Physica Medica 76 (2020) 38–43

Contents lists available at ScienceDirect

Physica Medica

journal homepage: www.elsevier.com/locate/ejmp

Original paper

Patient exposure data and operator dose in coronary interventional procedures: Impact of body-mass index and procedure complexity

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ARTICLE INFO

Keywords:
Coronary interventional procedures
Operator dose
Patient exposure data
Complexity index
Diagnostic reference levels

ABSTRACT

Purpose: The aim of this study was to assess patient exposure data and operator dose in coronary interventional procedures, when considering patient body-mass index and procedure complexity.

Methods: Total air kerma area product (P_{KA}), Air-Kerma (AK), Fluoroscopy time (FT), operator dose and patient body-mass index (BMI) from 97 patients' procedures (62 coronary angiography (CA) and 35 Percutaneous Coronary Intervention (PCI) were collected for one year. For PCI procedures, also the complexity index-CI was collected. Continuous variables for each of the 2 groups procedures (CA and PCI) were compared as medians with interquartile range and using Mann-Whitney *U* test. Multiple group data were compared using Kruskal-Wallis test (significance: $p < 0.05$).

Results: Median P_{KA} was 63 and 125 Gy cm^2 for CA and PCI respectively ($p < 0.001$); FT was 3 and 14 min, respectively ($p < 0.001$). P_{KA} and FT significantly increased ($p < 0.05$) with BMI class for CA procedures. P_{KA} and FT also increased in function of CI class for PCI, thought significantly only for FT ($p < 0.001$), possibly because of the low number of PCI procedures included; cine mode contributed most to P_{KA}. Significant dose variability was observed among cardiologists for CA procedures ($p < 0.001$).

Conclusions: Dose references levels for P_{KA} and FT in interventional cardiology should be defined - on a sufficient number of procedures- in function of CI and BMI classes. These could provide an additional tool for refining a facility's quality assurance and optimization processes. Dose variability associated with cardiologists underlines the importance of continuous training.

1. Introduction

Interventional cardiology (IC) procedures are important contributors of exposure to ionizing radiation in the general population in Europe [1] and in the USA [2]. Since the introduction of catheter-based interventional procedures, the frequency of these procedures has increased due to the Coronary Angiography (CA) interest and increasing therapeutic implications. These advantages include minimal invasiveness, reduced pain and risk, shorter hospital stay and lower cost.

Cardiac catheterization procedures are performed for CA, Percutaneous Coronary Intervention (PCI) or both purposes to visualize catheters, guidewires and other devices. During the procedures real-time fluoroscopy is used; exposure of patients and operator to X-rays during IC procedures can therefore be high. Radiation exposure of operators and patients during CA and PCI is currently a major concern, mainly due to the stochastic risk of cancer induction for operators and to possible deterministic effects, such radiation skin injury for the patients [3,4]. Guidelines and position papers have emphasized the need for interventional cardiologists to improve their awareness of the risks of radiation by continuous training in radiation protection and the development of quality-assurance programs [5]. Specifically, a clear focus has been put also on optimizing the dose to the patient; indeed, since the operator dose is proportional to the patient dose, optimizing the patient dose benefits both the patient and the operator.

While literature exists on how to properly use the fluoroscopic equipment during cardiac interventions to optimize the patient radiation dose [6], less information exists about factors that affect the operator radiation dose. Moreover, published data of operator radiation doses from cardiac interventions highlight the importance of controlling the factors that affect the operator dose and the need to incorporate

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https://doi.org/10.1016/j.ejmp.2020.05.006
Received 3 February 2020; Received in revised form 4 May 2020; Accepted 8 May 2020
1120-1797/

awareness of the operator dose into daily practice [7].

Another important aspect in relation to patient irradiation parameters is the complexity of the PCI procedure. The concept of complexity is related to both clinical and technical factors, such as for example patient's age, sex, the number of vessels treated, the presence of unstable angina, occluded arteries and bifurcation lesions [8] .

The objective of this study was to assess patient exposure data and operator dose in coronary interventional procedures, when considering patient body-mass index and procedure complexity.

2. Methods

2.1. Technical and clinical data collection

Prior to this study, a dose monitoring software was installed (DoseWatch, GE Healthcare Systems, Buc, France) and connected to the cardiology interventional suite. Data from CA and PCI procedures were collected, the latter including all forms of interventional procedures on the coronary arteries and associated grafts following a CA procedure or an elective one.

Information over these procedures were collected over a one-year period ending October 2017 and was approved by our Institutional Review Board.

All the procedures of the study were performed on a Siemens Artis ZEE interventional system (2012).

The following information were collected through the hospital RIS Omnipro (Xperthis, Belgium): time and type of procedure, clinical indication, elective or emergency patient, type of coronary disease (1 vessel, 2 vessels, ..), body-mass index (BMI, defined as weight (kg)/(height (m))^2), immediate complication, complication after 30 days, treatment, number of vessel treated, number of segments treated, CI, number of balloons, number of stents, sheet size.

The following technical and clinical factors have also been collected through the dose tracking system: patient age, sex, protocol name, total air kerma area product (P_{KA}, Gy cm^2), Air Kerma at the reference interventional point (AK, Gy), fluoroscopy time (FT, s), field of view (FOV, cm), patient body-mass index (BMI), performing physician, primary and secondary angle per series, frames per second. Note that the uncertainty of the chamber for P_{KA} as declared by the manufacturer is $\pm$ 15%.

2.2. Operator dose

To measure operator's (first, second and circulating nurse) doses, the dosimeters delivered with the real-time Radiation Insight Raysafe i2 (Unfors RaySafe, Sweden) were used.

The Raysafe i2 dosimeters use as operational quantity $H_p(10)$ (e.g. the personal dose equivalent at a depth of 10 mm according to ISO 4037). The reproducibility error is 10% or 1μSv, whatever is greatest, and the dose rate range is 40μSv/h-300μSv/h. The angular dependency is 5% within $\pm$ 5°, ± 30% within $\pm$ 50°, +200%/-100% within $\pm$ 90°.

The Raysafe i2 dosimeters were calibrated in ISO norms N60 reference beam against personal dose equivalent $H_p(10)$ at the second-standard calibration laboratory of the Belgian nuclear research centre [9].

We had 6 dosimeters (dose reported in μSv) and they were placed as follows:

- Operator 1 (principal cardiologist): one dosimeter at the level of the torso and outside the apron, one dosimeter at the level of the left eye (outside glasses), one dosimeter at the level of the left wrist.
- Operator 2 (cardiologist or nurse): one dosimeter at the level of the torso outside the apron. Operator 2 would assist only for few PCI procedures.
- Operator 3 (circulating nurse): one dosimeter at the level of the torso outside the apron.

There were 3 principal cardiologists involved in the study, with a range of experience varying from 5 to 20 years.

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

2.3. Complexity index estimation

The complexity of a procedure, which is calculated only for PCI procedures, can be affected by factors related to the patient's anatomy and the location and severity of the treated pathology [10,11].

A study by Balter et al.[12] evaluated the relationships of clinical factors and anatomical factors as a function of P_{KA} and of FT and the number of acquired images and proposed a definition of Complexity Index (CI):

$$CI = Noves * 1 + NoLesType * 0.\ \ 51 + No.\ Occl3m * 0.73 + NoSevTort * 0.69 + NoBifSt * 0.58$$

where No.Vessels is the number of vessels treated during the procedure, No.LesionType is the number of lesions type, No.Occl3m is the number of occlusion > 3 mm, No.SevTortuosityis the number of vessels with severe tortuosity, and No.BifStenting is the number of bifurcation stents placed during the procedure. In our study we implemented an automatic calculation of this CI in the RIS by leveraging the clinical information collected and stored in the RIS interface, after the procedure. For the analyses we also considered CI classes defined as: CI between 1 and 1.99 = 1, between 2 and 2.99 = 2 and so on.

2.4. Statistical analysis

Continuous variables for each of the 2 groups procedures (CA and PCI) were compared as medians with interquartile range and using Mann-Whitney *U* test, as preliminary data investigation showed non-normality. Box-Whiskers plot were used to represent the data graphically. Multiple group data were compared using Kruskal-Wallis test. Statistica for Windows (version 13.2, Statsoft, Inc) software was used for all analysis.

3. Results

Data from a total of 139 procedures were collected. Out of these, 42 patients have been excluded because not conform with the defined study protocol, e.g.: the first operator changed during the procedure, the Raysafe dosimeter was not used. Eventually, 97 exams (62 CA and 35 PCI, of which only 5 being elective) were eligible for data analyses.

3.1. Technical data

The most utilized FOV per procedure was the 22 cm (60% for CA, 54% for PCI), followed by the 32 cm for CA (27%) and by the 16 cm for PCI (28%).

When stratifying per cardiologist the 22 cm stayed the most utilized FOV for all three cardiologists both for CA and PCI procedures (range 50%-60% for CA and 56% for PCI). The next most utilized FOV by all cardiologists was the 32 cm for CA (range 18%- 32%) but we observed some differences for PCI, e.g. cardiologist 2 utilizing more 16 cm FOV (36%) while the other operator utilized mostly the 32 cm (33%). Note that only 2 of the 3 cardiologists performed PCI procedures.

In terms of frame rate utilized, the 7.5 fps for fluoroscopy acquisition and 15 fps for cine mode acquisition were utilized in most of the cases by all cardiologists (100% and 95% respectively).

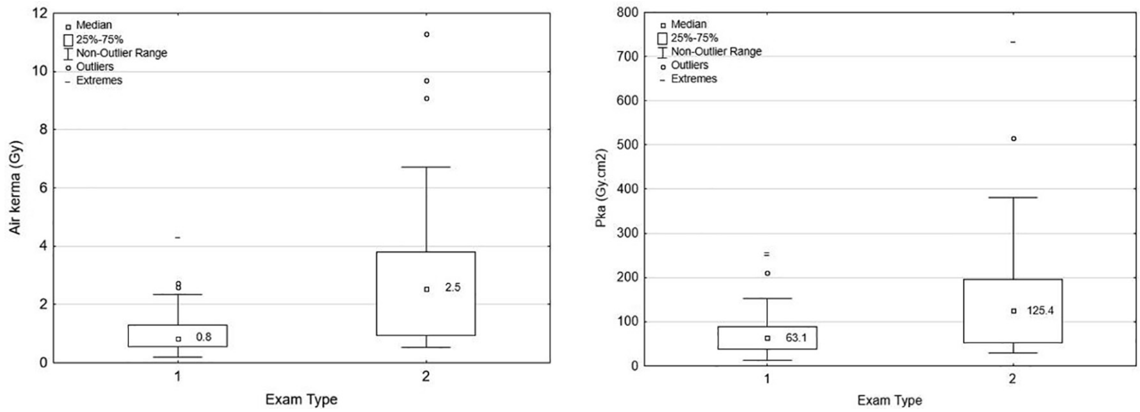

Fig. 1. Boxplots of AK and PKA for CA (1) and PCI (2) procedures. Median values are reported.

The percent of utilization of a primary and secondary angle between −30° and 30° per principal cardiologist showed differences in techniques among the operators for the primary angle utilization, with cardiologist 2 utilizing mostly (73%) smaller angulation and cardiologists 1 and 3 utilizing more often large angulation (58% and 47% respectively). For the secondary angle utilization instead, all cardiologists used mostly the smaller angles (range between 73% and 89%).

3.2. Patient exposure data

Typical clinical indications for the procedures were: angina (stable or instable) (45.2%), silent ischemia (15.1%), pre-surgery (12.3%), valvulopathy (6.8%), and other (20.6%) for CA procedures; and angina (stable or instable) (54.3%), silent ischemia (11.4%), post-heart team discussion procedures (13.2%), other (21.1%) for the PCI procedures.

Fig. 1 reports the box plot of the AK and P_{KA}, in function of the type of procedure. A statistically significant difference between CA and PCI was found both for AK and P_{KA} ($p < 0.001$) for the Mann-Whitney test.

In Fig. 2 the box plot of P_{KA} stratified per cardiologist and grouped per exam type is reported. A statistically significant difference ($p < 0.001$) in dose delivered per exam type is also found among cardiologists but for CA procedures only. Note that cardiologist 2 delivers almost half of the dose than cardiologist 1 (34.1 Gy cm2 vs 67.8 Gy. cm2 for CA procedures and 95.1 vs 162.4 Gy.cm2 for PCI procedures).

In Fig. 3 the influence of patient BMI on AK and on P_{KA} is shown: AK and P_{KA} increase with BMI classes, both for CA and PCI procedures. A significant difference ($p < 0.05$) among BMI classes was observed for

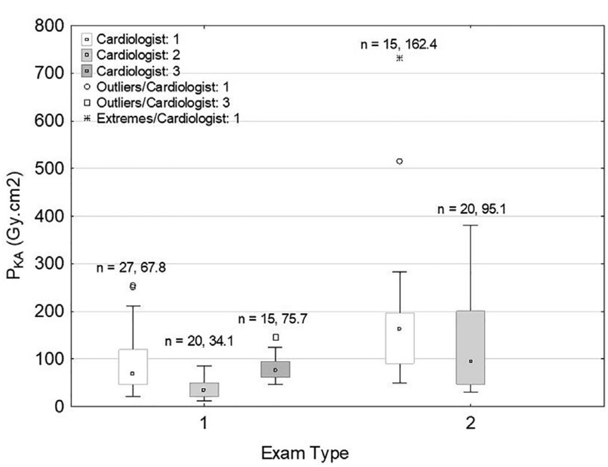

Fig. 2. PKA delivered by each cardiologist per exam type. Number of cases and median values are reported.

CA exams but not for PCI, both for AK and P_{KA}.

When analyzing the exam time duration, we observed that the median per type of procedure increased between 20.0 and 32.5 min in function of patient BMI for CA procedures, with a statistically significant difference among BMI classes ($p < 0.05$). For PCI procedures instead the exam time duration varied between 42.5 and 75 min, but no increasing trend was observed in function of the BMI class and no statistical difference was found among the different BMI classes ($p > 0.05$). A statistically significant difference was observed between CA and PCI procedures in general (p-value < 0.05).

When considering the total FT per type of procedure, we found a statistically significant difference when comparing the CA and PCI procedures ($p < 0.0001$), with a median x-ray time of 3.0 and 13.7 min per CA and PCI procedures, respectively. When comparing the BMI classes within one exam type, statistical difference ($p < 0.05$) was found only for CA procedures (median x-ray time range from 1.7 min to 7.0 min monotonically increasing in function of BMI class). No statistical difference was found instead for PCI procedures (range between 15.9 and 19.9 min with no increasing trend).

Fig. 4 reports the box plots of the total P_{KA} stratified per CI classes (left) and the contribution of cine and fluoroscopy mode acquisition to P_{KA}, also stratified per CI class. Note that CI = 0 indicates diagnostic procedures, for which the CI is not defined. While an increasing trend in P_{KA} is observed for CI classes 0, 1 and 2 (median 63.1 Gy cm2 vs. 94.8 Gy cm^2 vs 168.5 Gy cm^2), the same trend is not observed for CI class 3, possibly because of the low number of cases for this class. This was also reflected in the statistics that indicated no significant difference between P_{KA} among the different complexity index classes, when excluding the CI class = 0 ($p = 0.18$). As expected, the contribution of cine mode acquisition (15 fps) to the P_{KA} is higher than the contribution of fluoroscopy mode acquisition (7.5 fps) for diagnostic procedures and less complex PCI (class 1). Note also that the contribution to P_{KA} of cine mode acquisition decreases with the increase of the complexity of the procedure.

To explain the variability of P_{KA} within the same CI class, we studied the P_{KA} as a function of BMI. For CI = 1, the median P_{KA} increased from 30.7 Gy cm^2 for BMI class 1 to 224.3 Gy cm^2 for BMI class 5 showing an increasing trend with patient BMI. Similar results were observed for CI 2 and 3.

Fig. 5 reports the box plots of the FT (left) and the contribution of cine and fluoro mode acquisition to the total irradiation time (pedal time) (right), stratified per CI class. There was a statistically significant difference ($p < 0.001$) between median FT among CI classes. Again, also FT is increasing with complexity of the procedure. As opposite to Fig. 4 (right) in this case the largest contribution to the total irradiation time comes from the fluoro mode acquisition, which increases with the complexity of the procedure.

In Fig. 6 the stratification of the FT per BMI class, grouped by exam

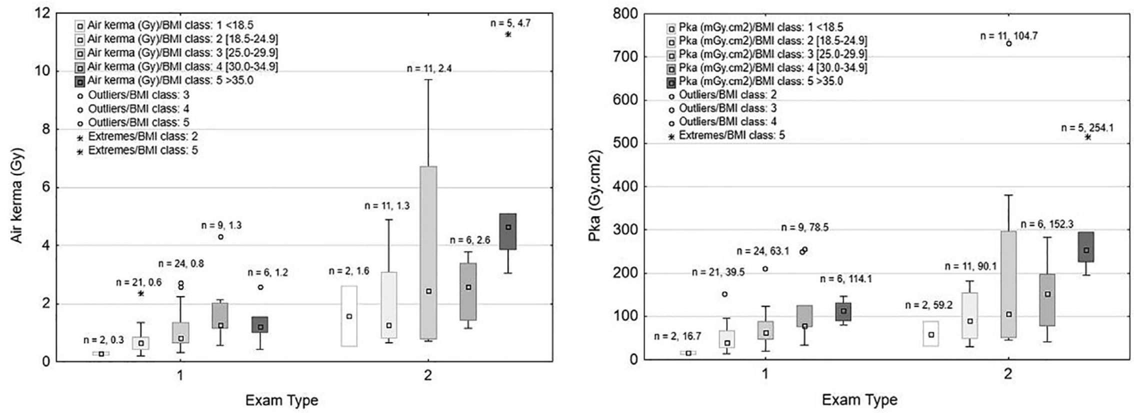

Fig. 3. AK and PKA values stratified per BMI classes for CA (1) and PCI (2) procedures. Number of cases n and median values are reported.

type, is reported. As it can been seen FT increases also with BMI class for CA procedures; a significant difference is also found among the different BMI classes (p-value = 0.005); for PCI procedures instead, no trend is observed (p-value = 0.6).

3.3. Operator dose

In Fig. 7 the operator 1 (principal cardiologist) dose levels for the different anatomical parts are compared between CA and PCI procedures. A statistically significant difference was found for each different anatomical part, between the CA and the PCI procedures (left eye, p-value = 0.02, torso p-value= < 0.001, left wrist p-value = 0.04).

For operator 2 the median dose for PCI procedures was 20.0 µSv, range 2–48 µSv and one exam with 123 µSv. When comparing the dose for the circulating nurse between the two procedures, there was no statistically significant difference (median value for CA = 1.0 µSv and PCI = 2.0 µSv p-value = 0.13).

When comparing the FT per operator for the CA and PCI procedures we found no significant difference across the operators both for CA (p = 0.54, range 2.7–3.3 min) and PCI (p = 1.0, range 11.9–13.7 min) procedures.

When stratifying operator dose for patient BMI, we observed an increasing trend in dose in function of the BMI class for the wrist (range 13–72 µSv for CA and 34–189 µSv for PCI), for the eye (range 2-11µSv for CA and 5–42 µSv for PCI) but in both case there was no statistically significant difference ($p > 0.05$). No increasing trend was observed for the dose to the torso. As an example, Fig. 8 reports the box plots of the eye dose.

When stratifying per CI, an increasing trend was observed in function of the CI class for wrist (range 49–59 µSv) and torso (46–86 µSv) but not for the eye, though the difference among the CI classes was not significant (p- value > 0.05).

4. Discussion

The aim of this study was to assess patient exposure data and operator dose in coronary interventional procedures, when considering patient body-mass index and procedure complexity.

When analyzing patient exposure data, we observed a statistically significant difference ($p < 0.001$) between P_{KA} for CA and PCI procedures with a median P_{KA} of 63.1 vs 125.4 Gy cm^2 respectively. The most recent national study on DRLs for cardiology procedures [13] reported as dose reference levels 71.3 Gy cm^2 for CA and 106.0 Gy cm^2 for PCI procedures, relatively close to the ones of this study. In terms of international dose levels, several articles have published DRLs of patient P_{KA}[14–25]. The most recent being the Finnish national DRLs [14] (30.0 and 75.0 Gy cm^2 for CA and PCI respectively), the Swiss DRLs [24] (50.0 and 100.0 Gy cm^2 for CA and PCI respectively), followed by the second RAY'ACT study [24] results in France (26.0 and 60.0 Gy cm^2 for CA and PCI respectively). There is also a recent study [25] who aimed at establishing European DRLs for interventional cardiology (30.0 and 75.0 Gy cm^2 for CA and PCI respectively).

Our values are closer to the Swiss DRLs and largely above the French, the Finnish data, and the European ones. While variation in CA and PCI doses across hospitals has to be expected [13], one reason for higher doses might be linked to the equipment aging. Note also that the European acceptability criteria for P_{KA} measurements accuracy is 35% [26].

Another interesting aspect related to P_{KA} variation for similar procedure is the impact of the operator. As shown in Fig. 2, a large variability in dose is associated with the operator performing the procedure, although this variability is found to be significant (p-value <

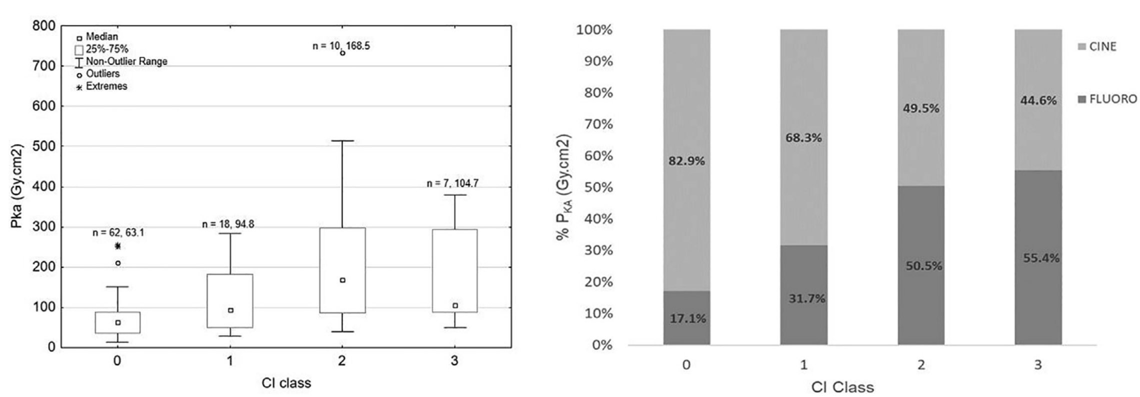

Fig. 4. Comparison of the PKA in function of the CI class (left) with number of cases n and median values reported. On the right the contribution of cine and fluoroscopy mode acquisition to PKA also stratified by CI class. Note that CI class equal to zero means diagnostic procedures (CA).

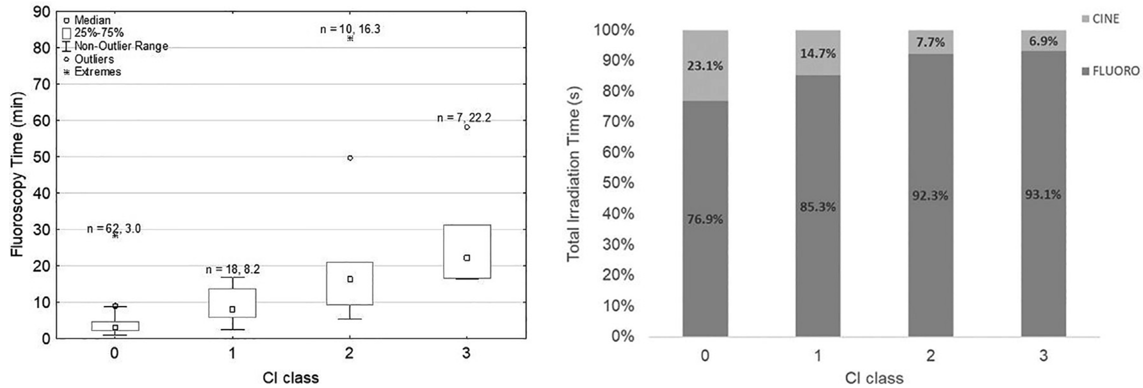

Fig. 5. Comparison of the fluoroscopy time per range of CI classes with number of cases and median values reported. On the right, the contribution of cine- and fluoroscopy-acquisition to the total irradiation time, stratified per CI class is reported.

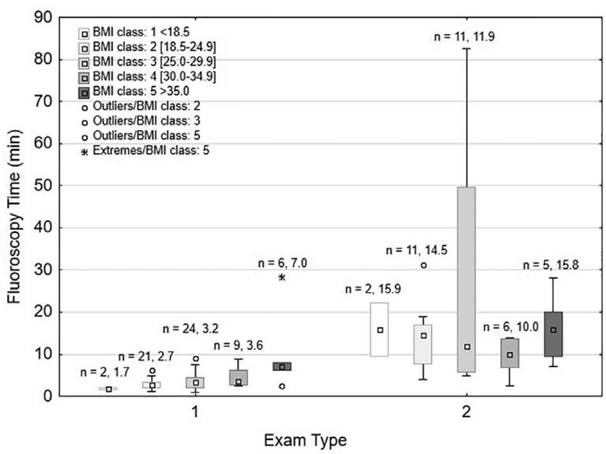

Fig. 6. Stratification of FT per BMI class grouped by exam type. The number of cases and median values per class are reported.

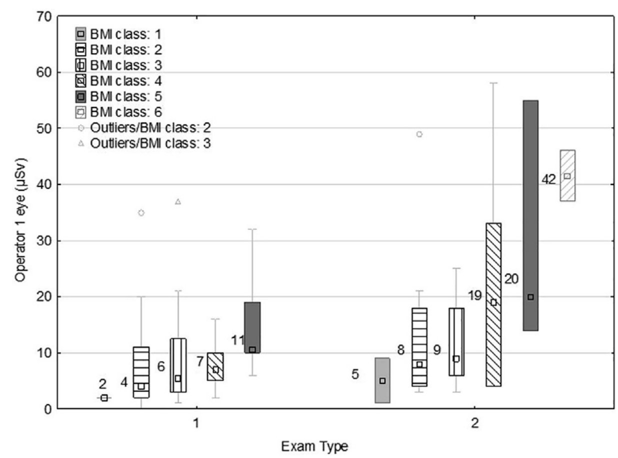

Fig. 8. Principal Operator eye dose stratified per patient BMI class for CA (1) and PCI (2) procedures.

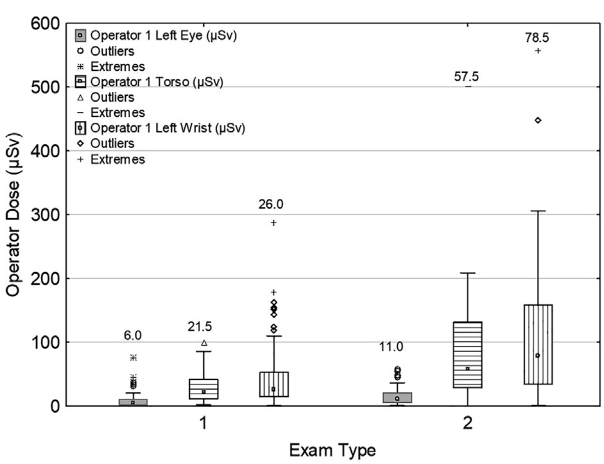

Fig. 7. Dose to the operator 1 (=principal cardiologist) in head, torso and wrist during CA and PCI procedures (left). Median values are reported (n is equal to 35 for each box plot as it is the total number of PCI procedures for this study).

0.001) only for CA procedures, possibly because of the relatively low number of PCI cases. Note that in our study operator 2, with the lowest dose variability has 20 years of experience, compared to operator 1 who has only 5 years of experience. This confirms that education and training remain an important aspect to be addressed in order to reduce dose variability in interventional cardiology.

Respect to earlier published study, this work adds at different levels. We studied the impact of patient BMI on P_{KA} and observed that P_{KA} increases with BMI class for both CA and PCI, although a significant statistical difference was found only for CA procedures. This could suggest that when defining DRLs, a stratification by BMI class could be considered. Indeed a recent study confirmed that obesity is the strongest predictor for both patients and operators to receive a high radiation dose [27]. Note however that for certain classes the number n of data points was too low, and that more data are needed for these classes to assess a solid significance. We also studied the total exam duration (min) and total FT (min) in function of BMI class and found the same trend as for Pka when stratifying per BMI class, suggesting that also for FT DRLs could take into account patient habitus, again for CA procedures only. When comparing the median FT of our study with published data [25] (CA = 4 min and PCI = 13 min), we observed that for lower BMI classes our median FT is much lower (1.7 min −3.6 min for BMI class 1–4) than 4 min and reaches 7 min only for higher BMI classes, for CA. For PCI instead the median values in function of BMI class varies between 10.0 and 19.9 min, to be compared with 12 min reported in literature. Not that the lack of significant difference that we found among BMI classes might be linked to the low number of cases for certain class group.

We studied also the operator doses during CA and PCI procedures. As showed in Fig. 7 the dose to the eye, torso and wrist for the first operator increases by 2, 2.7 and 3 respectively for PCI when compared to CA procedures. Note that we have some extreme cases. For example, the most extreme case for the first operator dose to the wrist (557 µSv) was a complex procedure of a patient with BMI of 36 and a cardiorespiratory arrest which required reanimation procedures, with chronic coronary total occlusion of the right main coronary artery plus flux restauration.

The dose to the torso for the second operator and during PCI procedures had a median value of 20.0 μSv (range 2–48 μSv). For one exam the dose was remarkably high (123 μSv). This was a CA followed by a PCI with 2 vessels to be treated for a very heavy patient (BMI = 37).

When stratifying first operator dose per BMI class we observed an increasing trend in dose in function of the BMI class for the wrist and for the eye but in both case there was no statistically significant difference ($p > 0.05$), probably due to the large 95% confidence interval and the relatively low number of cases in certain BMI classes.

The possibly most novel contribution of this work is the utilization of the CI concept when studying AK, P_{KA}, FT, operator dose. Note that one big advantage in our study was the fully automatic calculation of the CI thanks to interoperability and integration of relevant clinical information in the RIS interface. The concept of CI has been introduced by Bernardi et al. [10] and Balter et al. [11] but to the best of our knowledge no other studies have applied this concept in clinical settings. We observed a trend with higher P_{KA} for higher CI (Fig. 4) though for the same CI we observe some variability too. This has been explained by stratifying per BMI class which showed an increasing trend with patient BMI within the same CI class, suggesting again that not only the complexity of the procedure had an impact on P_{KA} but also the BMI. The same tendency was observed for FT, which significantly increased in function of the CI class (Fig. 5). When studying the impact of the cine mode and fluoroscopy mode acquisition on P_{KA} (Fig. 4, right) we observe that the cine mode contributes substantially to the dose especially for diagnostic or simple procedures. This might explain why we could not find a statistically significant difference among P_{KA} in function of complexity, as we found for the fluoroscopy time, which contributed mostly to the total irradiation time (Fig. 5, right).

When study the impact of the CI on operator dose, an increasing trend was observed in function of the CI class for wrist and torso, though not significant (p- value > 0.05).

In conclusion, dose references levels for P_{KA} and FT in interventional cardiology should be defined in function of CI and BMI classes. These could provide an additional tool for refining a facility's quality assurance and optimization processes.

Our study as also some limitations: (1) while we collected data for > 1 year, due to the rigorous quality check put in place during the study some data had to be discarded. This impacted the number of cases per BMI class or CI when stratifying the analyses, and therefore statistics. (2) For the operator and patient dosimetry, we utilized Raysafe dosimeters which were not always easy to place, especially in the wrist. It is possible that theromuluminescent dosimeters would have been more appropriate and accurate.

Acknowledgement

Camille La Fay for her support in collecting the data and Jérémie Dabin for the Raysafe dosimeter calibration along with manuscript editing.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejmp.2020.05.006.

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