquisition* and *fluoro.* We discovered that for fluoro, the values were similar across three labs. However, for *acquisition,* DAP/second was almost twice as high in lab 2 compared to the two other labs.

When we checked the default imaging settings, we discovered that cath lab 2 had a default of 15 FPS in *acquisition* and this was used 47% of the time (figure 16, left panel). In the other labs default framerate was set to 7.5 as default (Philips) and 10 FPS (Siemens). We reprogrammed the default setting to 7.5FPS, and simply by changing this setting, 15FPS usage decreased from 47% to 14% (figure 16, right panel), and DAP/second decreased on average 27%.

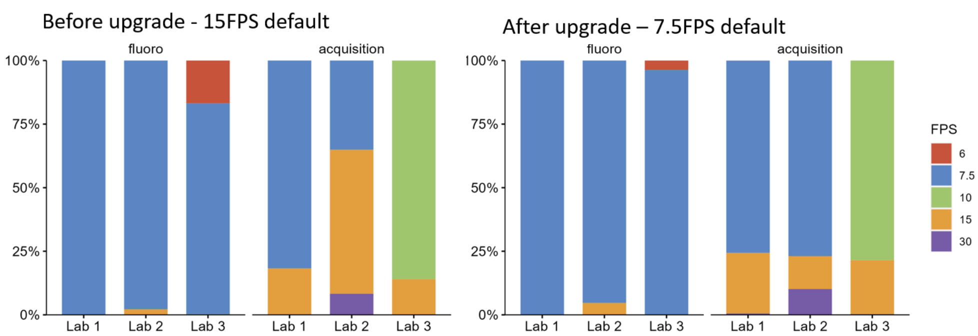


Figure 16: Importance of default setting on operator choice of imaging protocol. *The figure shows the percentage exposures and corresponding FPS setting (frames per second) for each cath lab. In the left panel, the default setting was 15FPS for acquisition in Lab2, and was used in 47% of exposures, whereas it was less in lab 1 and 2. After upgrading the default to 7.5FPS, 15 FPS usage fell to 14% as illustrated in the right panel.*

2.5.2 Projections and C-arm angulations

It is well known that C-arm angulation is an important determinant of both patient and operator exposure[63]. With increase in C-arm angulation, there is more patient tissue between the X-ray tube and detector. As a result, the X-ray system will increase voltage and current to preserve image quality. For the operator, the position of the under-table X-ray tube is also important. In left and cranial projections, the X-ray tube is closer to the operator, which increases the operator dose.

What is less known is which projections are used in everyday practice, their proportion, and how much they contribute to operator dose. This is important as new shielding devices should be validated in all commonly used angiographic projections. With a large number of RDSR data, this information is readily available. Figure 17 shows a three-dimensional representation of C-arm angulation for each exposure during 7681 routine cardiac procedures.

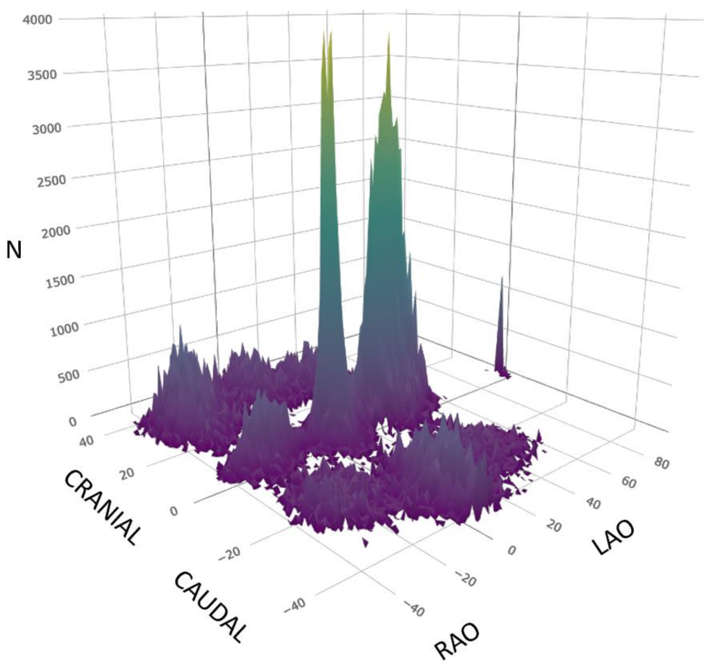


Figure 17: 3d representation of C-arm angulations used in routine clinical practice. *The vertical axis shows the number of exposures (N) according to the cranio-caudal and left-right tilt which is represented in the horizontal axes. Radiation dose structured reports from 7681 routine cardiac catheterization was used to create the illustration. It is easy to appreciate that Anteroposterior (AP) and Left Anterior Oblique (LAO) are the two most frequently used projections.*

2.6 Development of the FMX

After initial investigations with live dosimeters, bench testing and computer simulations, we concluded that with current shielding, the principal source of excess radiation to the operator is above the patient between the table- and ceiling-mounted shield. This led us to develop a novel flexible multi-configuration X-ray shield (FMX) that would address shortcomings of existing devices. The new shielding device should be sufficiently large as to extend both cranially and caudally to the vascular access site for optimal shielding efficacy. It should adapt to different morphologies and procedure types, and allow for easy vascular access, both radial and femoral, with maintained shielding. To save waste and cost it should be reusable and thus, would need an additional single-use sterile plastic cover.

The first prototype was made from paper (figure 18, left panel). To allow for vascular access with maintained shielding both cranially and caudally to the access site, we added three flaps that could be selectively opened and closed. To adapt to different patient morphologies, the flaps were made asymmetrical with two smaller and one larger flap.

The next step was to manufacture a functional prototype, which we made from discarded 0.5mm lead equivalent rubber apron material. We noticed that the flaps were too floppy, and to increase stability we started to experiment with adding battens of different sizes, design, and configuration (figure 18, right panel).

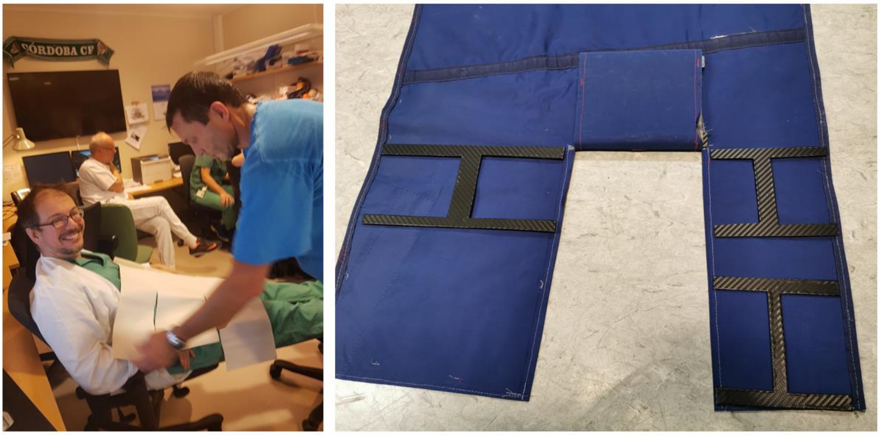


Figure 18: Early prototypes of the FMX. *The left panel is a picture of the three-flap configuration with a prototype made of paper. The right panel shows the first working prototype. To improve stability and ease of use, we experimented with a variety of battens in different configurations.*

The final FMX prototype (figure 19) was produced with commercially available 0.5 mm lead equivalent protective material which is CE-marked and conforms to IEC 61331-1:2014 standard on protective devices against diagnostic medical X-ray radiation (Scanflex Medical, Sweden). Battens were made of styrene acrylonitrile plastic and covered with a self-adhesive carbon fiber film then fastened with an extra strong polyester thread. Three battens were attached on the narrow flaps and two on the wide flap.

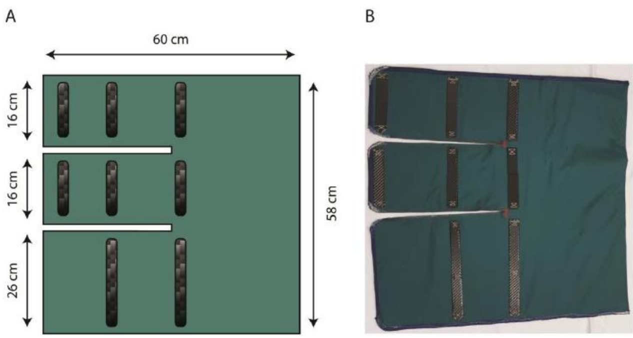


Figure 19. Final design of the FMX. *On the left is technical drawing of the FMX and on the right is one of the three fully functional prototypes used in the clinical trial (paper III)*

Figure 20 shows how the versatile design can adapt to different configurations and be used in cardiac catheterization, interventional radiology, or peripheral vascular interventions.

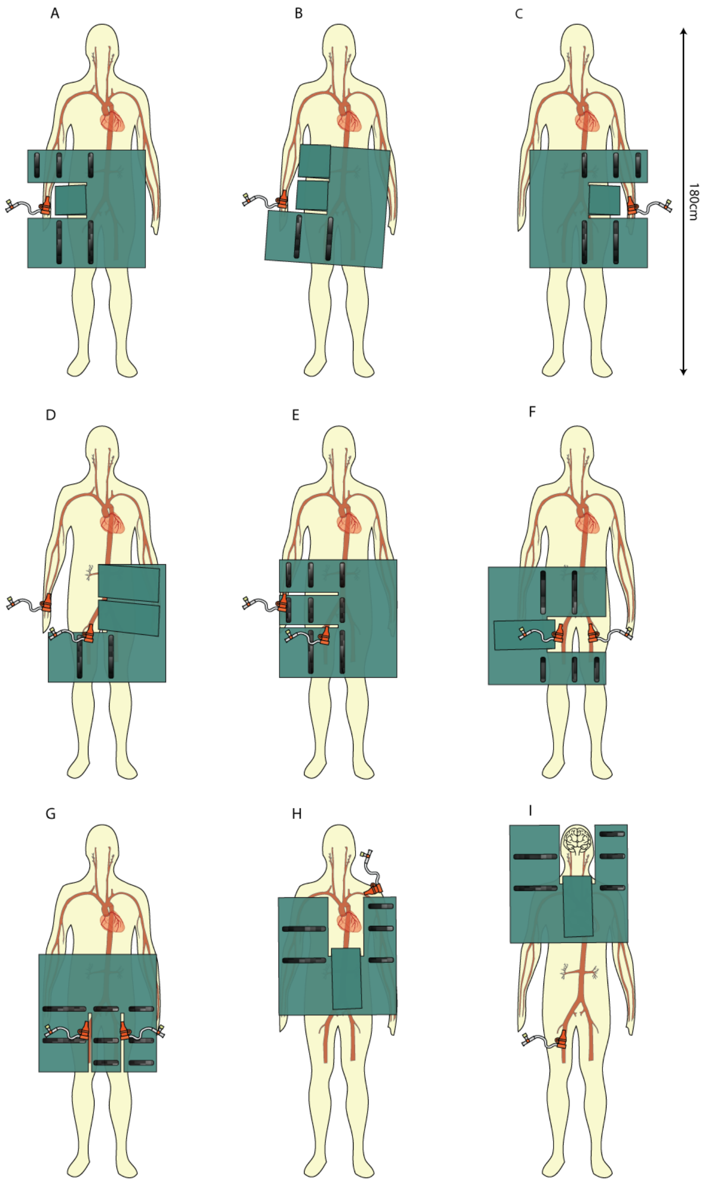


Figure 20: Versatile and flexible vascular access of the FMX. *The FMX is designed to be used in a broad range of X-ray guided procedures. The figure shows proposed positioning and flap configuration according to access site and procedure type: Right radial (A, B); left radial (C); right radial and femoral (D, E); bi-femoral (F); abdominal interventions (G); left subclavian (H); interventional neuroradiology (I).*

For the FMX to be repositionable during the procedure and allow the operator to open and close flaps, the FMX needed to be inside a sterile plastic cover. A commercially available low-density polyethylene bag with a thickness of 50 µm was modified in-house with additional welds to accommodate the flaps (Figure 21). Sterilization was done at the hospital's sterilization department using vaporized hydrogen peroxide.

Figure 21. Manufacturing a sterile plastic cover for the FMX. *In the left panel, an image of the welding machine used to produce the prototype of a plastic cover. The welds were checked for solidity and sealing with water (middle picture). To the right is the FMX with its plastic cover.*

3. Aims

- Assess temporal trends in patient and operator X-ray exposure between 2013 and mid 2019 at Haukeland University Hospital and the impact of upgrades in X-ray equipment and shielding, as well as operator awareness measures.

- Assess the effect of an optimized X-ray blanket in a controlled bench testing environment in a setup mirroring everyday practice.

- Assess the clinical shielding effect of the optimized X-ray blanket (Flexible Multi-configuration X-ray shield - FMX) in randomized controlled trial, and collect user feedback on function, relevance, and likelihood of adoption into clinical practice.

4. Summary of papers

4.1 Paper I

4.1.1 Aims

To assess temporal trends in patient and operator X-ray exposure between 2013 and mid 2019 at Haukeland University Hospital and the impact of upgrades in X-ray equipment and shielding, as well as operator awareness measures.

4.1.2 Materials and methods

Data regarding irradiation time, patient dose (DAP), and patient characteristics were extracted from the Norwegian Registry of Invasive Cardiology (NORIC) for procedures performed between the start of 2013 and mid-2019. Mandatory personal operator dosimetry records for all operators working in the cath lab were supplied by the Norwegian Radiation and Nuclear Safety Authority.

Figure 22. Illustration of a routine cardiac catheterization.

During the analyzed period, there were two lab upgrades (2016 and 2018). Live dosimetry became available in 2016 and all ceiling-suspended shields were upgraded the same year. Starting in 2018 an X-ray blanket placed on the patient was routinely used and some operators used an additional wheel-mounted side shield.

Patient dose (DAP) was analyzed in relation to lab upgrades, irradiation time and patient characteristics. To assess the effect of improved shielding and operator awareness on operator dose, relative operator dose (operator dose divided by patient dose) was calculated.

4.1.3 Results

Between the start of 2013 and June 2019, 21499 procedures were recorded at Haukeland University Hospital. During this period, mean DAP for coronary angiography decreased 37% from 2981 to 1891 $\mu Gy \cdot m^2$. ($p < 0.001$). For PCI, DAP decreased by 39% (from 8358 to 5055 μGy·m^2, figure 23). During the same period, an increase in mean patient weight was observed (+1.6 kg, $p < 0.001$), and there was a strong correlation between weight and DAP. ROD decreased by 56%.

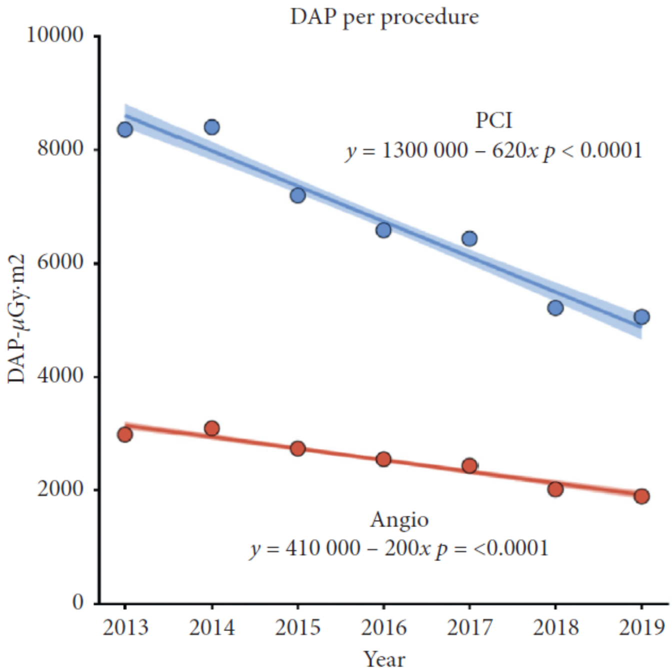


Figure 23. Mean dose area product (DAP) per procedure according to year. *Between 2013 and 2019 DAP per procedure decreased by 37% in coronary angiography and 39% in PCI. Figure adapted from paper I*[64].

4.1.4 Conclusion

In this study we found a temporal trend towards lower patient dose per procedure in coronary angiography and PCI. Upgraded X-ray equipment and imaging protocols as well as increased operator awareness are likely contributors to this trend. ROD decreased as well, demonstrating that operators received less radiation per given unit of DAP, which indicates better use of shielding and operator awareness.

4.2 Paper II

4.2.1 Aims

The aim of this article was to assess the effect of an optimized X-ray blanked (XRB) in a controlled bench testing environment with a setup mirroring everyday practice.

4.2.2 Materials and methods

RDSR data from 7681 cardiac catheterization procedures were analyzed to identify which C-arm projections are used in routine practice, and the amount of DAP given in each projection.

Using an anthropomorphic phantom and a high sensitivity scatter radiation detector, relative operator dose (ROD - operator dose divided by DAP) was measured at operator thyroid collar level for three shielding setups (no shielding, standard shielding, and standard shielding + XRB) in each angiographic projection. Standard shielding comprised a table- and ceiling-mounted shield.

Figure 24: Bench testing setup for measuring scatter radiation to the operator. *An anthropomorphic phantom was used to simulate the patient. The C-arm is in LAO-CRAN projection.*

Based on DAP given in each projection for a typical procedure (RDSR data) and the ROD measured in each projection in our experimental setup, annual operator dose was estimated for a typical operator performing 500 procedures/year. The relative contribution of each angiographic projection to operator dose according to shielding setup was also calculated.

4.2.3 Results

Adding the standard ceiling- and table-mounted protection reduces ROD in all projections. The reduction is smaller in left and cranial projections. As a consequence, in a routine cardiac catheterization where a standard shielding setup is used, an estimated 86% of operator dose comes from LAO-CRAN, LAO and CRAN projections. Adding an XRB reduces operator dose further and is more effective in the projections where the standard shielding setup offers less protection.

For an operator performing 500 procedures, the estimated annual operator dose would be 75.53 mSv with no shielding, 15.03 mSv with standard shielding and 0.77 mSv with standard shielding and XRB (figure 25).

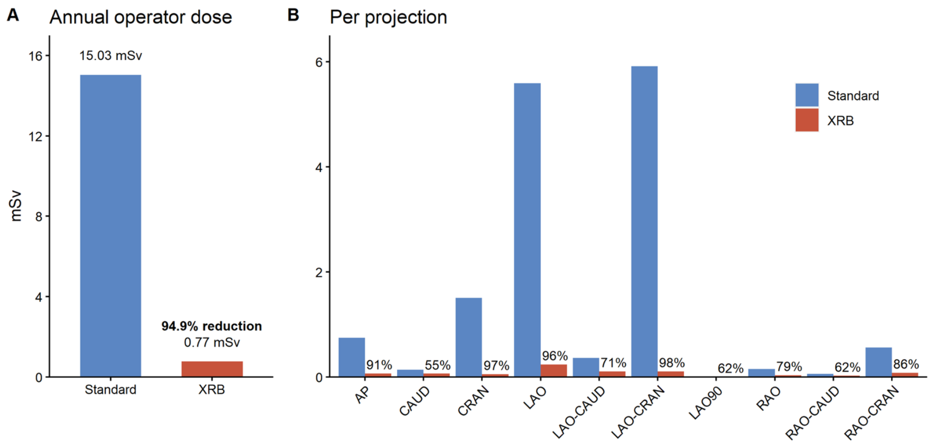


Figure 25: Annual operator dose estimates according to shielding setup for an annual caseload of 500 procedures. *A: Adding an X-ray blanket (XRB) to standard shielding resulted in a 94.9% reduction in annual operator dose. B: Annual operator dose per angiographic projections with and without and XRB. The percentage above the red columns represents percent reduction with an XRB. Figure adapted from paper II*[65]

4.2.4 Conclusion

The routinely encountered shielding setup with a table- and ceiling-mounted shield leaves unshielded areas at patient level. Adding an optimized XRB on the patient is a simple add-on shielding measure that has the potential to reduce operator dose by 94.9% and is especially effective in cranial and left projections where the table- and ceiling-mounted shield offers less protection.

4.3 Paper III

4.3.1 Aims

The aim of the study was to assess the clinical shielding effect of the optimized X-ray blanket (Flexible Multi-configuration X-ray shield - FMX) in randomized controlled trial, and collect user feedback on function, relevance, and likelihood of adoption into clinical practice.

4.3.2 Material and methods

Relative operator dose (operator dose indexed for given dose) was measured with a dosimeter attached to the thyroid collar in 103 consecutive procedures randomized in a 1:1 proportion to current routine setup or FMX + routine.

At the end of the study operators completed a survey with 11 questions regarding size, functionality, ease of use, likely to use, critical issues, shielding, draping, procedure time, vascular access, patient discomfort and risk. Each question had 3 grading options - *optimal*, *adequate* or *should be improved*.

4.3.3 Results

Median relative operator dose was 3.63μSv/μGy·$m^2 \times 10^{-3}$ (IQR 2.62,6.37) with routine setup and 0.57μSv/μGy·$m^2 \times 10^{-3}$ (IQR 0.27,1.06) with FMX + routine, which amounts to an 84.4% reduction ($p<0.001$). For an operator with an annual caseload of 500 procedures, estimated yearly dose would be 0.7mSv/year with FMX + routine. User feedback was 99% positive. All responded they would implement FMX in routine use if available. No critical issues were identified. There was no significant difference in patient radiation exposure.

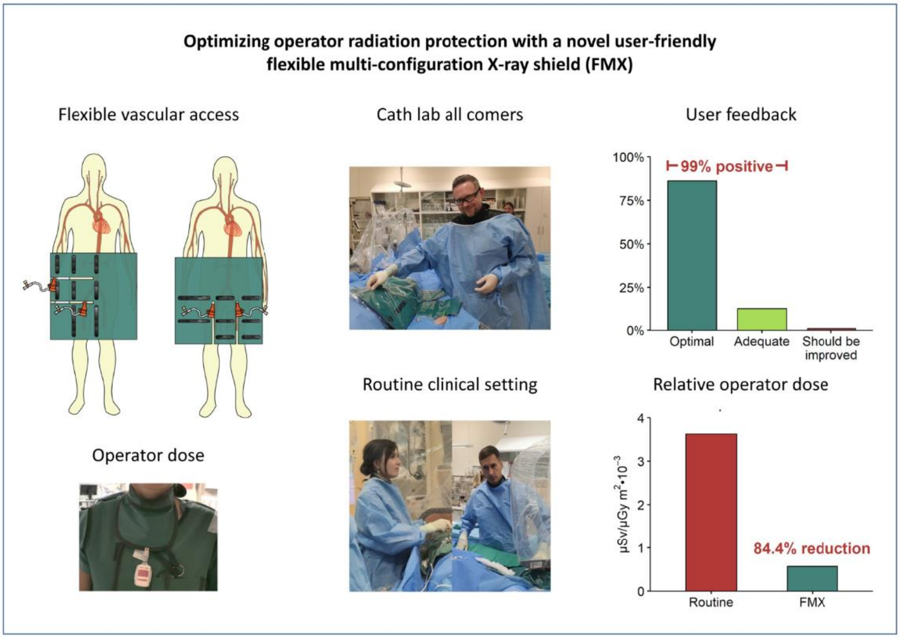


Figure 27. Graphical abstract from the clinical trial[65]. *Adding an FMX to routine shielding setup led to an 84.4% reduction in median operator dose. User feedback was 99% positive.*

4.3.4 Conclusion

In this randomized controlled trial, adding the FMX to a routine shielding setup with table- and ceiling-mounted shield reduced median relative operator dose by 84.4%. FMX for general routine use has potential to optimize radiation protection in the cath lab with minimal logistic and practical constraints and offers flexible visualization, access and shielding.

5. Ethical considerations

All research was conducted at Haukeland University Hospital and data were stored on the secure research server of Helse Vest (forskningsserveren) according to local guidelines.

The data protection officer (personvernombud) was consulted before the start of each of the articles and provided guidance on data minimization, and how to de-identify data prior to being stored on the research server.

5.1 Paper I

Retrospective analysis of existing registry data involves low risk as there is no impact on patient treatment. The major risks are related to incorrect data handling and storage which could lead to unauthorized access to data from individual procedures. This risk can be reduced by using de-identified and minimized data sets that only contain the relevant variables for the study as well as analyzing and storing data on a secure server. Prior to registry analysis, the Regional Committee for Medical and Health Research Ethics of Western Norway (REK Vest, application number 43193) was consulted and approved the study. As there was a large number of procedures (>20k) and analysis was limited to retrospective procedure data, REK Vest waived the need for informed patient consent.

5.2 Paper II

Bench testing was conducted on an anthropomorphic phantom and did not involve patients. Technical RDSR data from OpenREM was analyzed to create a reference of C-arm angulations used in clinical practice. REK Vest was consulted (application number 492676, *fremleggingsvurdering*) and concluded that since the project did not involve patient treatment nor clinical patient data apart from anonymized technical procedure data it did not need REK approval. The project was entered in the hospital electronic research registry (*eprotokoll* 3439-3439) and submitted to the data protection officer (*personvernombud*) who approved the study.

5.3 Paper III

For the randomized controlled study evaluating the effect of the FMX, REK Vest was consulted (application 395777, *fremleggingsvurdering*). Since the purpose of the study was to study operator exposure and did not modify patient treatment and involved negligeable patient risk, they concluded that it did not need REK approval but requested that it was submitted to the data protection officer for approval. The data protection officer approved the study (ref 2022/7305). As the study participants were the operators, they had to sign an informed consent form. The patients received oral information prior to the procedure. Data was stored de-identified with a separate identification key stored in a separate secure location.

6. Statistical considerations and sources of errors

All data collected was stored securely on the research server of Helse Vest (*forskningsserveren)* after appropriate data minimization and de-identification. Data analysis was performed in RStudio (RStudio: Integrated Development for R. RStudio, PBC, Boston, MA) using the R programming language for statistical computing and graphics (R Foundation for Statistical Computing, Vienna, Austria).

6.1 Paper I

6.1.1 Advantages of registry data

Registries have the advantage of being large data sets with real-life data from an all-comers population. In this regard, they are ideally suited for trend analysis, and with the large number of records, p-values tend to become highly significant.

6.1.2 Disadvantages and pitfalls of registry data

One of the major pitfalls of registries is related to how data are collected and the quality of the dataset. In NORIC, data are manually entered by the operators which introduces a risk of human error. In data science there is an expression "garbage in, garbage out" meaning that analysis of nonsense input data will yield nonsense results. As an example, in NORIC, the entry field for patient height patient weight are situated just beneath each other. If the operator inadvertently inverts height and weight for a person of 172cm and 83kg, the calculated body mass index would be 249.6 which introduces errors if included in the analysis. Sometimes the error is obvious, but it may be less evident such as if DAP and irradiation time are inadvertently inverted. Another possible error is if one number is lacking, for instance if the operator enters 298 µGy·m2 instead of 2981 µGy·m2. These errors are much harder to identify and correct. Missing data is also a concern. If the dataset is large and the missing data is random it may not affect analysis. However, if there is a pattern – if for instance one center or an operator systematically omits entering irradiation time, it may introduce significant bias.

6.1.3 Addressing sources of error in registry data

In our work on registry data from NORIC, a large part of data analysis was related to data cleaning and validation of data quality before analysis. We started by excluding extreme values (height <140 or >200 cm, weight <40 or >150 kg, DAP < 200 or >80.000 µGy·m2 and irradiation time <30 or >10800) as these values are likely to represent typing error or extreme procedures or patient morphology that do not represent the general trend. Records with extreme height, weight or body mass index were manually checked and corrected in case of apparent typing error. Finally, we created a filter of dose per second (<0.7 or >50 µGy·m2/s) to identify records with obvious mismatch between DAP and irradiation duration.

6.1.4 Missing data

In multiple linear regression, only complete records are included in the model and if a single variable is missing, the whole record is excluded from the analysis. Furthermore, for the calculation of ROD, we divided yearly dosimetry reading by given DAP. Excluding too many procedures would decrease the cumulative DAP and introduce an error. To circumvent this limitation and utilize the information from the entire dataset it is possible to use multiple imputations where an iterative series of predictive models is used to substitute the missing values. The complete data set can then be used for analysis. In our registry analysis we performed multiple imputations with the R-package MICE version 3.7.0 (Multivariate Imputation by Chained Equations in R).

6.1.5 Statistical analysis

Radiation data have a clear right-skewed distribution where some procedures have a longer irradiation time and higher DAP that can be related to procedure complexity. Non-parametric tests (Mann-Whitney U test and Kruskal-Wallis) were used to analyze the impact of lab upgrades on patient dose. Multiple linear regression was used to analyze temporal trends and correct for confounding variables.

6.2 Paper II

6.2.1 Positioning of the detector

During bench testing, the positioning of the X2 survey sensor was the most important source of variation between measurements. Scatter radiation intensity is inversely proportional to the distance to the source of radiation, and even minor changes in detector position led to a considerable variation in measured dose rate. The X2 detector is also directional. Changes in rotation should therefore also be avoided. Consequently, all precautionary measures were taken to be sure that the X2 scatter radiation detector would not move between measurement setups.

6.2.2 Sensor variability

Measured scatter radiation is proportional to the given dose and thus all measurements were normalized to given DAP read from the X-ray system. The measured quantity is thus dependent on both the precision of the DAP meter for the given dose and the X2 survey sensor for the recorded dose. In the setup used for our bench testing article[65] sensor variations depended on the intensity of scatter. In the *no shielding* setup where scatter radiation was higher, inter-measure standard deviation was +/-0.29%. In the *standard* shielding setup, which saw reductions ranging from 58 to 99% in relative operator dose dependent on projections compared to *no shielding,* standard deviation was +/- 1.51%. In the XRB setup, which saw another 55 to 97% reduction in relative operator dose, standard deviation was +/-4.02%.

To convey the inter-measurement variability of the experimental setup, we published all values in a scatter plot (figure 28) instead of calculating a multitude of p-values which would all have been significant due to the very small variation between measurements. This approach is concordance with a similar published reasearch[63].

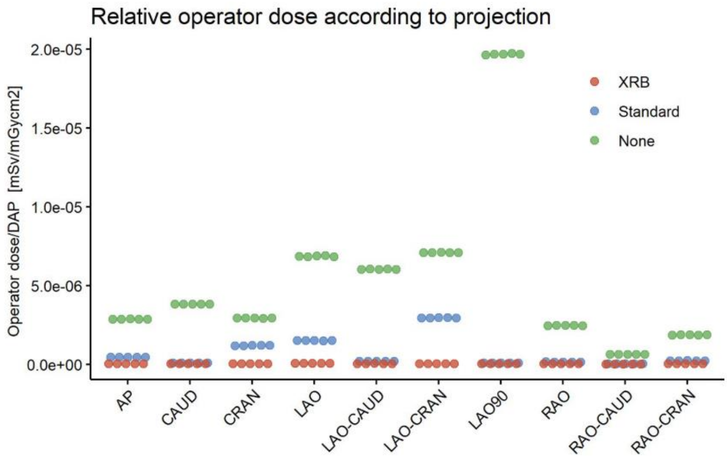


Figure 28: To illustrate inter-measurement variability of the experimental setup we published a scatterplot (bee swarm plot) of all data points. As can be seen the variation between measurements due to sensor variability was very small. Figure from article II[65]

6.2.3 RDSR and estimation of operator dose

We used RDSR data from real-life procedures to determine which projections are used and in what proportion. Combining this data with measurement of ROD in a bench testing setup allowed us to calculate to which extent each projection contributes to operator dose. Yearly operator exposure according to shielding setup could then be estimated by multiplying by annual caseload.

This approach is a significant improvement compared to previous similar research which have either focused only on patient dose[66], or operator dose per projection[63] without considering that not all projections are equally used in clinical practice.

6.3 Paper III

6.3.1 Sample size

For the prospective randomized study, the main statistical challenge was sample size calculation. For power analysis, an effect estimate is needed as well as standard deviation. Comparable recently published studies on X-ray blankets used median and interquartile range[56] and did not state the mean nor the standard deviation, and some pooled operator doses over a number of procedures[47, 57]. To properly estimate sample size, we performed a pre-study investigation based on 44 routine cardiac catheterizations in a comparable setup at the University Hospital in Liège, Belgium. In 23 out of 44 procedures, an additional generic non-sterile 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$\mu Sv/\mu Gy \cdot m^2 \times 10^{-3}$ (SE 0.48) with the pelvic shield which amounts to a 49.7% difference between groups. Pooled SD was 3.39 $\mu Sv/\mu Gy \cdot m2 \times 10^{-3}$. Based on ROD and SD from the prestudy, 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%.

6.3.2 Outliers and right-skewed distribution

From the pre-study pilot we knew that distribution of radiation data has a right-skewed distribution with some procedures yielding high operator dose. Thus, we used non-parametric Mann-Whitney U-test to assess differences in operator dose and change in median ROD as effect estimate. It should however be noted that in real-world practice, operators will regularly be exposed to extreme procedures that can be considered as outliers from a statistical point of view. The highest ROD was recorded during complex PCI of the right coronary artery where most of the procedure was done in left cranial projection. Although an outlier, this is not a very uncommon setting. Thus, using the median instead of the mean may omit the fact that outliers will occur regularly in everyday practice.

6.3.3 User feedback

User feedback was an important part of the clinical study. We collected both a formal 11-point questionnaire and informal feedback during inclusion. Only descriptive statistics were performed on the formal feedback as there was no control group against which to compare.

7. Discussion

Ionizing radiation have deleterious effects on human health and there is a need to protect workers and the public[1]. However, it is important to recognize that much of the knowledge on increased cancer risk following exposure to ionizing radiation is based on survivors from the atomic bomb during World War two[2, 67] who were exposed to large amounts of high-energy radiation in a short period of time. This is of course a different scenario from repeated exposure to low-intensity radiation. The ICRP recommends the use of a "Linear No Threshold model" in radiation protection work where even small doses of radiation are considered harmful[9]. In this model, cancer risk is linearly extrapolated, and small and large doses are considered proportionally equally deleterious on human health. The validity of the LNT model is however debated for exposures <100mSv[4].

Background radiation is estimated to be 2.4mSv/year [17] on world average but vary widely depending on location according to radon levels, altitude above sea level, and the presence of radioactive radioisotopes in natural materials such as rocks, soil, vegetation, and groundwater. Places with background radiation above 10 mSv/year are classified as high natural background radiation regions. Interestingly, evidence lacks for a clear link between living in these areas and an increased risk of cancer[68]. After the Chernobyl disaster in 1986, a 30km exclusion-zone was created around the nuclear reactor. Whereas the initial phase was characterized by very high dose rates and deleterious effects on surrounding life, the following years saw a surge in wildlife, including larger mammals, which seemed little affected by the increased levels of background radiation[69]. Thus, it is possible that organisms through evolution have developed adaptive mechanisms to cope with some level of variation in background radiation.

Hormesis is a term describing a beneficial effect arising from exposure to a very small amount of a toxic substance [70]. Radiation hormesis is the theory that small doses of radiation may trigger molecular cell responses that improve immune function, enhance cytogenetic protection, and may have a beneficial effect on the organism[71].

The debate is ongoing – is low-intensity radiation harmful, neutral, or even beneficial? More research is needed to determine if low-dose radiation is carcinogenic, and which level of annual exposure is acceptable.

However, until more data emerges on the topic, ICRP recommendations are considered best practice and should be followed[9]. These recommendations form the basis for European Directives[10] which are implemented through national legislation[12-14] and enforced through national radiation protection authorities.

The work presented here seeks to provide answers on how to reduce operator exposure to levels that can be considered safe. Reducing given dose is the first logical step and is beneficial both for the patient and operator. Operator dose can be further reduced by shielding, and we attempt to address shortcomings of existing shielding devices.

7.1 Registry data

Analysis of registry data can reliably assess changes over time, as well as compare cath labs and different hospitals. On a national and international level, registry data is invaluable to establish diagnostic reference levels, which in turn can and should be used as a benchmark against which a center can compare[39, 40, 72].

In the period leading up to this work, there were several upgrades in X-ray hardware, software, and shielding equipment at Haukeland University Hospital. Two of the three C-arm systems were upgraded (in 2016 and 2018) and the transparent lead-acrylic ceiling-suspended shields were replaced in all cath labs with a larger model with flaps on the lower end side (2016). In 2018, most operators started using an X-ray blanket in sterile draping placed on the patient.

To assess the impact of these upgrades, we analyzed a complete dataset of the 21499 procedures conducted at Haukeland University Hospital over a 7-year period documented in NORIC as well as operator dosimetry. This gave a unique insight into everyday practice, trends, and factors that influences patient dose[64]. We were able to document a trend towards older and heavier patients and confirmed that patient weight strongly correlates with higher given dose. Despite a trend towards heavier patients and no change in irradiation time, for each passing year, we observed a reduction in patient dose with a highly significant, almost 40% reduction in patient dose per procedure both for coronary angiography and PCI. We were also able to show that the newer X-ray equipment contributed significantly to lower patient doses. In line with our findings, Stocker *et al*. later published the results from a larger registry study including 3.7 million PCI procedures from 860 cardiac catheterization laboratories in Germany between 2008 and 2018. They reported a similar 36% decrease in patient dose[73]. Interestingly, they observed a large variation in median patient dose between cath labs suggesting that improvements can be made to flatten the difference in patient dose between centers.

In comparison, in our registry data, median DAP for PCI was 4017 µGy·m2 in 2019, which is slightly higher than median DAP in Germany in 2018 (3070). Nevertheless, our center is situated inside the interquartile range of at typical catheterization lab in Germany. Compared to the proposed European diagnostic reference levels, our center did not exceed the recommended exposure limits. In the final year monitored (2019), the mean DAP per procedure was 1891 for coronary angiography and 5055 µGy*m2 for PCI, compared to the proposed European DRL of 3500 and 8500 µGy*m2 for coronary angiography and PCI respectively[40].

RDSR data gives even more detailed information from each procedure and allows for comparison of specific settings and protocols. In our preliminary analysis we found that most operators used the default settings. Simply changing the default from 15 to 7.5FPS leads to an instant meaningful reduction in given dose. This stresses the point that X-ray systems should have sensible default settings. In this regard the after-sales services have a significant role to play in upgrading software and settings in older C-arm systems.

Taken together, the work presented in Paper I show the importance of gathering and analyzing real-world data to gain valuable insights into current practice and target areas of improvement. It is important to have national and international standards against which every cath lab should be compared.

7.2 Improving existing shielding devices.

In Paper I, we documented close to 40% reduction in given dose between 2013 and 2019 but a 70% reduction in operator dose, indicating that improved shielding and operator awareness can further reduce operator exposure.

It is well-known that lead equivalent shielding is highly effective at stopping diagnostic X-rays[41]. [51-53] Most cath labs have an array of table- and ceiling-mounted shields which can provide reasonable operator protection given they are used correctly and in all procedures. However, design is important to maximize efficacy and the table-mounted shield should be wide enough to protect both first and second operator. As illustrated in figure 29, it is easy to appreciate that an operator standing behind the table-mounted shield in panel A will be substantially less protected than an operator standing behind the protection in panel B.

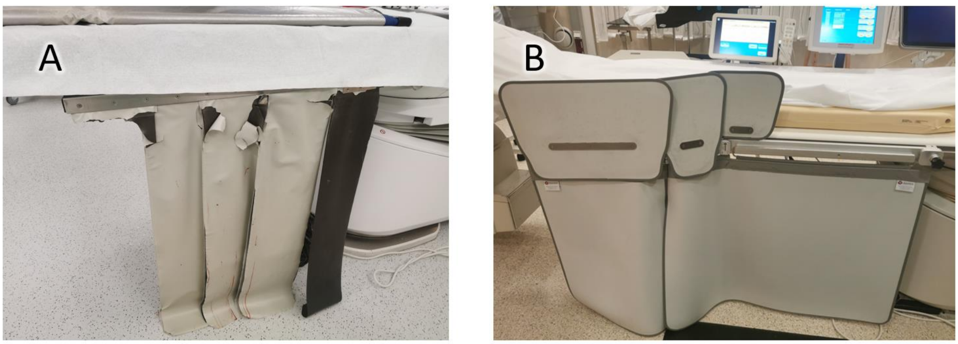


Figure 29. Different table-mounted shields. *In panel A an outdated defective model with flaps without top shields. In panel B a wide, continuous shield with three table flaps.*

Upgrading the table- and ceiling-mounted shields is easy, affordable and has no impact on cath lab logistics.

New comprehensive devices have been proposed and have shown promise in terms of protection of the operator[51-53]. However, high acquisition costs and clutteredness are major obstacles to widespread uptake. X-ray blankets as an add-on to existing shielding are available in different formats but existing models have their limitations. Whereas single-use XRB adds waste and cost, reusable XRB are either non-repositionable or simple designs inserted in a plastic bag with limited features for vascular access with maintained shielding. So far, in clinical testing, these devices have only shown a moderate and highly variable protection with reduction in operator dose ranging from 20-72% [47, 49, 56-60].

7.2.1 Pilot investigations

Live dosimeters give the operator instant feedback on the impact of shielding and positioning. The educational value of live dosimeters has been documented in several studies where their use was linked to a reduction in operator dose that was likely due to changes in operator behavior and better use of existing shielding[74-76]. In our preliminary investigations we noticed large differences in operator exposure after simple position change of the ceiling-suspended shield and this sparked investigations on positioning of shielding elements and the consequence of unshielded areas. In pilot bench testing, we showed the importance of achieving continuous shielding between the patient and operator, and either horizontal or vertical unshielded areas lead to similar large increases in operator exposure. These are seemingly evident observations but are still largely under-recognized by operators. Without shielding, we measured more scatter radiation below the table which is expected since the X-ray source is situated under the table. However, with the presence of table- and ceiling-mounted shield, the highest intensity of residual scatter radiation was on the upper part of the operator's trunk which is where the mandatory dosimeter is worn[8]. Investigative Monte Carlo simulations corroborated that the main source of residual scatter is from unshielded areas above the patient.

Based on these findings and clinical experience, we concluded that there is an unmet need for a user-friendly, easy-to use shielding device that would bridge the gap between routine shielding and the bulky and costly new devices[51-53]. The improved device should leave no unshielded areas between the patient and operator. Design should be versatile and adapt to different access points and procedures both in interventional cardiology and radiology with maintained shielding. It should be stable enough to not move during the procedure, but still be repositionable by the operator, and adapt to all projections without impeding the imaging area. In an acute setting, the system should be easily removable to immediately access the patient. To achieve general uptake, it should be safe for the patient and operator, reasonably priced, and easily integrated in existing workflow with minor impact on logistics and procedure time. To limit waste and cost, it should be reusable.

7.2.2 Bench validation

To improve shielding, we developed a novel FMX that would address the unshielded area above the patient. Its asymmetrical three-flaps design would make it versatile and allow for easy vascular access with maintained shielding. To assess its efficacy in a setting resembling as much as possible real-life cardiac catheterization, we used an anthropomorphic X-ray phantom in one of our cath labs.

It is well known that angiographic projections will influence patient and operator dose rate[63, 77], and should be included in bench testing. Steeper angulations of the C-arm will increase the amount of tissue situated between the X-ray source and detector and cause the X-ray system to increase current and voltage. In left projections, the under-table X-ray source is tilted towards the operator, leading to higher operator exposure, whereas in right projections, the X-ray source is further away. Kuon *et al* found that without shielding, LAO-CRAN and LAO-CAUD were associated with the highest operator dose[63] with an 18-fold increase in LAO 60º - Caudal 30º compared to AP projection. Although their work is highly relevant, they did not test the effect of shielding. Furthermore, they used a measurement point at a height of 100 cm which would be directly behind the table-mounted shield in a routine setup. Agarwal et al. published an observational study where they analyzed patient dose rate as a function of C-arm angulation[77]. Their findings corroborated that steep angulation was associated with higher patient dose but did not measure operator dose.

In the current work we wanted to evaluate the effect of shielding in different projections, but also incorporate information on to what extent each projection is used in everyday practice. Through analysis of RDSR data, we were able to show that left projections which are more irradiating to both patient and operator represented 45.6% of DAP compared to 27.9% in right projections. Additionally, we were able to show that the routinely encountered table- and ceiling-mounted shield are effective in caudal projections but less in left and cranial projections. Thus, left, and cranial projections were the main determinants of excess operator exposure in a routinely encountered shielding setup. We were then able to show that the FMX was particularly effective in these projections, with a measured 94.9% decrease in operator dose[65].

7.2.3 Validation in clinical use

Our bench testing showed that an optimally positioned X-ray blanket has the potential to reduce scatter radiation at operator thyroid collar level by 94.9%[65]. In comparison, previously published clinical studies evaluating the effect of X-ray blankets placed on the patient have only shown moderate effect ranging from 20-72% [47, 49, 56-60].

Measurements with live dosimeters done during routine cardiac catheterization procedures made us aware that shielding devices tend to move during the procedure which reduces shielding effect. Thus, it is likely that the difference in shielding efficacy between bench testing and the observed clinical effect in previous studies is related to residual unshielded areas during live procedures. This stresses the importance of clinical validation of shielding efficacy in a routine cardiac catheterization setting in a variety of procedures.

The novel design of the FMX aimed at improving operator shielding by increasing size for better coverage of unshielded areas, but also by proposing features for vascular access which would allow for protection cranially and caudally to the access site. When the flaps are closed around the vascular introducer it would provide added stability and reduce unintended movement during the procedures.

Right radial access was used in ≈90% of procedures in our clinical study which is in concordance with ESC guidelines which since 2015 recommends radial as the favored approach[78]. However patient and procedural constraints may impose the need for other access sites such as left radial femoral or even a combination of these. In the US, femoral approach is still much used, and in 2018 only ≈60% of coronary angiography and ≈50% of PCI were done by radial approach[79]. Thus, it is important that shielding devices are adapted to several access sites. Stability and continuity between shielding devices are essential, and shielding should be maintained regardless of patient morphology, access site, table- and c-arm position.

In our clinical study[80], we observed an 84.4% reduction in median operator dose. This is encouraging and shows that FMX is a step closer to bridging the gap between bench and clinical efficacy and has a potential to significantly improve operator protection compared to available devices. In this regard, data on efficacy is important to motivate operators, not only to ensure uptake, but ensure continuous adherence in the long run.

7.2.4 Patient considerations

Improving operator protection should not be detrimental to patients. In this regard it should be mentioned that historically, it was common practice to cover the patient with lead shields to protect the patient from radiation. However, with better understanding of X-ray physics, patient shielding is no longer considered useful and has largely been abandoned[81]. The reason is that shielding in the field of view (inside the primary beam) will introduce a radio-opaque structure causing the X-ray system to increase current and voltage thus increasing patient dose. Shielding outside the field of view will not influence the given dose, but since scatter radiation in the patient is mostly internal, external shielding is ineffective. Furthermore, there is a possibility of backscattering from the X-ray blanket. In this regard one clinical study found an increase in radiation to a dosimeter placed on the patient umbilicus directly beneath the X-ray blanket, but no change in given dose assessed by DAP or Air Kerma [45]. In our clinical study, we did not find any difference in the given dose upon FMX use. To investigate and quantify the phenomenon of backscatter, we conducted pilot investigations where we attached a bi-directional DAP-meter to an anthropomorphic phantom. We found a small, non-significant 1% increase in scatter radiation below the X-ray blanket. Thus, as long as the X-ray shield stays out of the primary beam, improved operator shielding should not pose a risk to the patient.

7.2.5 Operator considerations

Whereas we have shown that it is possible to reduce operator exposure significantly with the novel FMX, it will only be truly effective if used in all procedures.

Reducing operator exposure has two sides. On the one hand, it is desirable to improve current shielding devices and make them more user-friendly. On the other hand, it is equally important to convince operators that shielding is necessary and effective. In that regard, it has been shown that operators regularly omit the use of already available shielding [61]. In poorly motivated operators, proposing even more shielding may not result in the desired effect. Operator awareness campaigns and continuous education programs may help educate operators and clinical data on efficacy is important to motivate operator uptake and adherence. It is also important that a new shielding device is not perceived to hamper patient access, cath lab logistics or add unnecessary procedure time.

Psychological aspects are important as well and support from key opinion leaders may increase interest and attractiveness of operator shielding. Operators are first and foremost physicians, but they are also susceptible to general marketing principles. *Brand coolness* is a concept used in marketing and related to the perceived characteristics; extraordinary, aesthetically appealing, energetic, high status, rebellious, original, authentic, subcultural, iconic, and popular[82]. If the new device is perceived as cool this will increase the likelihood of uptake. Figure 30 shows an example of a logo and slogan for the FMX.

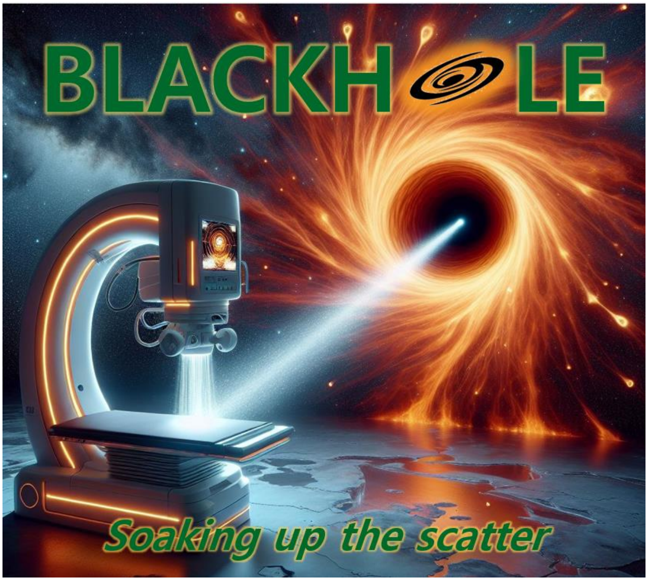


Figure 30. Proposed marketing name and slogan for the FMX. *The illustration shows one of the more creative marketing ideas that was conceived during the design process to increase attractiveness of the FMX and promote clinical use (AI-generated image using Bing Image Creator).*

To address these critical operator dependent issues, there was a strong focus on user feedback and validation both during the design, prototyping, and clinical testing to optimize design and identify elements that could represent an obstacle to general uptake. In our randomized controlled trial, both structured and more informal feedback was overwhelmingly positive, with no critical design issues, and minimal impact on procedure logistics.

7.3 Operator health concerns

The ICRP recommends using the LNT threshold model[9] in radiation protection work. In this model, any radiation may be harmful and should be kept as low as reasonably achievable. Although the validity of the LNT threshold model is still debated regarding cancer risk for low-dose radiation, with current knowledge, it seems prudent to follow the widely accepted recommendations from the ICRP. Furthermore, cancer is not the only health concern related to radiation.

The deterministic effects for developing cataract have been estimated to occur after an accumulated dose of 500mSv[15]. Thus, for an operator at, or close to, the annual dose limit of 20mSv, the deterministic dose for cataract could theoretically be reached after 25 years of practice.

Extremities are considered less radiosensitive than internal organs but are closer to the radiation source and may intentionally or inadvertently enter the primary beam. Chronic radiation dermatitis has been described amongst operators and hair loss is neither insignificant nor desirable[35].

Prolonged and repeated use of heavy PPE is a source of spine, knee, and hip problems[31, 36], which have an impact on quality of life, sick leave and may represent an obstacle to recruitment. It is desirable to reduce the use of PPE or at least, to use lighter PPE. Our work has focused on improving shielding that is not worn by the operator. In this regard we show that a conventional protective setup with the addition of an FMX can significantly reduce operator exposure without increasing the weight on the operator. Although it would need further validation in a multicenter trial with several measurement points, it shows that there is a possibility that operators in the future can use less PPE.

A recent (2023) consensus statement from European Association of Percutaneous Cardiovascular Interventions on radiation protection for healthcare professionals working in catheterization laboratories during pregnancy seems to indicate that when adequate measures are taken, the risk for the fetus is low[83]. An exposure of the fetus to 1mSv excess radiation could increase the risk of spontaneous congenital malformation from 4% to 4.002%, and the risk of developing childhood cancer from 0.07% to 0.079%. Although the absolute risk increase is small, all measures should be taken to reduce fetal doses as much as possible. Our estimations both in bench testing and in clinical trials indicate that it is possible to lower operator dose to close or event below 1mSv/year outside the protective lead aprons[64, 65]. Since the lead aprons attenuate an additional >90% of scatter radiation[41] it should be possible to bring the dose to the fetus well below 1mSv.

7.3.1 Perceived concerns

Beyond the physical burden of working in an environment with ionizing radiation, the psychological impact should not be underestimated. Staff not only need to be below reglementary dose limits – they need to feel safe and that they are not at risk of developing long-term health problems due to their work conditions. The linear no-threshold model stipulates that any exposure may be harmful. In this regard it may be difficult for operators to accept an exposure of up to 20mSv/year which is an eightfold increase compared to background radiation. More strikingly, the annual limit for the extremities is 500mSv which corresponds to a 208-fold increase in background radiation. Previously estimated "safe" doses of 150 mSv/year to the eye lens was changed to 20mSv/year in 2011 after new data emerged indicating it was more radiosensitive than previously thought[15]. How can the operators be sure that the current recommended dose limits will not be revised in the future?

Women of childbearing age are of special concerns as interventional cardiology to date remains a largely male-dominated specialty, and perceived health risk of radiation exposure may act as a barrier for recruitment and has been cited as a reason to choose a different career path[37]. ICRP recommendations[9] and EU directives[10] do not prohibit pregnant operators to work in the cath lab, as long as the dose to the fetus is <1mSv for the remainder of the pregnancy. However, in some EU member states, national legislation has not been updated and there is still limited access to the catheterization lab during pregnancy[83]. Furthermore, although the estimated risk for the fetus is low[83], this does not mean future mothers feel safe or wish to work in an environment where they are repeatedly exposed to ionizing radiation. These concerns are of course not attenuated by the fact that some countries still restrict access to the cath lab for pregnant operators.

Thus, there is a need to not only reduce operator exposure to levels which are safe according to current knowledge, but to levels that feel safe for the operators.

It is necessary to develop new devices that are not only effective, but easy to use in all procedures. They need to be rigorously investigated through dosimeter measurements during live procedures, but also computer simulations to validate shielding efficacy and alleviate operator concerns.

8. Conclusion

Improving operator X-ray protection is important to reduce long-term health risk of working in the cath lab and alleviate operator concerns. Modern X-ray equipment with optimized imaging protocols reduces both patient and operator exposure. Shielding is effective at stopping X-rays, but unshielded areas expose the operator to significant excess radiation.

Adding the FMX to the routinely encountered shielding setup with a table- and ceiling mounted shield is a user-friendly, low-tech, and low-cost device that has the potential to effectively eliminate openings between shielding devices and further reduce operator dose.

Operator awareness, education and motivation are important to ensure correct usage and adherence to radiation protection measures.

9. Future perspectives

The focus of our research has been on interventional cardiologists performing coronary angiography and percutaneous coronary intervention. Although this represents most cardiac catheterization, there are a multitude of other fluoroscopy guided procedures, both in cardiology and in interventional radiology.

Structural heart interventions are typically done by femoral approach, and the FMX could be directly investigated and validated in this setting.

Pacemaker implantation is another procedure with its own singularities as the operator must be close to the left chest of the patient where the routinely used table- and ceiling- mounted shields are not at all adapted.

There are also other staff members, especially during structural interventions where there is both an anesthesiologist and a sonographer present during fluoroscopy. How to best protect these staff members should be investigated and could be the object of future research.

Using lighter PPE or even shedding PPE would be a gamechanger in interventional cardiology to ensure a long career and avoid orthopedic problems. In our clinical trial, we show that it is possible to approach radiation levels at thyroid collar where lead may not be needed. It would be interesting to conduct a larger multi-center study with several measurements points on the operator to confirm the finding of the current research.

Monte Carlo simulations can be used to simulate dose distribution both on the operator and the patient and investigate different shielding devices. Creating an easy-to use open-source simulation framework of a cath lab which could be used by researchers from all over the world would contribute to better understanding of radiation risk for the patient and operator. It could fuel the development of better shielding devices, and better estimate fetal risk in pregnant operators and patients.

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Review Article

Temporal Trends in X-Ray Exposure during Coronary Angiography and Percutaneous Coronary Intervention

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Background. Percutaneous coronary intervention exposes patient and staff to ionizing radiation. Although staff only receive a small fraction of patient dose through scatter radiation, there are concerns about the potential health effects of repeated exposure. Minimizing both patient and occupational exposure is needed. *Objective*. This article investigates patient and operator X-ray exposure over time in coronary intervention in relation to upgraded X-ray equipment, improved shielding, and enhanced operator awareness. *Materials and Methods*. Data regarding irradiation time, patient dose, and patient characteristics were extracted from the Norwegian Registry for Invasive Cardiology (NORIC) for procedures performed from 2013 to mid-2019. Personal operator dosimetry records were provided by the Norwegian Radiation and Nuclear Safety Authority. Improved operator shielding and awareness measures were introduced in 2018. *Results*. In the period 2013 through June 2019, 21499 procedures were recorded in our institution. Mean dose area product (DAP) for coronary angiography decreased 37% from 2981 μGy·m^2 in 2013 to 1891 μGy·m^2 in 2019 ($p < 0.001$). For coronary intervention, DAP decreased 39% from 8358 μGy·m^2 to 5055 μGy·m^2. Personal dosimetry data indicate a 70% reduction in operator dose per procedure in 2019 compared to 2013. The most pronounced reduction occurred after improved radiation protection measures were implemented in 2018 (−48%). *Conclusions*. This study shows a temporal trend towards considerable reduction in X-ray doses received by the patient and operator during cardiac catheterization. Upgraded X-ray equipment, improved shielding, and enhanced operator awareness are likely contributors to this development.

1. Introduction

Each year, approximately 450,000 percutaneous coronary intervention procedures are performed in the United States [1]. During these procedures, the acquisition of X-ray images exposes patient and staff to ionizing radiation. The potential harmful effects can be divided in two categories. Deterministic effects occur at a certain threshold of absorbed dose such as skin erythema, cataract, or epilation. Stochastic effects are random effects due to radiation-induced DNA damage that may increase the lifetime risk of developing malignancies. Most data on stochastic effects are derived from survivors from the Hiroshima bomb where high exposures lead to increased risk of cancer [2]. Although the effect of low-dose radiation is still debated [3, 4], there are growing concerns among interventional cardiologists about the potential harmful health impact of long-term exposure to scatter radiation [5–9]. The International Commission on Radiation Protection recommends that X-ray exposure should be kept as low as reasonably achievable with recommended dose limits of <20 millisievert (mSv) effective dose per year for staff working in the cardiac catheterization lab (cath lab) [10]. For comparison, the global average natural background radiation exposure is 2.4 mSv/year [11], and a CT-scan typically exposes a patient to effective doses in the magnitude of 1–10 mSv [12].

During coronary angiography and percutaneous coronary intervention (PCI), staff wear a personal dosimetry badge, which measures exposure to scatter radiation. Operator dose is proportional to patient dose, which decreases with the square of the distance from the radiation source and can be further effectively reduced by shielding. Shielding equivalent to 0.5 mm lead (Pb) reduces the transmitted scatter radiation by >90% [13]. A combination of table- and ceiling-mounted shields are used to reduce staff exposure. They are, however, bulky and cumbersome, and gaps between the different shielding components tend to appear during the procedure when the operator is shifting table position, height, and angle of C-arm. Thus, operator awareness is crucial for optimal use. In addition, staff exposed to >1 mSv year are required to wear lead aprons. These, however, do not protect the extremities and are heavy, uncomfortable, and can lead to orthopedic problems [5].

Patient effective dose is determined by several factors, and hence more complex to quantify. Some factors are easily quantifiable, such as patient weight and exposure time. Others vary during the procedure—irradiation field size, pulse rate, collimation, and angle of the X-ray tube. As effective dose is not directly available with existing equipment, the dose area product (DAP) is most frequently used to document patient exposure. DAP is the product of dose expressed in gray multiplied by the area irradiated. Common units are microgray meters squared (μGy·m^2) and gray centimeters squared (Gy·cm^2). An estimate of patient effective dose in mSv can also be calculated by multiplying DAP with a conversion factor [14].

In this study, we aimed to investigate patient and operator X-ray exposure over time in coronary intervention in relation to upgraded X-ray equipment, improved shielding, and enhanced operator awareness.

2. Materials and Methods

The study uses registry data in retrospective exploratory analyses of patient and operator radiation exposure during coronary angiography and PCI. Our data are limited to procedures performed in three full-time cardiac cath labs at Haukeland University Hospital, Norway, from January 2013 to June 2019. The Norwegian Registry for Invasive Cardiology (NORIC), which records nearly every coronary procedure performed in Norway, provided data on patient characteristics and procedural details such as DAP, irradiation time, and operator. The study was approved by the local ethics committee prior to data extraction and analysis.

The Norwegian Radiation and Nuclear Safety Authority provides a personal dosimetry subscription service including personal thermoluminescent dosimeter badges, which record both H10 and H0.07 (dose equivalent to the soft tissue at depths of 10 mm and 0.07 mm, respectively). The badges are worn by all cath lab staff and returned for dosimetry readings every two months. These readings were used to assess occupational exposure. Operator dose in this article refers to H10 measurements of the operators. Dosimetry data from nurses working in the cath labs were not included in the analysis since NORIC does not document which nurses are present during the procedures.

Between 2013 and 2019, two of the three cath labs were upgraded with new C-arms, and improved shielding measures were introduced. In January 2016, a Siemens Axiom Artis dFC from 2005 was replaced with a new Siemens Artis Q. In September 2018, a biplane Siemens Axiom Artis dBC from 2006 was upgraded to a Philips Azurion7 B12/12 biplane. The third cath lab, a Philips Allura Xper FD10 C, installed in October 2009, did not undergo any upgrades. Additionally, the transparent ceiling-mounted protective shields in all three cath labs were replaced with larger panels with lead curtains on the lower side in 2016. The same year, real-time dosimetry (Philips DoseAware®) was installed, providing instant feedback on radiation exposure during the procedures. In 2018, a program to increase awareness on radiation protection with focus on the importance of operator shielding [15, 16] was initiated. This led to the introduction of routine use of a 40 × 75 cm pelvic lead shield being placed directly adjacent to the ceiling arm mounted transparent shield. In large patients or complex procedures, an additional wheel-mounted side screen was used at operator's discretion. Real-time dosimetry measurements performed during clinical cases to validate the approach-suggested substantial benefit, and improved shielding was generally implemented by staff.

Statistical analyses were performed in RStudio: integrated development for *R* version 1.1.456 (RStudio, Inc., Boston, MA). Graphics were produced with the ggplot2 package 2.2.1. Between-group differences were evaluated using Student's *t*-test for continuous variables and the chi square test/Fisher's exact test for categorical variables. Temporal trends were evaluated with linear regression for continuous variables and logistic regression for categorical variables. Impact of C-arm upgrade was analyzed with the Kruskal–Wallis test by ranks (one-way ANOVA on ranks), followed by the Wilcoxon–Mann–Whitney test for pairwise comparison for each lab before and after upgrade. The associations between observed patient DAP and irradiation time, patient weight, time elapsed from start of study, upgrades of the X-ray equipment, and whether PCI or angiography was performed were evaluated using multiple linear regression.

2.1. Missing Data and Data Cleaning. Data on patient sex and age are automatically derived and calculated in NORIC based on information in the national identity number and the date of procedure. Height, weight, irradiation time, and DAP are manually entered in the registry. 1.3% of patient weight and 2.3% of patient height values were missing. Extreme values (height <140 and >200 cm and weight <40 and >150 kg) were manually checked and corrected in case of apparent typing error. For the analysis of irradiation time and DAP, only complete cases that included both variables were included. Extreme values (DAP < 200 or >80.000 μGy·m^2 and irradiation time <30 or >10800 s) were excluded as they most probably represent input error or extreme procedures that do not represent the general trend. An additional filter on dose per second (<0.7 or >50 μGy·m^2/s) was added to exclude observations with mismatch between dose and irradiation time as these most probably represent input error. A total of 3.7% of irradiation time and DAP values were excluded from primary analysis. For the analysis of the ratio between yearly operator dose in mSv and patient DAP, a complete dataset was required, and missing DAP values were imputed using the MICE package version 3.7.0 (Multivariate Imputation by Chained Equations in R). Five imputed datasets were created using predictive mean matching. Mean DAP per procedure was estimated in each imputed dataset separately and then combined using Rubin's rules.

3. Results

3.1. Patient Characteristics. In the total material, 70.5% of the patients were male. The proportion did not change significantly from 2013 to 2019. Mean patient age was 66.8 years, and females were on average 4.3 years older than males (65.6 vs 69.9 years, $p < 0.001$). From 2013 to 2019, mean age increased with 1.2 years ($p < 0.001$). Age increase was slightly larger for men (1.5 years) than women (0.7 years). Mean (median) body mass index (BMI) for all patients was 27.2 (26.7) and higher in men (27.5) than in women (26.6, $p < 0.001$). From 2013 to 2019, mean BMI increased from 27.0 to 27.4 ($p < 0.001$), mostly driven by a BMI increase in men (+0.6, $p < 0.001$), whereas there was no significant change in female BMI. A complete list of patient characteristics is available in Table 1.

3.2. Procedural Characteristics. A total of 21499 procedures were recorded in NORIC from 2013 to June 2019. 54% of procedures were diagnostic coronary angiography and 46% PCI. Between 2013 and 2019, the proportion of PCI increased from 41.7% to 47.9% ($p < 0.001$). Mean DAP was higher in PCI than in coronary angiography (6793 vs 2574 μGy·m^2, $p < 0.001$) and decreased in both groups (−39% and −37%, respectively, Table 2, Figure 1(a)). Mean irradiation time was longer in PCI (1217 vs 373 seconds, $p < 0.001$) and decreased for coronary angiography (−9%) but not for PCI (Table 2, Figure 1(b)). The ratio of DAP divided by irradiation time was calculated to evaluate trends in patient exposure corrected for changes in irradiation time per procedure and decreased both for coronary angiography (−30%) and PCI (−39%)

3.3. Influence of Weight and Age on Irradiation Time and Patient Dose (DAP). Increased patient weight was correlated to higher DAP per procedure (Figure 2(a)). In patients weighing 50–60 kg, mean DAP was 1189 μGy·m^2 in angiography and 3722 μGy·m^2 in PCI. In patients 100–110 kg, mean DAP was to 4061 μGy·m^2 in angiography and 9915 μGy·m^2 in PCI. Patient weight had only a minor effect on irradiation time (Figure 2(b)). There was a small trend towards increased irradiation time with increasing patient weight in coronary angiography, but no such trend was present in PCI.

Patient age impacted irradiation time, and older patients had a trend towards longer procedures (supplementary Figure 1(a)). In patients aged 50–55 years, mean irradiation time was 5 minutes (*m*) 24 seconds (*s*) in angiography and 17 m 36 s in PCI. In patients aged 80–85 years, mean irradiation time increased to 7 m 18 s in angiography (+35%) and 22 m13 s (+26%) in PCI. Despite increasing irradiation time with increasing patient age, there was no trend towards higher DAP per procedure in older patients (supplementary Figure 1(b)). This may be explained by lower patient weight (supplementary Figure 1(c)) in both older males and females, as well as a larger proportion of female patients as patient age increases (supplementary Figure 1(d)).

3.4. Impact of the C-Arm Model on Patient Dose (DAP). Between 2013 and 2019, two out of three cath labs were upgraded. There was significant variation in DAP per procedure between cath labs. Newer labs had on average lower doses both for angiography and PCI (Figure 3, supplementary Table 1). In January 2016, a Siemens Axiom Artis dFC monoplane from 2005 was replaced with a Siemens Artis Q, which leads to a decrease in mean DAP of 40% for angiography from 3333 (median 2630) μGy·m^2 to 1978 (median 1553) μGy·m^2 ($p < 0.001$). In September 2018, a Siemens Axiom Artis dBC biplane from 2006 was upgraded to a Philips Azurion 7 Biplane, and the mean DAP for angiography was reduced with 50% from 3303 μGy·m^2 (median 2294) to 1650 μGy·m^2 (median 1230, $p < 0.001$). Similar decreases were observed for PCI.

3.5. Multivariable Analysis of Factors Influencing Patient Dose (DAP). A multivariable linear regression model was created evaluating patient DAP as function of days elapsed since 1st January 2013, procedure type (angiography or PCI), patient weight, irradiation time, and upgrade of two of the cath labs (categorical variable as before/after upgrade of the cath labs). The linear regression equation retained significance for all tested variables with adjusted R-squared 0.6239, and p value for the model <0.001. The model indicates that patient weight, irradiation time, lab upgrade, and whether PCI was performed are all independent variables influencing patient DAP. Furthermore, time elapsed from 2013 was an independent factor for reduction in patient DAP, suggesting that other factors not included in the model contributed to reduction in patient exposure as time progressed. The complete values are available as supplementary Table 2.

3.6. Relationship between Improved Operator Shielding Measures and Operator Dose. A total of 14 operators were active during the analyzed period, including fellows. As data collection ended in June 2019, data for the whole of 2019 were extrapolated.

Mean yearly operator dose decreased from 7.5 mSv (range 1.7–20.3) to 2.6 mSv (range 0–5.7) from 2013 to 2019 (supplementary Table 3). To correct for case load and

Table 1: Patient characteristics.

	2013	2014	2015	2016	2017	2018	2019	Change 13–19	P value
Age in years, mean (median)	66.5 (67)	66.2 (67)	66.7 (68)	66.9 (68)	67.1 (68)	67.4 (69)	67.7 (69)	1.2	0.001
Weight in kg, mean (median)	81.7 (80)	82.3 (81)	81.8 (80)	83 (82)	82.4 (81)	82.6 (82)	83.3 (83)	1.6	<0.001
BMI, mean (median)	27 (26.4)	27.1 (26.6)	27 (26.6)	27.4 (26.7)	27.3 (26.8)	27.3 (26.8)	27.4 (27.1)	0.4	<0.001
Male sex	69.1%	71.3%	69.7%	71.4%	69.8%	70.4%	73.5%	4.4%	NS
Male age in years, mean (median)	65.2 (66)	65 (66)	65.4 (66)	65.7 (67)	65.8 (67)	66.2 (67)	66.7 (68)	1.5	0.002
Female age in year, mean (median)	69.6 (70)	69.3 (70)	69.7 (71)	69.9 (71)	70 (71)	70.5 (72)	70.3 (72)	0.7	0.02
Male weight in kg, mean (median)	86.3 (85)	86.6 (85)	86.6 (85)	87.2 (85)	87 (85)	87.2 (85)	87.7 (86)	1.4	0.003
Female weight in kg, mean (median)	71.2 (70)	71.6 (70)	70.6 (69)	72.5 (71)	71.9 (70)	71.4 (70)	71.4 (70)	0.2	NS
Male height in cm, mean (median)	177.9 (178)	177.8 (178)	177.6 (178)	177.8 (178)	177.7 (178)	177.7 (178)	178 (178)	0.1	NS
Female height in cm, mean (median)	164 (164)	164.2 (164)	164.3 (164)	164.2 (164)	163.6 (164)	163.9 (164)	163.8 (164)	−0.2	NS
Male BMI, mean (median)	27.2 (26.8)	27.4 (26.8)	27.4 (27)	27.5 (26.9)	27.5 (26.9)	27.6 (27.1)	27.7 (27.4)	0.5	<0.001
Female BMI, (median)	26.5 (25.6)	26.5 (26)	26.2 (25.7)	26.9 (26.2)	26.8 (26.3)	26.6 (26.1)	26.6 (25.8)	0.1	NS

P values calculated with linear regression for continuous variables and logistic regression for categorical variables with year elapsed as independent variable. BMI = body mass index; kg = kilogram.

number of operators, the sum of all dosimeter readings of both consultants and fellows was calculated and divided by the total number of procedures performed in the cath lab within each year. The calculated operator dose per procedure showed a 70% reduction from 0.0227 mSv/procedure in 2013 to 0.00685 mSv/procedure in 2019 ($p = 0.004$, Table 2). The largest yearly change was observed between 2017 and 2018 (−48%) and coincided with the introduction of improved operator shielding measures (Figure 4). To further investigate the effect of shielding, the ratio between received operator dose (mSv) and patient dose (DAP) was calculated. Figure 5(a) illustrates the pooled ratio for all operators active in the cath lab including fellows. Between 2013 and 2019, the ratio of operator dose divided by given DAP went from 4.48×10^{-6} to 1.98×10^{-6} mSv/μGy·m^2, which corresponds to a 56% reduction ($p = 0.02$). All operators had reduced dosimetry readings per year during the period, but there was a large interoperator variability. In Figure 5(b), the yearly mSv/DAP ratio was calculated separately for the consultants that were active throughout the investigated period in order to illustrate individual changes over time.

4. Discussion

Our data show a strong decrease in patient and operator exposure during cardiac catheterization between 2013 and 2019. This finding is likely due to a combination of different factors including new X-ray technology, better operator shielding, and increased awareness.

4.1. Patient Characteristics. Our large dataset that covers 21499 procedures performed in our cath lab between 2013 and 2019 shows a trend towards an older, slightly overweight population. The majority of the patients in our data were men that were on average younger than female patients and reflect the known epidemiology of ischemic coronary heart disease [17].

4.2. Procedural Characteristics. Between 2013 and 2019, there was a large reduction in patient DAP per procedure, whereas there was only a minor reduction in irradiation time per procedure. Thus, other factors than procedure time such as improved X-ray technologies are likely to explain the observed reduction in DAP per procedure.

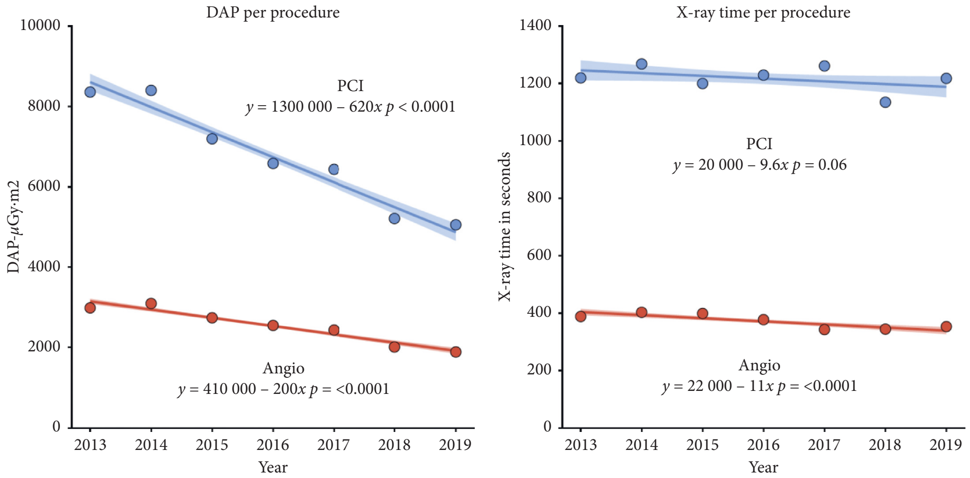
4.3. Influence of Weight and Age on Irradiation Time and Patient Dose (DAP). Increased patient weight was correlated to increased patient dose, and doubling of patient weight lead to roughly a three-fold increase in DAP. In the future, the interventional cardiologist is more likely to encounter overweight patients, stressing the importance of better X-ray technology and shielding. Older age was associated with longer irradiation time per procedure, which probably reflects more challenging anatomy and heavily calcified lesions as patient age increases. There was, however, no trend towards increased DAP. The explanation for this is that there is a trend towards lower body weight both in males and females with increasing age. Also, there is a larger proportion of female patients in the older age groups, and females have on average a lower body weight than men.

4.4. Impact of the C-Arm Model on Patient Dose (DAP). X-ray technology is evolving. In the X-ray tube, development of powerful flat emitters that replace conventional helical

Table 2: Procedural characteristics.

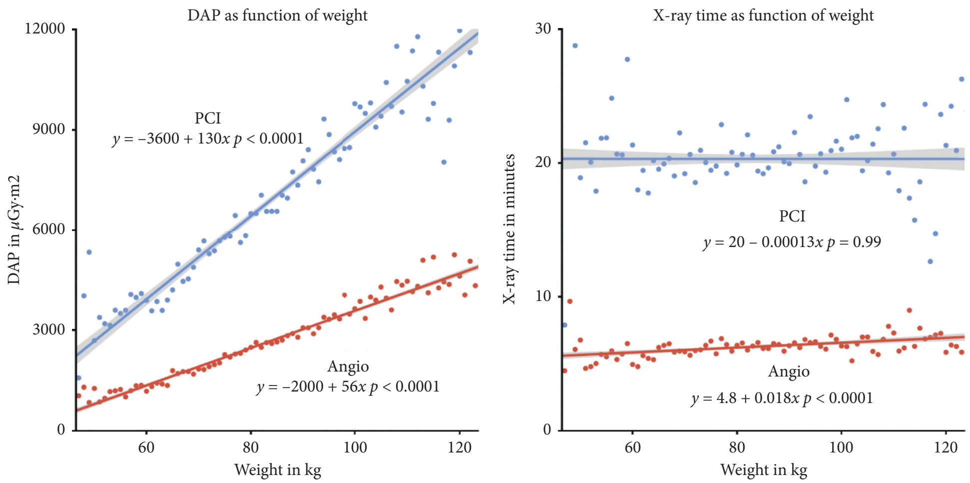
	2013	2014	2015	2016	2017	2018	2019 (including 30th June)	2019 (projected)	Change 13–19	*P* value
Number of procedures	3318	3268	3210	3275	3372	3348	1708	3444	4%	NS
Number of patients	2915	2922	2851	2935	3057	3015	1564	3154	8%	0.02
Coronary angiography	1934	1837	1661	1664	1807	1777	890	1795	−7%	N. S
PCI	1384	1431	1549	1611	1565	1571	818	1650	19%	0.005
% where PCI was performed	41.7	43.8	48.3	49.2	46.4	46.9	47.9		15%	<0.001
Total operator exposure (mSv)	75.3	77.2	72.9	52.8	62.5	32.1	11.7	23.6	−69%	0.004
Operator exposure per procedure (mSv/procedure)	0.0227	0.0236	0.0227	0.0161	0.0185	0.00959	0.00685	0.00685	−70%	0.004
% valid observations DAP/ irradiation time analysis (valid/ total)	85.7% (2844/3318)	98.3% (3212/3268)	98.3% (3157/3210)	98.1% (3213/3275)	98.5% (3321/3372)	98.5% (3297/3348)	97.5% (1665/1708)			
Mean irradiation time angiography in seconds (median)	388 (275)	403 (296)	399 (287.5)	377 (277)	343 (240)	344 (253)	353 (246)		−9%	<0.001
Mean irradiation time PCI (median)	1219 (954)	1268 (992)	1200 (957)	1229 (986)	1261 (981)	1135 (890)	1218 (978)		0%	N. S
Mean DAP angio μGy·m^2 (median)	2981 (2322)	3091 (2528)	2735 (2203)	2545 (2083)	2431 (1992)	2014 (1592.5)	1891 (1416)		−37%	<0.001
Mean DAP PCI μGy·m^2 (median)	8358 (6313.5)	8400 (6856)	7196 (5729)	6583 (5184)	6436 (5157)	5210 (4043)	5055 (4017)		−39%	<0.001
DAP/irradiation time, angio	7.7	7.7	6.9	6.7	7.1	5.9	5.4		−30%	0.003
DAP/irradiation time, PCI	6.9	6.6	6	5.4	5.1	4.6	4.2		−39%	<0.001
DAP/irradiation time, all	7.1	6.9	6.2	5.7	5.6	4.9	4.4		−38%	<0.001

P values calculated with linear or logistic regression when appropriate with years elapsed since 2013 as independent variable. DAP = dose area product; mSv = millisievert; PCI = percutaneous coronary intervention; μGy·$m2$ = microgray squared meters.



(a) (b)

FIGURE 1: Trends in dose area product (DAP) and irradiation time per procedure. Between 2013 and 2019, there was a trend towards reduced DAP per procedure (a). On average, yearly reduction in DAP per procedure was 620 μGy·m^2 in PCI ($p < 0.001$) and 200 μGy·m^2 in coronary angiography ($p < 0.001$). Dots represent mean DAP per procedure. The linear regression line and standard error were calculated on the entire dataset ($n = 20709$). For irradiation time (b), there was a small but significant trend towards a reduction in irradiation time of 11 seconds per procedure per year in angiography ($p < 0.001$).



(a) (b)

FIGURE 2: Influence of patient weight on dose area product (DAP) and irradiation time. Patient weight had a strong correlation to DAP (a). The dots represent the mean DAP for all patients with a specific weight. The linear regression line and standard error were calculated on the entire dataset ($n = 20\,709$). Each additional kilogram patient weight leads to an increase in 130 μGy·m^2 in PCI and 56 μGy·m^2 in coronary angiography ($p < 0.001$).Patient weight had only a minor influence on irradiation time (b).

coils allows for shorter pulse width and better filtration that results in a more efficient photon spectrum. Smaller focal spot size leads to enhanced image sharpness. Detectors with higher dynamic range and bit depth improve image detail accuracy and contrast. Advances in detector technology also include use of thicker scintillators to improve efficiency in conversion of X-rays to image signals. Augmented data processing power allows for software algorithms that

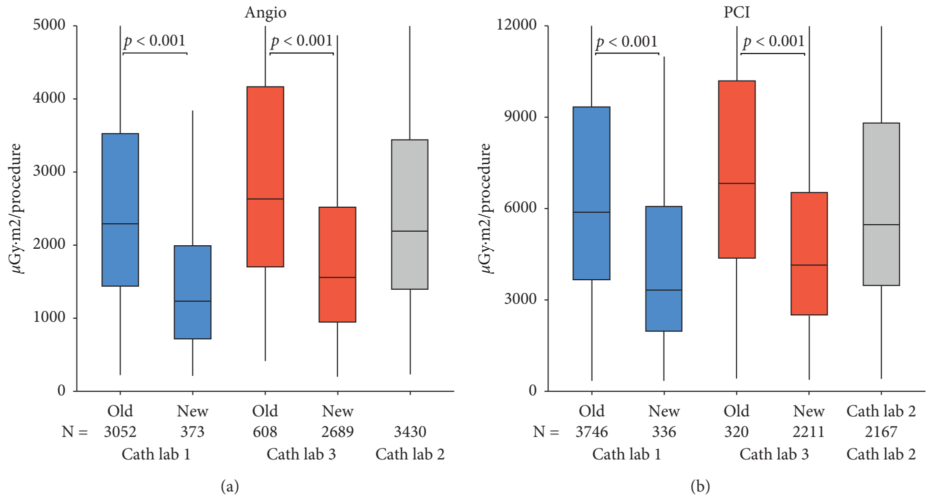


FIGURE 3: Influence of C-arm upgrade on dose area product (DAP). Boxplot representing DAP per procedure in the three cath labs at our institution before and after C-arm upgrade. Newer C-arms were associated with lower DAP per procedure both in isolated coronary angiography (a) and in PCI (b). Cath Lab 1, Siemens Axiom Artis dBC installed in 2006 was replaced with a Philips Azurion 7 B12/12 in 2018, which led to a 50% reduction of mean DAP in angiography and 41% in PCI ($p < 0.001$). Cath Lab 3, Siemens Artis Axiom dFC installed in 2005 was replaced in 2016 with a Siemens Artis Q. Mean doses on the new lab was 28% lower in angio and 32% lower in PCI ($p < 0.001$). Cath Lab 2, Philips Allura Xper FD10C installed in 2009 did not undergo an upgrade.

enhance image quality and compensates for movement without increased radiation dose. Improved user interface includes default low-dose settings and reduced framerates that can easily be changed by the operator during procedures. All these improvements contribute to more efficient imaging, and our data indicate that newer X-ray systems significantly reduce the radiation required to perform cardiac catheterizations.

4.5. Multivariable Analysis of Factors Influencing Patient Dose (DAP). Reducing patient dose is beneficial for the patient and at the same time reduces operator dose. Multivariable linear regression allows us to evaluate the impact of several factors on patient dose, such as weight, irradiation time, procedure type (PCI or angiography), and lab upgrades. In our analysis, all the aforementioned factors were correlated to patient DAP. Days elapsed since the start of registration was also independently correlated to reduced patient doses, and this suggests that there are other factors not included in the model that have contributed to the reduction in patient dose between 2013 and 2019. Lower frame rates, using more low-dose fluoroscopy instead of high-dose cinefluorangiography, better collimation, and less-angulated projections, are all known to reduce patient dose [18] and are highly operator dependent. The dataset does not contain data about these important parameters, but it is possible that increased awareness and training have led to changes in operator behavior, which have contributed to reduction in patient dose. Our results underscore the importance of an integrated approach that addresses multiple factors influencing patient exposure. Operator training and awareness are crucial to further decrease X-ray doses.

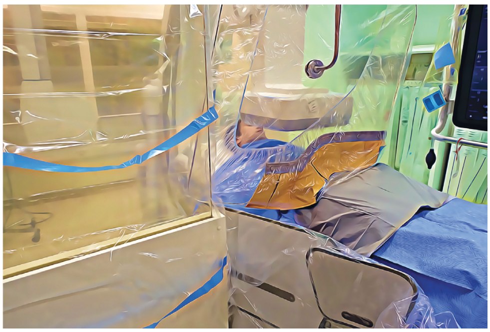


FIGURE 4: Improved operator shielding setup. Large ceiling-mounted protective shield with panel curtains on the lower end was installed in all cath labs in 2016. Pelvic lead apron was introduced as a standard of care at our center in 2018. Wheel-mounted mobile shield to the left of the operator was used at operator's discretion.

4.6. Relationship between Improved Operator Shielding Measures and Operator Dose. Between 2013 and 2019, we observed a marked reduction in mean operator dose per procedure.

The ratio of received operator dose divided by given DAP was calculated as an indicator of operator shielding that is

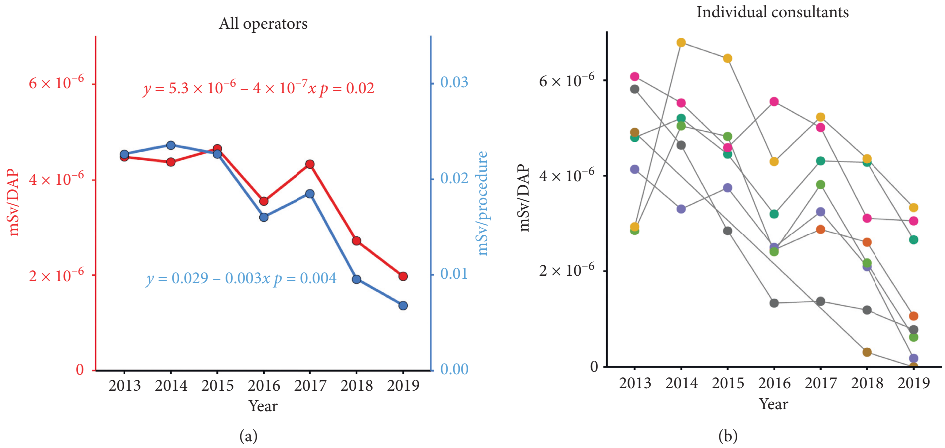


FIGURE 5: Trends in operator exposure. The ratio between received operator dose and given dose (mSv/DAP) is presented to assess the effects of operator shielding and is not affected by procedure numbers or irradiation time. (a) Pooled trends for mSv/DAP (in red-left, y-axis) and mSv/procedure (blue-right, y-axis) for all operators and fellows working in the cath lab. Between 2013 and 2019, there was a change in mSv/DAP from 4.48×10^{-6} mSv/μGy·m^2 to 1.98×10^{-6} mSv/μGy·m^2, which corresponds to a 56% reduction ($p = 0.02$). The reduction in mSv/procedure was larger at 70% ($p = 0.004$) as it is influenced by reduced given dose (DAP) per procedure. (b) Interoperator variability between consultants employed throughout the period.

not affected by variations in DAP per procedure. The largest change was between 2017 and 2018 and coincides with the introduction of improved radiation protection. During the introduction of these measures, real-time dosimetry badges were actively used over a period of three months in early 2018. Measurements included dosimetry readings on legs, truncus, and head and helped identify areas for improved radiation shielding. Instant feedback on the effects of radiation reducing behavior likely contributed to increased operator awareness and improved practice.

Although all operators had a trend towards lower radiation exposure, a large interoperator variability was observed. The yearly exposure is of course highly dependent on number of procedures and procedure type. Physicians performing the most complex procedures such as chronic total occlusions are expected to have a higher radiation exposure. However, even when correcting for these factors using the ratio received mSv divided by given DAP, there was still a substantial interoperator variability. This may point to differences in operator behavior and shielding and the possibility for a more focused awareness campaign targeting operators with higher received to given dose ratios.

4.7. Implications. Newer X-ray systems with modern detectors significantly reduce the radiation required to produce adequate images, but there is a limit to how much the doses can be lowered without losing vital information in the X-ray images. Thus, simple measures such as reducing fluoroscopic pulse rates, maximal collimation, and optimal position of the patient between the X-ray tube and detector are equally important to reduce patient exposure.

Radio protective garments reduce scatter radiation by >90% in the usual X-ray energy spectra used during coronary angiography [13]. However, they tend to be heavy, uncomfortable, and do not protect operator extremities. Thus, a particularly attractive option is to improve externally mounted shielding that in the future may allow the operators to reduce wearable lead thickness or ideally eliminate its necessity altogether. This may have the added benefit of reducing orthopedic problems and repetitive strain injuries [5, 19]. Our data suggest a significant effect of optimally combining simple available measures as larger ceiling-mounted protective shields with panel curtains, pelvic lead apron, and side shield to eliminate scatter radiating gaps between the patient and operator. Whether such measures may be improved sufficiently to minimize radiation exposure alone or if more sophisticated solutions [20] are required should be further investigated.

4.8. Limitations. This is a retrospective, registry-based study, which limits analysis to observations and hypothesis generation. Although mandatory, we do not have the possibility to verify if a personal dosimeter was worn by all operators during all procedures. Radiation protection measures were widely adopted, but we do not have data on the exact percentage, in which pelvic shielding and wheel-mounted side screen was used.

5. Conclusion

Our data show a strong trend towards lower patient and operator exposure during percutaneous coronary procedures in the period 2013–2019. Newer X-ray equipment was associated with reduced DAP. The decrease in operator dose was larger than the reduction in DAP, and the largest reduction coincides with the introduction of improved radiation protection measures. This suggests that increased awareness and use of simple external X-ray shielding can have potential to substantially reduce operator radiation exposure.

Data Availability

The data used to support the findings of this study are restricted by the Regional Ethics Committee for Medical and Health Research Ethics of Western Norway in order to protect patient privacy. The data are available upon request to the Norwegian Registry for Invasive Cardiology (noric@helse-bergen.no, https://www.kvalitetsregistre.no/registers/norsk-register-invasiv-kardiologi-noric) for researchers who meet the criteria for access to confidential data.

Conflicts of Interest

The authors declare that there are no conflicts of interest regarding the publication of this paper.

Acknowledgments

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Supplementary Materials

Supplementary table 1: mean and median DAP per procedure according to the C-arm model, installation year, and type of procedure Supplementary table 2: multivariable linear regression evaluating the effects of procedure type (PCI/coronary angiography), days elapsed since the start of 2013, lab upgrades, patient weight, and irradiation time on DAP per procedure Supplementary table 3: dosimetry data of yearly operator exposure in mSv (H10), calculation of mSv per procedure, and mSv per given DAP. Supplementary Figure 1: five plots exploring the relationship between age, weight, sex, irradiation time, and DAP. (*Supplementary Materials*)

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PLOS ONE

RESEARCH ARTICLE

Effect of an optimized X-ray blanket design on operator radiation dose in cardiac catheterization based on real-world angiography

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Abstract

Background

There is increasing concern and focus in the interventional cardiology community on potential long term health issues related to radiation exposure and heavy wearable protection. Optimized shielding measures may reduce operator dose to levels where lighter radioprotective garments can safely be used, or even omitted. X-ray blankets (XRB) are commercially available but suffer from small size and lack of stability. A larger XRB may reduce operator dose but could hamper vascular access and visualization. The aim of this study is to assess shielding effect of an optimized XRB during cardiac catheterization and estimate the potential reduction in annual operator dose based on DICOM Radiation Dose Structured Report (RDSR) data reflecting everyday clinical practice.

Methods

Data accumulated from 7681 procedures over three years in our RDSR repository was used to identify projection angles and radiation doses during cardiac catheterization. Using an anthropomorphic phantom and a scatter radiation detector, radiation dose to the operator (mSv) and patient (dose area product—DAP) was measured for each angiographic projection for three different shielding setups. Relative operator dose (mSv/DAP) was calculated and multiplied by DAP per projection to estimate effect on operator dose.

Results

Adding an optimized XRB to a standard shielding setup comprising a table- and ceiling-mounted shield resulted in a 94.9% reduction in estimated operator dose. The largest shielding effect was observed in left and cranial projections where the ceiling-mounted shield offered less protection.

Competing interests: The authors have declared that no competing interests exist.

Abbreviations: AP, Anteroposterior (projection); CAUD, Caudal (projection); cath lab, Cardiac catheterization lab; CRAN, Cranial (projection); DAP, Dose Area Product; LAO, Left Anterior Oblique (projection); LAO90, Left Anterior Oblique 90˚ (projection); mSv, milliSievert; PCI, Percutaneous Coronary Intervention; RAO, Right Anterior Oblique (projection); RDSR, Radiation Dose Structured Report; mGy, milliGray; XRB, X-ray Blanket.

Conclusions

An optimized XRB is a simple shielding measure that has the potential to reduce operator dose.

Introduction

During coronary angiography and percutaneous coronary intervention (PCI), the patient and operator are both exposed to ionizing radiation. The operator is not exposed to the primary beam, but to radiation that occurs when a small amount of the photons that reach the patient are scattered towards the operator. Although the operator dose is only a fraction of the patient dose during a given procedure, the operator may perform hundreds of procedures each year [1], and there are growing concerns about the potential negative health effects of repeated exposure over many years of professional life as an interventional cardiologist. In addition, staff exposed to >1 mSv per year is required to wear radioprotective clothing during procedures. They do, however, not protect the operators' head or extremities, are heavy, and may lead to orthopedic strain injuries over time [2]. Improving the shielding around the source of scatter is thus a particularly attractive option as it would also protect areas not covered by radioprotective garments and may reduce operator dose to levels where lighter protection can be worn.

An ideal setup to fully protect the operator from radiation exposure would be a continuous X-ray shielding wall between the patient and operator. Some comprehensive solutions have been proposed [3], but with limited uptake amongst interventional cardiologists. In everyday practice the most common setup is a combination of table- and ceiling-mounted lead shields. This setup tends to leave a gap at patient level and recently there has been an increased focus on placing a X-ray blanket (XRB) on the patient to improve shielding continuity (S1 Fig). Clinical trials have found highly variable effect with reductions in operator dose ranging from 20 to 76% [4–10], but size, design, shielding properties and positioning of the blanket were not standardized. Available XRBs are of limited size which may limit the protective effect. A larger blanket may improve shielding but could hamper access and visualization as well as handling. Based on real time personal dosimetry, phantom pilot measurements and clinical pilots, we designed a customized lead blanket that would maximize coverage area, while retaining flexibility of vascular access and ease of use for the operator.

For assessing clinical efficacy of radiation shielding measures used during cardiac catherization, it is important to incorporate the multiple projections needed to properly visualize the coronary arteries as this strongly influences operator dose [11]. Yet, little data is available on projections used in everyday practice nor how they influence the protective effect of an XRB. In this study, we use data from a large number of real-world procedures to determine which C-arm angulations are used and in which proportion. This information is then used to test the XRB in a controlled standardized setup mirroring everyday clinical practice to estimate annual operator dose reduction potential.

Material and methods

The XRB

Preliminary pilots indicated that XRB size and positioning were critical for operator protection. The optimal position of the XRB was found to be as cranially as possible without impeding on the imaging area (S2 Fig). Also from the initial pilots, we concluded a 60 cm x 60 cm format would represent a good balance between patient cover, being light enough to handle and small enough to fit inside a sterile plastic cover if needed. A prototype was created using a CE-marked XRB with lead equivalency of 0.5mm (Scanflex Medical AB). The prototype was informally tested during clinical procedures with encouraging real-time dosimetry readings.

Real-world cath lab dose and projections

Radiation data at our institution are stored in OpenREM which is an opensource PostgreSQL database that stores DICOM Radiation Dose Structured Report (RDSR) data for each procedure. These RDSR data contain key details from each exposure such as C-arm angulation, dose area product (DAP) and imaging geometry. Data were extracted from 7681 procedures performed at three cath labs in our institution between February 2017 and March 2020. As the data were fully anonymized and consisting of retrospective procedural data from a large number of procedures with no identifiable personal health data, the regional ethics board waived the requirement for informed consent. Radial approach was used in >80% of cases. PCI was performed in approximately 40% of cases and the data also include weekly CTO (chronic total occlusion) sessions. Median fluoro time per procedure was 470 seconds (IQR 218–943 seconds) and median cine duration 39 seconds (IQR 28–58 seconds). Mean and median DAP per procedure was 36101 $mGycm^2$ and 24129 $mGycm^2$ (IQR 12818–45209 $mGycm^2$). Exposures in different projection angles were grouped into AP, CRAN, CAUD, LAO, LAO-CRAN, LAO-CAUD, RAO, RAO-CRAN and RAO-CAUD and LAO90. Angiographic projection grouping categories were defined so that unidirectional projections such as LAO or RAO also included +/-10˚ in the cranio-caudal direction, CAUD and CRAN +/-10˚ in the left-right direction and AP +/- 10˚ in any direction. For each projection, the total accumulated DAP and fraction of total accumulated DAP was calculated. The underlying data set of DAP and C-arm angulation for each exposure is available as S1 File.

Cath lab measurement setup

Measurements were done in a cath lab equipped with a Philips Allura Xper FD10C C-arm from 2009 where the X-ray source is located 33.5 cm above floor level. Table height was set to "0 cm" where the lower edge of the table is 88.5 cm above the floor, or 55 cm above the X-ray source. Source-to-image distance (SID) of 100 cm was used, 20x20 cm^2 field of view and 15 frames per second cine protocol. A high framerate cine protocol was chosen as it produces sufficient scatter radiation for reliable measures. To simulate the patient, a Kyoto Kagaku Whole Body Phantom PBU-50 corresponding to a person measuring 165 cm and 50kg was used. Protective elements included a ceiling-mounted Mavig OTS54011 lead acrylic X-ray shield and a Kenex 312/DS-039/5 table-mounted lower body X-ray shield, both providing 0.5mm lead equivalent protection. Scatter radiation was measured with a Raysafe X2 Survey Sensor placed 140 cm above floor level, and 40 cm caudally and laterally to the center of the primary beam (Fig 1). This position corresponds to a dosimeter worn on the left shoulder of an operator measuring 180 cm standing close to the patient as is the case in radial procedures. The X2 has a directional sensor with backscatter protection on the back. During measurements, it was directed towards the patient. For each measurement, operator dose was measured with the X2 sensor, whereas patient dose, DAP, was collected from the C-arm.

Projections and XRB shielding effect

Three setups were compared: 1) A “no shielding” setup with only the table-mounted shield, 2) a “standard” shielding setup with ceiling-mounted shield in addition to the table-mounted shield, and 3) an optimized shielding setup named “XRB” where an adequately sized and

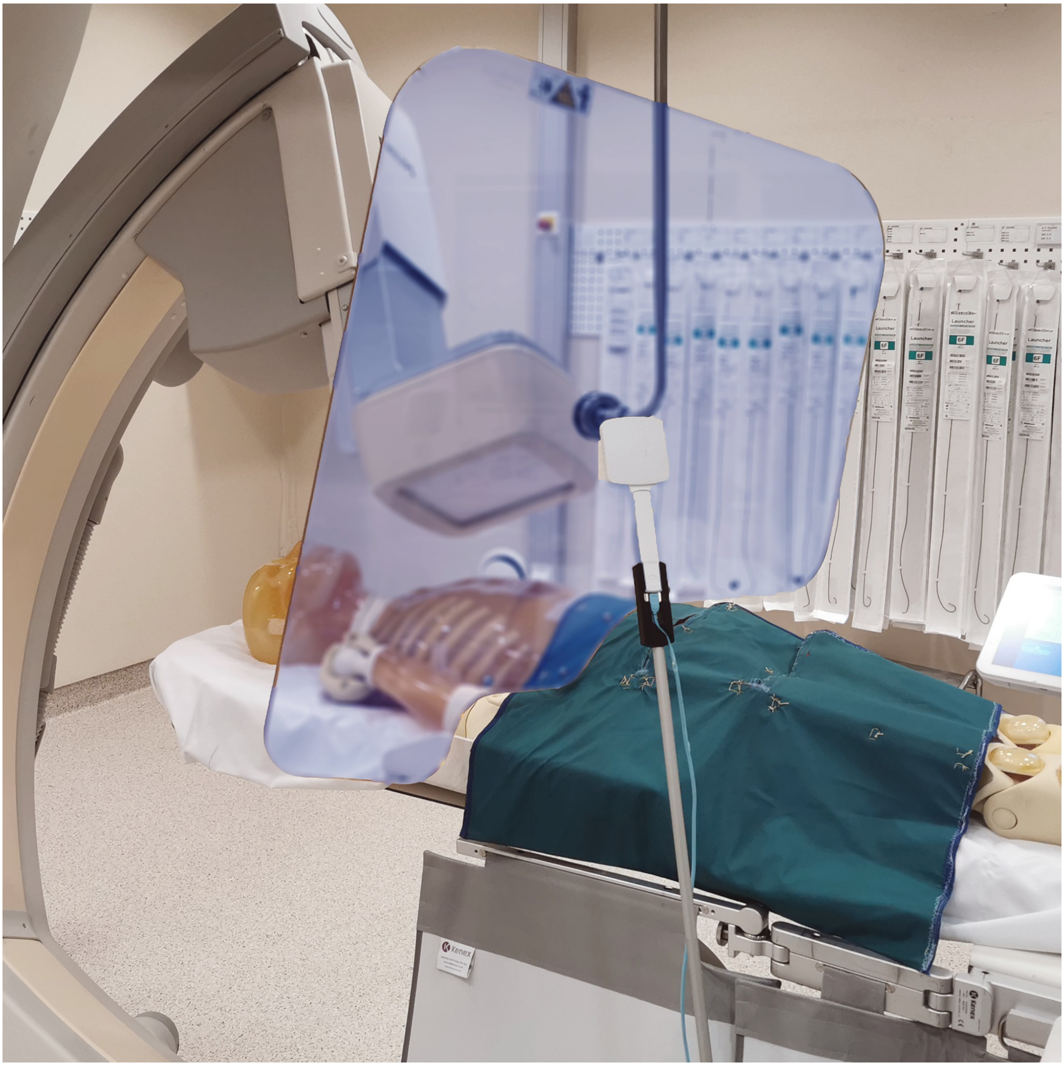

Fig 1. Illustration of measurement setup. A 60x60cm X-ray blanket (flexible features not shown) is positioned just caudally to the image detector, and the X2 Survey sensor in the center of the photo is placed 140cm above the floor, 40cm caudally and laterally to the center of the primary beam. This corresponds to the position of the operator's left shoulder during cardiac catheterization using a right radial approach.

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positioned XRB was added to the standard setup (Fig 1). When used, the ceiling-mounted shield was positioned 10 cm caudally to the imaging detector and rotated 30˚ around its vertical axis so the lateral edge would be more cranial than the medial edge. In the horizontal plane the ceiling-mounted shield was positioned 5 cm above the patient surface which represents a realistic real-world positioning since in clinical practice it is difficult to position the shield in direct contact with the patient. The XRB was positioned directly caudally to the imaging detector. For each projection, the mean angle in the left-right and cranio-caudal directions obtained from our RDSR depository was used, and measurements were repeated five times.

Calculation of shielding effect

Operator dose is measured in millisievert (mSv) whereas patient dose is quantified in Dose Area Product (DAP in mGycm^2). The relationship between these is described by the relative operator dose which is the ratio between operator dose in mSv and patient DAP measured in mGycm^2. It is a validated parameter for assessing effect of radiation protection devices in invasive cardiology [12]. As it normalizes received operator dose to given patient DAP, it allows for direct comparisons regardless of irradiation duration or imaging protocol. It is important to acknowledge that when tilting the C-arm, the amount of patient tissue between the X-ray source and detector increases, and the X-ray system will automatically adapt tube current and voltage to maintain image quality. Thus, to make correct comparisons between angiographic projections, it is necessary to correct for this variation by dividing received operator dose by given patient DAP.

Annual operator dose reduction with an XRB

To assess potential effect on real life annual operator dose based on mSv/DAP ratio measurements for the different shielding setups, clinical DAP readings were extracted from OpenREM. Clinical DAP was distributed to projections according to the proportion in which they were used and DAP per year per operator was calculated. Yearly DAP per operator was then multiplied with the mSv/DAP ratios for all projections in the different shielding setups for estimating annual operator dose.

Data analysis

Data analysis was done in RStudio: integrated development for R version 1.1.456 (RStudio, Inc., Boston, MA). Plots were created with the ggplot2 version 3.3.3 package. The corresponding author had full access to all the data in the study and takes responsibility for its integrity and the data analysis.

Results

Real-world cath lab dose and projections

Fig 2A is a scatterplot of a random sample of 200 000 exposures from our RDSR data that illustrates the variation in C-arm projection angle used, as well as visual fit according to grouping categories. The percent DAP spent in each projection is presented in Fig 1B. LAO (21.8% of all DAP) was most commonly used, followed by RAO-CRAN (14%) and LAO-CRAN (11.8%). The least used were LAO90 (0.8%), RAO (5.8%) and CRAN (7.4%). For each projection group we summarized the number of exposures, percent DAP and mean angle in the cranio-caudal and left-to right direction (S1 Table).

Projections and XRB shielding effect

The relative operator dose of each measurement according to shielding setup and projection group is plotted in Fig 3 and the corresponding numeric values as well as percent reduction between shielding setups are available in Table 1. As illustrated in Fig 3, the values recorded per setup and projection were very consistent with only minor variation between

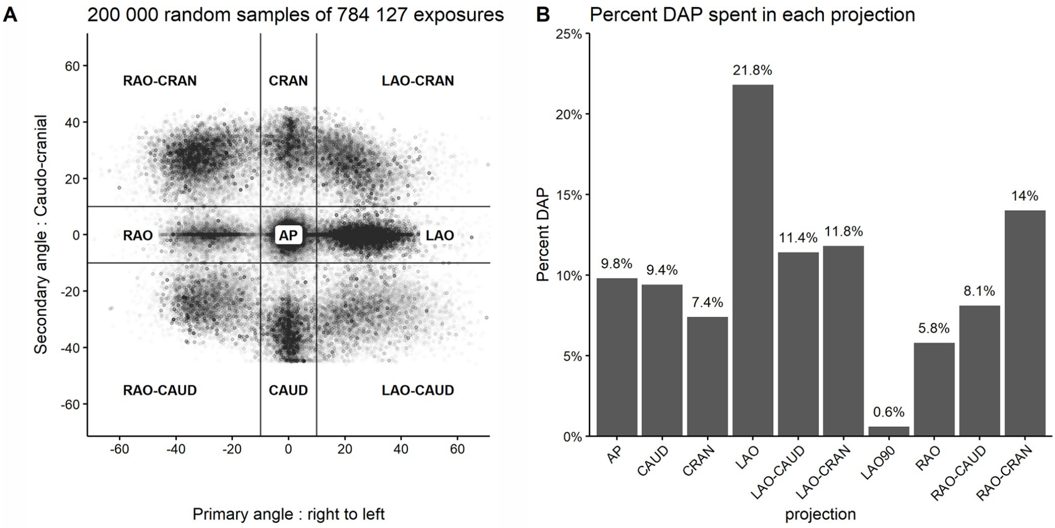

Fig 2. C-arm angulation and percentage DAP in each projection. Panel A: Scatterplot showing the precise C-arm angulation of 200 000 random samples out of 784 154 exposures. Only a sample was plotted to avoid overplotting and improve visualization. Although a large variation in C-arm angulation is present, it is easy to visualize the natural grouping categories. Panel B: Percentage DAP recorded in each projection. LAO (21.4%) and RAO-CRAN (14%) are where most patient doses are given.

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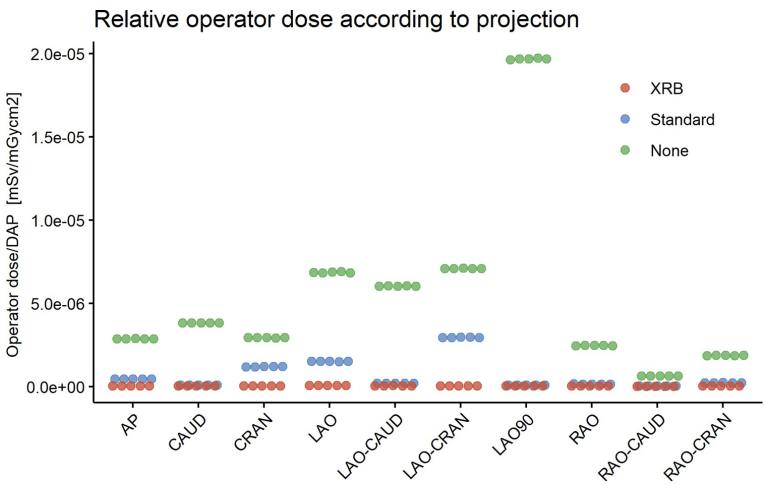

Fig 3. Relative operator dose according to angiographic projection and shielding setup. Each measurement was repeated five times and all measured values are individually plotted. The plot shows that standard shielding is least effective in left and cranial projections (CRAN, LAO, LAO-CRAN), whereas with the XRB the relative operator dose is consistently low. Thus, the XRB is more effective in the projections where the standard shielding has least effect.

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Table 1. Relative operator dose according to angiographic projection and shielding setup.

	Relative operator dose ($mSv/mGycm^2$)			Reduction in relative operator dose		
Projection	None	Standard	XRB	Standard vs None	XRB vs Standard	XRB vs None
AP	2.9E-06	4.5E-07	3.9E-08	-84.4%	-91.2%	-98.6%
CAUD	3.8E-06	8.7E-08	3.9E-08	-97.7%	-54.6%	-99%
CRAN	2.9E-06	1.2E-06	4.0E-08	-59.2%	-96.7%	-98.6%
LAO	6.9E-06	1.5E-06	6.4E-08	-78%	-95.8%	-99.1%
LAO-CAUD	6.0E-06	1.9E-07	5.5E-08	-96.9%	-70.7%	-99.1%
LAO-CRAN	7.1E-06	3.0E-06	5.2E-08	-58.4%	-98.2%	-99.3%
LAO90	2.0E-05	8.7E-08	3.3E-08	-99.6%	-62.4%	-99.8%
RAO	2.5E-06	1.5E-07	3.3E-08	-93.7%	-78.9%	-98.7%
RAO-CAUD	6.3E-07	4.4E-08	1.7E-08	-93%	-62.4%	-97.4%
RAO-CRAN	1.9E-06	2.4E-07	3.4E-08	-87.4%	-85.5%	-98.2%

XRB = X-ray blanket. Standard = standard shielding setup.

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measurements. In the no shielding setup, LAO90 (normalized to 1) resulted in the highest relative operator dose, followed by LAO-CRAN (0.36) and LAO (0.35), whereas RAO-CAUD (0.03), RAO-CRAN (0.10) and RAO (0.12) yielded the lowest relative operator dose. Adding a standard shielding setup resulted in a reduction in relative operator dose across all projections, but the reduction was highly variable. It was least effective in LAO-CRAN (-58.4%), CRAN (-59.2%) and LAO (-78%), whereas it was more effective in the right and caudal projections. Thus, in this setup, the highest relative operator dose was seen in three projections accounting for 41% of all DAP (LAO-CRAN (normalized to 1), LAO (0.51) and CRAN (0.40)).

Adding an XRB resulted in an additional reduction in relative operator dose. As seen in Fig 3, the reductions followed a complementary pattern where the XRB was the most effective in the projections where the ceiling-mounted shield was less effective. In LAO-CRAN, reduction in relative operator dose was -98.2%, in CRAN -96.7% and in LAO -95.8% whereas it had least additional shielding effect in CAUD (-54.6%) and RAO-CAUD (-62.4%). The resulting effect was that with an XRB, the relative operator dose was consistently low, with small variations between projections.

Annual operator dose reduction with an XRB

To estimate operator dose, it is necessary to combine given patient dose (DAP) with the relative operator dose (operator dose/DAP) in each projection according to shielding setup. In our hospital, a full-time consultant will on average perform approximately 500 procedures per year. Annual DAP per operator was estimated by multiplying case load by mean DAP per procedure from our RDSR repository. DAP was distributed to each projection according to the percentage in which it was used (Fig 2) then multiplied with measured operator dose/DAP (Fig 3) according to shielding setup (Fig 4, S2 Table). For the XRB shielding setup, calculated annual operator dose would be 0.77 mSv. If standard shielding was used, annual operator dose would be 15.03 mSv, and with no shielding 75.53 mSv. Thus, adding an optimally placed XRB to a standard shielding setup resulted in an estimated 94.9% reduction in yearly operator dose compared to standard shielding. Fig 4B examines the relative contribution of each projection to the annual operator dose. With standard shielding, CRAN, LAO-CRAN, and LAO are responsible for 86% of annual operator dose, as these projections are both frequently used (41% of all DAP) and where standard shielding is least effective.

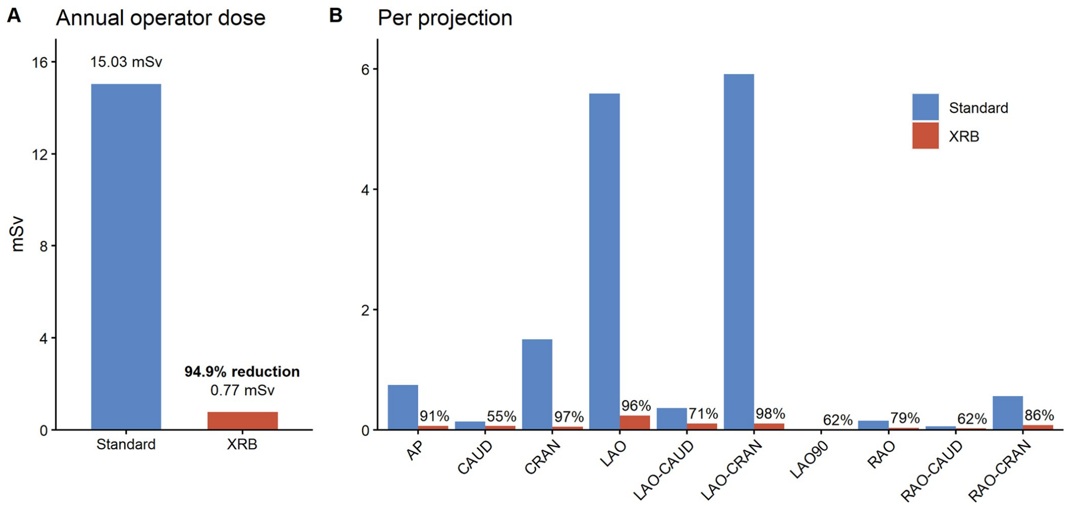

Fig 4. Annual operator dose estimates according to shielding setup. Calculations are based on a case load of 500 procedures / year and mean DAP per procedure 36 102 mGycm^2. A: Adding an X-ray blanket (XRB) to standard shielding resulted in a 94.9% reduction in annual operator dose. B: Contribution of each projection to annual operator dose. The percentage above the red columns represent percent reduction with an XRB compared to standard shielding. In the standard setup, CRAN, LAO and LAO-CRAN are responsible for the majority (86%) of operator dose. These are the projections where the ceiling-mounted shield is least effective and where adding an XRB leads to the largest incremental reduction in operator dose.

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Discussion

Our data show that adding an XRB to a standard shielding setup has the potential to substantially reduce operator radiation dose during cardiac catheterization. However, shielding effect is highly variable in the different angiographic projections.

Real-world cath lab dose and projections

Coronary angiography and PCI are dynamic procedures which require multiple angiographic projections to properly examine the three-dimensional anatomy of the coronary arteries with a two-dimensional imaging system. Each patient is unique, and depending on which artery needs treatment, the optimal C-arm position will be different. In everyday practice, the C-arm is positioned to the desired angle by the operator or assisting radiographer. This has the advantage that if visualization is suboptimal, the operator can easily adapt the position of the C-arm, but also means there will be a large variation in which C-arm angulations are used. Although there are publications that have tried to establish a set of angiographic projections that minimize patient and operator dose [13], little is known about what is done in routine clinical practice. This is important to address as C-arm angle influences the patient and operator dose by several folds. Through our RDSR data repository we were able to analyze a large number of procedures and establish a reference for angiographic projection angles and in which proportion they are used during a procedure. As expected, and as illustrated in Fig 2A, there is a large variation in C-arm angulations. To our knowledge, it is the first time this type of data has been published. Not surprisingly, LAO is the most commonly used projection as it is used for positioning the diagnostic catheters and gives a good visualization of the three segments of the right coronary artery. The CRAN and LAO-CRAN are also extensively used to visualize left anterior descending artery and are particularly useful for bifurcation lesions affecting diagonal branches. Our data suggest that these three common projections represent a substantial proportion (41%) of the given radiation in clinical practice. Such findings are of particular relevance when assessing the effect of different operator shielding measures as indicated in this study.

Shielding element size, positioning, and operator dose

Our measurements indicate striking effect of adding an XRB to existing shielding but warrant sufficient size and optimal positioning. This implies adequate coverage of the relevant field of scatter as well as placing the blanket as cranially as possible without impeding on the imaging detector. In cardiac catherization, the interface between the patient and ceiling-mounted shield is particularly vulnerable when table height and position are shifted during procedures. In this regard it is important to remember that interventional cardiologists often work in a stressful setting where a meticulous repositioning of shielding elements cannot be expected. In our experience, if the XRB is well-placed at the start of the procedure it will not compromise the images in the standard views, and no repositioning was needed during measurements on the anthropomorphic phantom. Interestingly, our initial investigations suggest that a well-positioned XRB will counteract the effect of a gap between the patient and the ceiling-mounted shield. On the contrary, if the XRB is placed too caudally, the shielding effect is quickly lost.

Projections and XRB shielding effect

Our data show that with no shielding, left and cranial angulations of the C-arm expose the operator to proportionally larger amounts of scatter radiation. This was expected, since when the detector is tilted cranially or to the left, the under-the-table X-ray source comes closer to the operator and thus increases scatter radiation to the operator. This has previously been described in the literature [11], but to our knowledge how this influences the shielding effect of a ceiling-mounted shield or an XRB has not been evaluated. What our measurements add to current knowledge is that the ceiling-mounted shield have a limited shielding effect in left and cranial projections. The addition of a well-positioned adequately sized XRB complements the ceiling-mounted shield and is proportionally the most effective in the projections where the ceiling-mounted shield have least effect. The addition of flaps to the ceiling mounted screen may provide some additional benefit [8].

Annual operator dose reduction with an XRB

Our data show that adding an optimally placed, rather large (60 cm x 60 cm), 0.5mm lead equivalent XRB to a typical protection setup with a ceiling- and table-mounted shield, could reduce yearly operator dose at shoulder height by 94.9%. This is far better than the 20–76% that have previously been described in clinical studies [4–8]. However, in these studies, blanket position was not standardized, and dislodgement of the XRB or suboptimal positioning of the ceiling-mounted shield may have contributed to lesser shielding effect. Furthermore, some of these studies used single usage sterile XRBs that typically measure only 40 cm x 40 cm and offer 0.125 to 0.25 mm lead equivalent protection. It should be noted that in our measurements, the relatively high doses observed in the standard and no shielding setup likely reflect fixed positioning of the dosimeter to detect the maximum operator dose during a procedure. However, this does not affect the relative benefit of XRB. Optimizing existing XRB design is likely to be a promising path for reducing operator dose with relatively low cost and logistic challenges.

Perspectives

Use of an optimized XRB can substantially reduce operator dose and is a particularly attractive measure in a field of much concern. It is easily incorporated into existing workflows as it adds minimal procedure time and cost. Compared to more comprehensive shielding solutions it does not need any physical alteration of the cath lab and can be used in a low-resource setting. While we have primarily discussed cardiac procedures, a similar approach could potentially be employed in a variety of medical fields including vascular as well as abdominal and orthopedic surgery.

Limitations

This article describes an idealized lab setup to assess and improve radiation protection in the cath lab. Further clinical validation should be the subject of future studies. The present study was not designed to assess whether adding an XRB to a shielding setup influences patient dose.

Conclusion

Adding an XRB of sufficient size can be highly effective at reducing relative operator dose across all angiographic projections and may substantially reduce annual operator dose. An XRB is a low threshold measure that can easily be incorporated into existing workflows. The benefit is largest in the left and cranial projections that are responsible for an estimated 86% of operator dose in our clinical practice. Optimized XRB placement is required in order to prevent radiation from the gap between the patient- and a ceiling- mounted shield.

Supporting information

S1 Fig. Mechanism of action of an X-ray blanket on reducing operator exposure to scatter radiation. Most of the photons of the primary beam are absorbed in the patient. Only a small fraction traverses the patient and creates an X-ray image when it reaches the image detector. The operator is not exposed to the primary beam, but to scatter radiation that occurs when the primary beam interacts with patient tissue (A). Placing an X-ray blanket over the patient shields the operator from scatter radiation (B).
(TIF)

S2 Fig. XRB positioning and relative operator dose. To investigate the importance of correctly positioning the ceiling-mounted-shield (CMS) and the X-ray blanket (XRB), four setups were compared in anteroposterior projection to a setup with only table-mounted shield (referred to as "No shielding). In setup A, the CMS was positioned close to the patient and relative operator dose was measured to 35.2% compared to no shielding. With the addition of the XRB positioned 15 cm caudally to the CMS (setup B) relative operator dose was 31.9%, indicating only a small additional shielding effect of the XRB when placed too caudally. With the XRB well-positioned (setup C) close to the image detector and the CMS raised 15cm above de patient relative operator dose was 5.7%. With an optimally placed CMS and XRB (setup D) relative operator dose was 1.5% compared to no shielding.
(TIF)

S3 Fig. Descriptive terms of C-arm angulations. C-arm angulation is described by the direction in which the C-arm detector above the patient is tilted. If the X-ray detector is tilted towards the head the projection is termed cranial (CRAN), towards the feet caudal (CAUD), and left or right anterior oblique (LAO/RAO) according to tilt in the left-right direction.

Combinations are also possible such as RAO-CRAN.
(TIF)

S1 Table. Angiographic projections, C-arm angulation, and percent DAP.
(PDF)

S2 Table. Estimated annual operator dose according to angiographic projection and shielding setup.
(PDF)

S1 File. Data file containing C-arm angulation and DAP for each individual exposure and detailed scatter radiation measurement data from the X2 sensor.
(ZIP)

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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

Cedric Davidsen, MD; Kristian Ytre-Hauge, PhD; Andreas Tefre Samnøy, PhD; Kjell Vikenes, MD, PhD; Patrizio Lancellotti, MD, PhD; Vegard Tuseth, MD, PhD

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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For Sources of Funding and Disclosures, see page XXX.

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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 microSievert [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

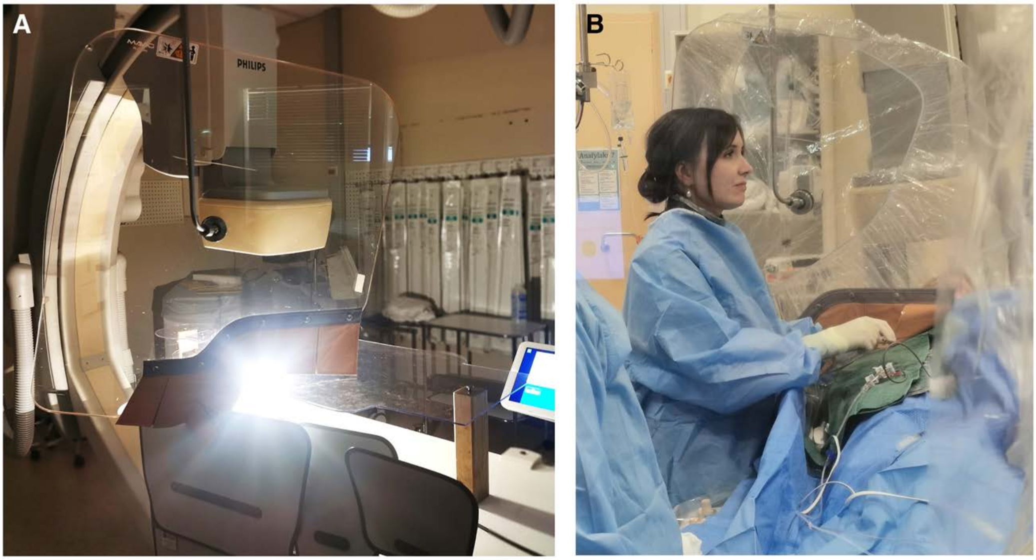

Figure 1. Scatter radiation and mechanism of action of the flexible x-ray shield.
A, Illustration of unshielded scatter radiation from the patient in a routine shielding setup using photons from the visible part of the electromagnetic spectrum. **B**, The flexible x-ray shield seals the gaps between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

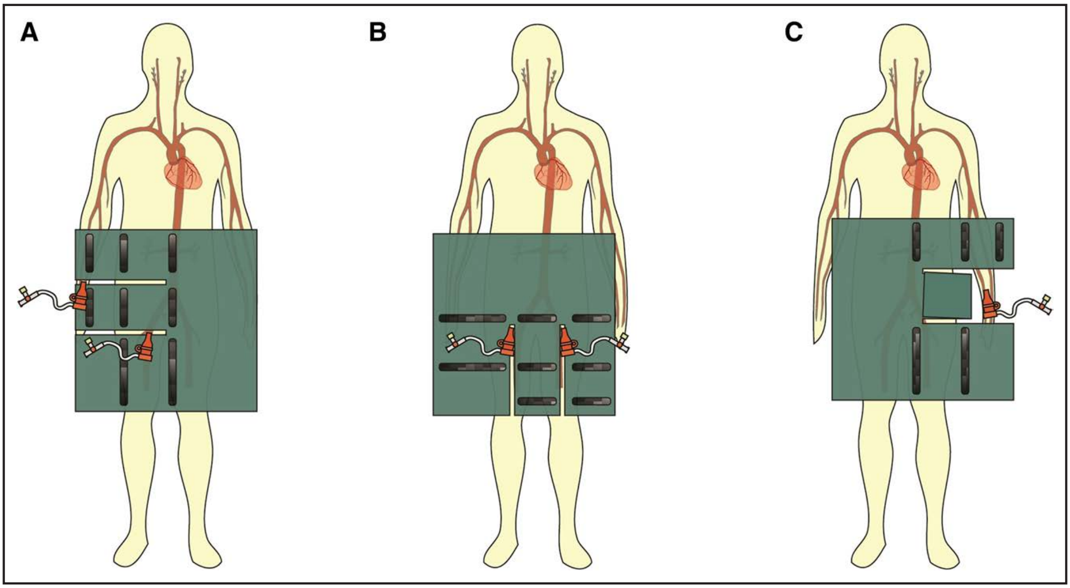

Figure 2. Illustration of the novel flexible multiconfiguration x-ray shield.
The versatile design can adopt multiple configurations to accommodate variations in patient morphology, access site, and type of procedure. **A**, Combined radial and femoral access. **B**, Double femoral access. **C**, Left 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/m²	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.

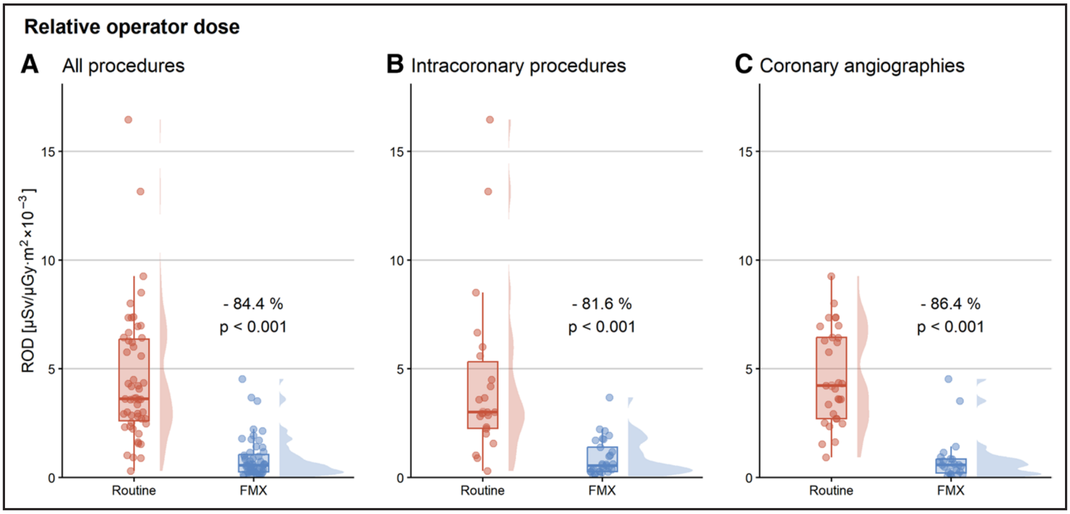

Figure 3. Relative operator dose (ROD) according to shielding setup.
Adding the flexible multiconfiguration x-ray shield (FMX) resulted in a median reduction of 84.4% of ROD (P<0.001) across all procedures (**A**). It was similarly effective in both intracoronary procedures (**B**) and during coronary 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·m²×10⁻³, 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

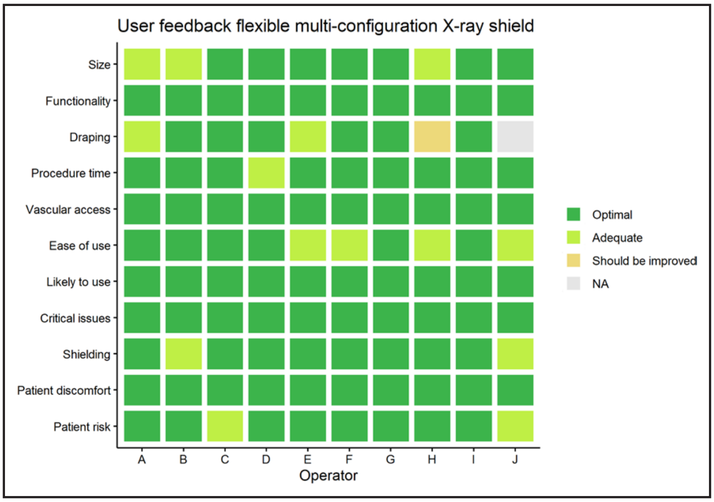

Figure 4. User feedback on functionality and user-friendliness.
Participating operators answered a feedback form with 11 questions and 3 grading options (optimal, adequate, and should be improved). About 86% of feedback was optimal, 13% adequate, 1% should be improved. No critical issues were identified.

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) μSv/μGy·m^2×10^{-3} compared with 4.9 and 8.1 μSv/μGy·m^2×10^{-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/μGy·m^{2}×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/μGy m^{2}×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.

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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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