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Polish Journal of Medical Physics and Engineering
The Journal of Polish Society of Medical Physics
ISSN 1898-0309, doi: 10.2478/pjmpe-2025-0004
March 2025
Vol 31, Issue 1

Scientific Paper

Investigation of factors affecting dose-area product during single-vessel percutaneous coronary intervention at the General Hospital of Ioannina "CHATZIKOSTA"

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(received 5 September 2024; revised 19 November 2025; accepted 10 January 2025)

Abstract

Introduction: To process and analyze radiation exposure data from a patient population that underwent single-vessel percutaneous coronary interventions.

Materials and Methods: Dose-area product, fluoroscopy time and number of cineangiography frames were retrospectively collected from 289 patients between January 8, 2021 and February 20, 2023, and their medians were compared with the established national and international diagnostic reference levels. Several patient-, disease-, and procedure-related variables were analyzed in a multiple linear regression statistical model with a dose-area product as the primary endpoint.

Results: The present dose-area product data exceeded most of the proposed diagnostic reference levels (1.8 to 3.0 times higher than the updated European benchmarks), while the opposite trend was observed for fluoroscopy time and cineangiography frames. Through multivariate analysis, each 5 units increase in body mass index led to a 1.17-fold change in dose-area product (95% confidence interval: 1.13 to 1.20); female dose-area product was lower than male (0.83, 95% confidence interval: 0.78 to 0.89); elective (vs ad-hoc) procedures were associated with a decrease in dose-area product (0.88, 95% confidence interval: 0.82 to 0.95); treating complex (vs simple) lesions increased dose-area product by a factor of 1.15 (95% confidence interval: 1.07 to 1.24); each two minute rise in fluoroscopy time conferred a 1.08-fold change in dose-air product (95% confidence interval: 1.07 to 1.09).

Conclusions: Elevated dose-area product underscores the need for investigation. Multivariate analysis demonstrated that higher bone-mass index, male gender, procedural complexity, ad-hoc percutaneous coronary interventions and fluoroscopy time were associated with the highest increase in dose-area product.

Keywords: percutaneous coronary intervention; factors; analysis; diagnostic reference levels; dose-area product.

Introduction

Interventional Cardiology (IC) procedures offer great benefits to patients due to their minimally invasive nature, however, unavoidably expose both patients and staff to variable amounts of radiation. Enhancements of cardiologists' clinical skill levels as well as innovations in catheter and stent technology, enabled the execution of more complex and long-lasting percutaneous coronary interventions (PCIs) but with the cost of higher radiation exposure.[1] Previous studies demonstrated that even an experienced interventional cardiologist at a busy hospital may be exposed to doses that cannot be dismissed from a cancerogenic perspective.[2,3] Additionally, an extensive literature search revealed a multitude of case reports documenting patient radiation-induced skin injuries in patients after PCIs.[4-6] Therefore, it is important to control the dose level and mitigate risk associated with these procedures.

Indispensable tools for procedural dose judgment are diagnostic reference levels (DRLs) that should be nationally established and regularly updated.[7] At a local (hospital) level medical physicists should be responsible for routinely recording dose metrics and comparing their median values with national or international DRLs as part of the procedure optimization efforts. For IC procedures, a plethora of works[8-26] provided national or international DRL values that act as triggers for further examination of the practice. In this field, DRLs were

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Authors' contribution:
A – Research concept and design, B – Collection and/or assembly of data, C – Data analysis and interpretation, D – Writing the article, E – Critical revision of the article, F – Final approval of the article.

commonly proposed in terms of the three most readily available dose-related metrics, namely dose–area product (DAP), fluoroscopic time (FT) and number of cineangiography frames (NCF).[27] However, DAP is recognized as a far more reliable indicator of stochastic risk compared to the other two suboptimal dose metrics.[28]

Determining the factors associated with increased dose metrics, particularly DAP, is an essential step in identifying opportunities for future dose reduction. Along these lines, numerous studies[23,29-35] have assessed various technical, procedural and patient-related variables as radiation dose predictors. Most of these studies demonstrated that several factors pertaining to the complexity of PCI procedures were among the strongest predictors for both patients and operators to receive elevated doses. Remarkably, one of these[33] implemented in clinical settings a complexity index (CI) concept, as introduced by Bernardi et al.[36] and Balter et al.[37], encompassing the most important clinical and technical dose determinants.

In the present study, radiation exposure data from a patient population who underwent single-vessel PCIs in a catheterization laboratory were processed and analyzed. Following International Commission on Radiation Protection (ICRP) guidelines[7], median values of the three metrics were calculated and compared with established national and international DRLs from the literature, as part of a quality assurance program. Additionally, several primary determinants of radiation dose were identified.

Materials and Methods

Data collection

A total of 289 consecutive patients who underwent successful single-vessel ad-hoc and elective PCIs, between January 8, 2021 and February 20, 2023, were enrolled in the study. Procedures were performed by two cardiologists, with one serving as the first operator and the other as an assistant. The two first operators, designated as A and B hereafter, of the catheterization laboratory have the same level of experience (> 100 PCIs per year for ≥ 5 years). Patient characteristics such as weight, height, and age, as well as procedural details including the number of balloons-stents deployed, operators names, vascular territory of the lesion, number of treated vessels, DAP, FT, access route and adjunctive technology (if utilized), were collected for each procedure. The examination protocols were directly generated and printed out from the coronary angiography system at the end of each procedure and included the NCF acquired, cineangiography and fluoroscopy DAP, time and frames per second (fps). Chronic total occlusions (CTOs) and multi-vessel PCIs were excluded due to their significant variation in morphology and technical complexity, which could potentially complicate the interpretation of results and limit the meaningfulness of the findings.

Coronary angiography system

Our catheterization laboratory houses a Siemens single-plane (SIEMENS, Artis Zee, Erlangen, Germany) cardiac angiography unit introduced into service in 2014. The system is equipped with an in-built DAP meter (PTW, Diamentor K1S, Freiburg, Germany) calibration checked, prior to data collection, by a Siemens technician using a semiconductor dosimeter (PTW, DIADOS, Freiburg, Germany) with a calibration factor traceable to German national primary standard laboratory of Physikalisch-Technische Bundesanstalt (PTB). The uncertainty of the DAP-meter, as declared by the manufacturer, is ± 15%. Normal (vs low or high) dose mode for both fluoroscopy and cineangiography acquisitions at a speed of 15 fps was preferentially applied in all of the examined processes. Three image intensifier field sizes with diameters of 25 (routinely used), 20, 16 and 10 cm were available, along with the option for continuously adjustable rectangular field limitations. Quality assurance tests were conducted consistently during the project's timeline to verify the proper functioning of the equipment.

Complexity index (CI) evaluation

CI was evaluated based on the relationship outlined by Balter et al.[37] in the following manner:

$$CI = No.Vessels + No.LesionType \times 0.51 + No.Occlusion > 3Mths \times 0.73 + No.SevTortuosity \times 0.69 + No.BifStenting \times 0.58 \quad \text{Eq. 1}$$

where No.Vessels is the number of vessels (equal to 1 in this study) treated during the procedure, No.LesionType is the number of lesions with an American Heart Association/American College of Cardiology (ACC/AHA) complexity type greater than B2, accessed according to modified AHA/ACC grading system classification,[38] No.Occlusion > 3Mths is the number of occlusions lasting more than 3 months (excluded from this study), No.SevTortuosity is the number of vessels with severe tortuosity (two or more bends ≥ 90°) and No.BifStenting is the number of bifurcation stents placed during the procedure. Lesion type and the presence of severe tortuosity were blindly accessed by the two first operators. The procedures were then categorized into two groups based on different grades of complexity: simple (CI = 1) and complex (CI > 1).

Statistical Analysis

The data was tabulated utilizing Microsoft Excel 2007® (Microsoft Corporation, Redmond, USA) and subsequently imported into the SPSS® software package (IBM, version 25.0, Chicago, USA) for the statistical analysis. Categorical variables are presented in terms of counts and percentages. Continuous variables are described by either mean ± standard deviation (SD) or median with interquartile range (IQR), depending on the normality of their distribution which was assessed using

Shapiro-Wilk test. For normally distributed variables, means between two groups were compared using the Student's t-test. In contrast, when dealing with variables not following normality, differences between two groups were assessed using the (non-parametric) Mann-Whitney U test. Correlations between variables, assessed in terms of Pearson's r-correlation coefficients and corresponding p-values, were estimated through simple linear regression analysis. A multiple linear regression analysis was conducted using DAP as the primary endpoint and investigating various predictors; the natural logarithm of DAP was modeled due to its positively skewed distribution. Predictor variables that were deemed as key descriptors of radiation, patient, disease, or procedure and exhibited a significant ($p \leq 0.10$) impact on the primary endpoint at the preliminary univariable linear regression analysis were incorporated into model. Dummy coding was employed to handle multi-level categorical predictor variables in both regression analyses. The assumptions of our multilinear model were checked in SPSS through various diagnostic tools, including histograms and normal probability-probability (P-P) plots, scatter plots of the residuals, variance inflation factor (VIF) values, Durbin-Watson test etc. A free intercept was employed in the multivariate analysis. The obtained exponentiated beta-coefficients provide the relative influence of each variable on the primary endpoint. High-order (partial) correlation analysis was conducted via the multiple regression model to isolate and assess the specific relationship between DAP and a predictor variable, free from the effects of other potential confounders. Statistical significance was evaluated using a 2-tailed alpha level of 0.05.

Results

Baseline characteristics for the entire study population (n = 289) are summarized in **Table 1**. Considering all patients, the mean age was 62.8 ± 13.3 years, with males accounting for the majority (84.4%). 85.1% of the patients proceeded with ad-hoc PCIs, while the remainder electively. The right radial access (RRA) was utilized in 84.1% of the cases. 268 procedures were performed on a single lesion, while 21 procedures were carried out on double lesions within the same vessel. Clearly, ST-elevation myocardial infarction (STEMI) was the predominant indication for PCI.

Table 1. Patient and procedural characteristics.

Baseline characteristics		**n = 289**
Age, years		62.8 ± 13.3
Male, sex		244 (84.4%)
BMI[a], kg/m^2		28.5 ± 4.1
PCI type	ad-hoc	246 (85.1%)
	elective	43 (14.9%)
Access site	RRA	243 (84.1%)
	other	46 (15.9%)
Number of lesions treated per PCI	1	268 (92.7%)
	2	21 (7.3%)
Indication for PCI	STEMI	120 (41.5%)
	NSTEMI	78 (27%)
	other	91 (31.5%)
Location of lesion	LAD	172 (59.5%)
	LCX	48 (16.6%)
	RCA	69 (23.9%)
First operator	A	137 (47.4%)
	B	152 (52.6%)
NS	0	6 (2.1%)
	1	207 (71.6%)
	2	63 (21.8%)
	>2	13 (4.5%)
UAT		13 (4.5%)
CI	1 (simple)	213 (73.7%)
	> 1 (complex)	76 (26.3%)

[a]*Weight was not recorced in five cases.*

BMI: Body-mass index; PCI: Percutaneous coronary intervention; RRA: Right radial access; STEMI: ST-elevation myocardial infarction; NSTEMI: Non-ST-elevation myocardial infarction; LAD: Left ascending artery; LCX: Left circumflex artery; RCA: Right coronary artery; NS: Number of stents; UAT: Utility of adjunctive technology; CI: Complexity index.

Stents were deployed in 97.9% of the patients, of whom 59.5% had lesions in the left anterior descending (LAD) artery, 16.6% in the left circumflex (LCX) artery and 23.9% in the right coronary artery (RCA). On average, 1.9 ± 0.9 balloons were used and 1.3 ± 0.6 stents implanted per therapeutic process. Number of procedures was well-balanced between the two operators. Adjunctive technologies (intravascular ultrasound (IVUS), fractional flow reserve (FFR), optical coherence tomography (OCT) and rotablation) were employed in 4.5% of procedures. Most of the procedures (73.7%) were classified as simple (CI = 1). The mean body-mass index (BMI) for the available data was 28.5 ± 4.1 kg/m^2, indicating that a typical cardiology patient in our catheterization laboratory falls into the overweight category. Weight was not recorded in five cases, leading to 1.7% missing data for BMI.

Median with IQR values of the three exposure metrics obtained by the present work for all PCI types are displayed in **Table 2**. Also shown are the means of percentages distribution of the two acquisition modes (fluoroscopy and cineangiography) in relation to the total metric. Median values of the three metrics associated with ad-hoc PCI procedures were significantly higher than those of elective procedures, with p-values less than 0.001 for DAP and NCF, and p = 0.03 for FT. In general, 35-45% of total DAP is attributable to cineangiography, which claims only 7.5-10% of the total exposure time, depending on PCI type.

Table 3 displays data derived from the present study along with published national and international DRLs.[8-26] In the context of single-vessel PCIs, the current DAP values are comparable with those derived from Queensland's study[15] through more complex procedures, but notably higher (1.7- to 2.7-fold) than the proposed levels for India,[23] Philippines[24] and Ireland.[25] Regarding pooled (single- and multi-vessel) operations, the current median DAP values closely align with our national DRLs[14] and those recommended by Switzerland (for elective PCIs),[8] Bulgaria[13] and Malta.[21] Moreover, the current data are higher than the levels reported from the rest of the European countries. Note that they are approximately 1.8 times greater than the highest value quoted in the updated European DRLs.[16-18,20,22,25] Our DAP values are kept under the levels proposed by Switzerland (for ad-hoc procedures),[8] USA[12] and South Korea.[19] When it comes to FT and NCF, our medians are lower than all the reported data from single-vessel PCI studies. However, comparing the current data related to single-vessel approaches with those acquired through pooled (encompassing both single- and multiple-vessel) approaches lacks meaningful context, as the single-vessel values in their dataset may potentially be smaller than our own.

Table 2. Median with IQR values of the three exposure metrics obtained by the present work for all PCI types. The means of percentages distribution of the two acquisition modes (F and C) in relation to the total (T) metric are also shown.

Metric		PCI type					
		ad-hoc (n = 246)		*elective (n = 43)*		*combined (n = 289)*	
		Median (IQR)	**Percentage to *T* (%)**	**Median (IQR)**	**Percentage to *T* (%)**	**Median (IQR)**	**Percentage to *T* (%)**
DAP (Gy cm^2)	*T*	138.0 (106.8-177.0)		116.6 (76.3-139)		135.3 (102.8-172.8)	
	F	75.6 (53.4-103.2)	55.6	68.3 (45.6-99.8)	64.5	74.2 (52.6-102.7)	56.9
	C	58.4 (45.4-79.0)	44.4	34.8 (26-47.1)	35.5	56.2 (40.6-77)	43.1
Time (min)	*T*	11.1 (8.7-14.0)		9.4 (6.9-12.5)		10.9 (8.5-14)	
	F	10.0 (7.8-13.0)	90.1	8.6 (6.3-11.4)	92.5	9.7 (7.6-13)	90.4
	C	1.0 (0.8-1.3)	9.9	0.6 (0.5-0.8)	7.5	1.0 (0.8-1.3)	9.6
NCF		909 (748-1176)		551 (416-753)		869 (695-1141)	

PCI: Percutaneous coronary intervention; IQR: Interquartile range; T: Total; F: Fluoroscopy; C: Cineangiography; DAP: Dose-area product; NCF: Number of cineangiography frames.

Table 3. Comparison of the present median values for the three exposure metrics and PCI types with national and international DRLs.

Country	PCI type	DRL (75th percentile)[a]		
		DAP (Gy·cm²)	FT (min)	NCF
Switzerland[8]	ad-hoc	260	20	2800
	elective	110	20	1500
Belgium[9]	combined[b]	106.0		
UK[10]	elective[c]	50	13	
Croatia[11]	combined	72	19	1270
USA[12]	ad-hoc	199	18.1	
	elective	193	18.5	
Bulgaria[13]	ad-hoc	140		
Greece[14]	combined	129.3	17.8	
Queensland[15]	ad-hoc[d,e]	129	17.4	
Finland[f,16]	ad-hoc	75	15	
France[f,17]	combined	60	11	666
Europe[1]	elective	85		
Norway[f,18]	ad-hoc	48.1		
	elective	56.6		
South Korea[19]	elective	171.3	22.3	1942
Germany[f,20]	ad-hoc	55	13	
	elective	48	13	
Malta[21]	ad-hoc	126		
Spain[f,22]	combined	78	15	1337
India[23]	ad-hoc[d]	72	15.1	1245
	elective[d]	49.8	18.2	1128
Philippines[24]	ad-hoc[d]	68.2	13.7	
	elective[d]	70.1	14.3	
Ireland[f,25]	ad-hoc[d]	50.2		
	ad-hoc	68.3		
	elective[d]	51.9		
	elective	96.5		
Thailand[26]	combined	91.3		
present study (median)	ad-hoc[d]	*138.0*	*10*	*909*
	elective[d]	*116.6*	*8.6*	*551*
	combined[d]	*135.3*	*9.6*	*870*

[a]*75th percentile of the metric distribution in total study population or of the median measured in the facilities participating in multicenter surveys, unless explicitly stated otherwise;* [b]*combined: ad-hoc & elective PCIs;* [c]*single stent procedures;* [d]*single-vessel procedures;* [e]*CA ± left heart catheterisation and/or left ventriculography plus PCI;* [f]*European updated studies.*

PCI: Percutaneous coronary intervention; DRL: Diagnostic reference levels; DAP: Dose-area product; FT: Fluoroscopic time; NCF: Number of cineangiography frames; CA: Coronary angiography.

Given the aforementioned comparison, it is evident that among the three exposure metrics, the current DAP values stood out significantly, being higher than most of the reported DRLs. Hence, the ensuing findings were derived from an analysis exclusively centered on this particular metric. Specifically, **Table 4** displays the p-values resulting from the univariate regression analysis assessing the relationship between the response variable (DAP) and predictor variables, whether they are continuous or fall into dichotomous or polytomous categorical types. **Table 4** additionally shows Pearson's r-coefficients, derived from the aforementioned analysis, for statistically significant correlations ($p \leq 0.10$) which were categorized as follows: very weak ($r < 0.2$), weak ($0.2 \leq r < 0.4$), moderate ($0.4 \leq r < 0.6$) and strong ($r \geq 0.6$). A strong relationship was observed between DAP and CI as well as FT, while its association with BMI and NCF was moderate. Moreover, DAP was weakly correlated with number of stents (NS) and very weakly with gender, PCI type and utility of adjunctive technologies (UAT). No significant link was found between DAP and age, access route, artery type, operator as well as indication for PCI. Consequently, these variables were not incorporated into the multilinear model.

In the present multiple regression model for LnDAP, examination of plot residuals uncovered no violations of the assumptions regarding their adherence to a normal distribution and manifestation of homoscedasticity. Moreover, 76% of the variance in LnDAP dataset was explained collectively by the independent variables ($r^2 = 0.76$). The Durbin-Watson statistic test yielded a value of 1.9, close to the ideal value of 2, indicating non-autocorrelation in the residuals of the model.

Table 4. Univariate regression analysis results

Predictor variables		**Response variable (DAP)**		
		p-values	**r-coefficient**[a]	**correlation strength**[b]
Age		0.41		
Gender (male: 0; female: 1)		0.02	0.14	very weak
BMI		< 0.0001	0.40	moderate
Access route (RRA: 0; other: 1)		0.20		
Artery type	LAD & LCM: 0; RCA: 1	0.17		
	LAD & RCA:0; LCM: 1	0.19		
Operator (A: 0; B: 1)		0.59		
NS (≤ 1 stent: 0; > 1 stent: 1)		< 0.0001	0.28	weak
Indication for PCI	other: 0; STEMI:1	0.27		
	other: 0; NSTEMI:1	0.62		
PCI type (ad-hoc: 0; elective: 1)		< 0.01	0.19	very weak
UAT (no: 0; yes: 1)		0.038	0.12	very weak
CI (simple: 0; complex: 1)		< 0.0001	0.66	strong
NCF		< 0.0001	0.49	moderate
FT		< 0.0001	0.70	strong

[a]*Pearson's r-coefficients and the association correlation strength are displayed when $p \leq 0.10$;* [b]*Very weak ($r < 0.2$), weak ($0.2 \leq r < 0.4$), moderate ($0.4 \leq r < 0.6$) and strong ($r \geq 0.6$).*

DAP: Dose-area product; BMI: Body-mass index; RRA: Right radial access; LAD: Left ascending artery; LCX: Left circumflex artery; RCA: Right coronary artery; NS: Number of stents; STEMI: ST-elevation myocardial infarction; NSTEMI: Non-ST-elevation myocardial infarction; PCI: Percutaneous coronary intervention; UAT: Utility of adjunctive technologies; CI: Complexity index; NCF: Number of cineangiography frames; FT: Fluoroscopic time.

Figure 1 depicts multivariate regression analysis results expressed as fold change (exponentiated beta coefficients) in DAP derived from the impact of each predictor variable, with the associated changes accompanied by 95% confidence intervals (95% CI) and p-values. Clearly, neither NS nor UAT exhibited a significant impact on DAP, as evidenced by the p-values of 0.83 and 0.16, respectively. Compared with males, lower DAP was found in females (0.83, 95% CI: 0.78 to 0.89). Each 5 units increase in BMI led to a 1.17-fold change in DAP (95% CI: 1.13 to 1.20). As expected, elective (vs ad-hoc) procedures were associated with a modest decrease in DAP (0.88, 95% CI: 0.82 to 0.95). Moreover, treatment of complex lesions was associated with an increase in DAP by a factor of 1.15 (95% CI: 1.07 to 1.24). Each two-minute rise in FT conferred a 1.08-fold change in DAP (95% CI: 1.07 to 1.09). Although NCF was among the contributors of elevated DAP, its influence was nearly negligible (1.00033, 95% CI: 1.00026 to 1.00041). High-order (partial) correlation analysis results are presented in **Table 5**. Specifically, partial correlation coefficients between DAP and predictor variables are displayed, along with the corresponding measures of correlation strength for those relationships that reach statistical significance ($p \leq 0.10$). After adjusting for potential confounding variables, DAP exhibited a strong association exclusively with FT. The relationship between DAP and CI diminished from strong to moderate. Correlation coefficients of DAP with BMI and gender increased, yet their associations remained moderate and weak, respectively. The correlation between DAP and NCF remained unchanged, while the association between DAP and PCI type weakened. In contrast to the findings from the zero-order correlation analysis (**Table 4**), no significant link was found between DAP and NS or UAT.

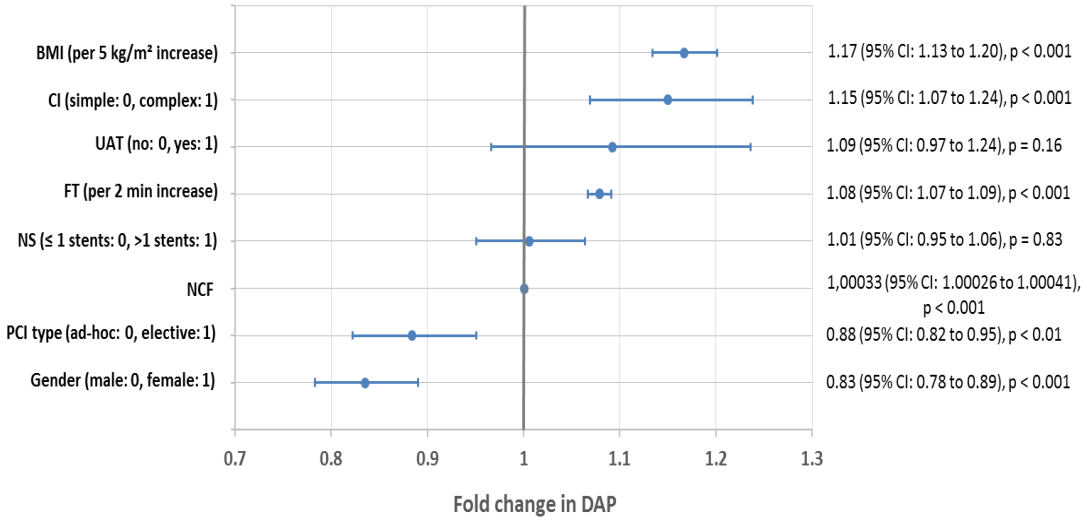


Figure 1. Multivariate regression analysis results expressed as fold change (exponentiated beta coefficients) in DAP accompanied by 95% CI and p-values. Error bars represent 95% CI.

DAP: Dose-area product; BMI: Body-mass index; CI: Complexity index; UAT: Utility of adjunctive technologies; FT: fluoroscopic time; NS: Number of stents; NCF: Number of cineangiography frames; PCI: Percutaneous coronary intervention; 95% CI: 95% Confidence intervals.

Table 5. High-order (partial) correlation analysis results.

Predictor variables	Response variable (DAP)		
	p-values	partial correlation coefficient[a]	correlation strength[b]
Gender (male: 0; female: 1)	< 0.001	0.14	very weak
BMI	< 0.001	0.59	moderate
NS (≤ 1 stent: 0; > 1 stent: 1)	0.34		
PCI type (ad-hoc: 0; elective: 1)	0.10	0.09	very weak
UAT (no: 0; yes: 1)	0.76		
CI (simple: 0; complex: 1)	< 0.001	0.35	weak
NCF	< 0.001	0.49	moderate
FT	< 0.001	0.69	strong

[a]*Partial correlation coefficients and the association correlation strength are displayed when $p \leq 0.10$;* [b]*Very weak ($r < 0.2$), weak ($0.2 \leq r < 0.4$), moderate ($0.4 \leq r < 0.6$) and strong ($r \geq 0.6$).*

DAP: Dose-area product; BMI: Body-mass index; NS: Number of stents; PCI: Percutaneous coronary intervention; UAT: Utility of adjunctive technologies; CI: Complexity index; NCF: Number of cineangiography frames; FT: Fluoroscopic time.

Discussion

By comparing our median values for the three exposure metrics with the proposed national and international DRLs, we can gauge where our hospital's current patient and staff dose practices stand in relation to established benchmarks. With respect to FT and NCF, the present data were lower than most of the recommended DRLs. On the other hand, the present DAP values surpassed the majority of them, underscoring the potential for a heightened level of radiation exposure in our environment when contrasted with the established safety standards in those countries. Notably, the most significant disparities emerge when comparing present DAP to the updated European levels,[16-18,20,22,25] with our values ranging from 1.8 to 3.0 times higher. While pinpointing the exact cause of these considerable differences remains challenging, it is reasonable to infer that these discrepancies may, at least in part, be attributable to the comparatively lesser radiation protection training received by the interventionists at our hospital, in contrast to the training provided to interventionists in the aforementioned European countries with updated standards. For instance, in Spain, all interventionists have been required since 1999 to obtain official certification in radiological protection for interventional practices, issued by the relevant health authority.[22] A trend towards a progressive reduction in DRLs during procedures was confirmed by these revised results, emphasizing the importance of following ICRP's recommendations for regular updates not exceeding 5 years.[7] However, comparison of the present findings with those derived from pooled procedures should be approached with caution. Interestingly, the observed differences could either diminish (in the case of FT and NCF) or become more pronounced (in the case of DAP) when focusing on the data from single-vessel procedures within the pooled dataset.

In patients undergoing PCIs, the tissue that receives the highest radiation dose is the skin.[39] Patient skin dose evaluation can be accomplished by means of DAP.[39,40] DAP-based alert levels for a maximum skin dose (MSD) of 2 Gy, which is considered as the skin transient erythema threshold, fell within the range of 150 to 300 Gy·cm^2.[1] According to present results, 38.8% of procedures exceeded a value of 150 Gy·cm^2, while 1.7% of procedures exceeded 300 Gy·cm^2. However, no cases of deterministic radiation-induced skin effects in patients have ever been reported in our catheterization laboratory. Compared to Siiskonen et al.,[1] the present data demonstrated a roughly 2.4-fold increase in the percentage of procedures exceeding 150 Gy·cm², as expected, given that our median DAP surpasses their established European DRL. On the other hand, our procedural percentage associated with a DAP greater than 300 Gy·cm^2 was approximately 0.6 times smaller, because complex PCIs were excluded from this work.

In light of these findings, it is imperative to delve into the factors responsible for the current elevated DAP and to evaluate potential contributors to the increased radiation exposure. In this context, through univariate analysis a moderate correlation ($r = 0.4$) between DAP and BMI was obtained, mirroring the value of Larrazet et al.[29] Additionally, when assessing the Spearman's rank correlation coefficient for these two variables to compare with the findings of Neil et al.,[41] we obtained a value of 0.37, which aligned to their reported value (0.42). After accounting for potential confounders through high-order (partial) correlation analysis, the association between DAP and BMI was strengthened, approaching the lower boundary of strong categorization. Furthermore, the present multivariate analysis revealed that BMI is a predictor of higher DAP, aligning with the findings of several prior studies.[23,30-32,34] In fact, thicker patients necessitate higher doses due to the automatic exposure control (AEC) feature, which amplifies tube voltage and current to uphold optimal radiation levels at the image receptor, compensating for the increased amount of tissue traversed by X-rays.

In addition to BMI, gender was incorporated into analysis to account for the impact of patient size on DAP. Consistent with the findings of previous studies,[23,27,30,34,35] current results showed that males were associated with higher DAP than females, even though both groups have similar median BMIs (27.9 [IQR: 25.7 to 31.1] kg/m^2 for males vs 28.6 [IQR: 25.8 to 31.2] kg/m^2 for females, $p = 0.14$). A potential reason for this gender-based difference could be weight as males were heavier than females, with median weights of 85 (IQR: 76 to 95) kg and 72 (IQR: 65 to 82.8) kg, respectively ($p < 0.001$). Note that Verdoia et al.[42] demonstrated that weight should be considered as the preferred anthropometric index when optimizing radiation exposure during IC procedures. However, most studies have primarily utilized BMI for addressing this matter since it provides a more realistic description of patient's thickness at the site of interest.[43] Furthermore, weight of patients cannot be easily modified, whereas the reduction of the amount of their BMI exposed through the use of non-lead shielding materials has the potential to decrease DAP.[34] Unfortunately, the development of such materials remains a challenging task, necessitating additional research efforts.

In the context of investigating the association between PCI type and DAP, both the present multiple regression analysis and those conducted by Subban et al.[23] as well as Smith and Rivers[27] revealed that ad-hoc PCIs were linked to increased DAP. This was an expected finding and can be attributed to the diagnostic component, during which cardiologists primarily utilize cineangiography-dominated projections to assess the lesion, resulting in a significant increase in radiation exposure. However, this trend was not demonstrated by Sadick et al.[44] who found no significant differences in DAP between primary and elective procedures.

A group of researchers[27,29-31,33] observed that heightened radiation exposure was linked to procedural complexity, which was assessed by considering various factors related to patient's anatomy and to the severity of the treated pathology. In this

study, it was considered practical to investigate the impact of procedural complexity on DAP by employing an index that comprehensively encompasses clinical, anatomical, and technical factors previously identified as significant contributors to dose.[36,37] Along these lines, CI exhibited a strong correlation with DAP (r = 0.66) through univariate analysis, similar to the finding in the study of Bernardi et al. (r = 0.716).[36] However, this strong association attenuated to a moderate one after adjusting for potential confounders using high-order (partial) correlation analysis. Moreover, a trend with higher DAP for higher CI was derived from the multilinear regression model. Being aware of these correlations can provide valuable guidance for pre-procedure planning. For instance, when treating complex lesions, especially in high-BMI patients, radiation management strategies can be integrated into the planning process to minimize radiation exposure while ensuring effective treatment. Consistent with earlier investigations,[1,23,29] the present work revealed that FT exerted a notable influence on DAP. Additionally, it was observed that NCF emerged as a significant predictor of increased DAP, albeit to a lesser extent, aligning with the findings reported by Subban et al.[23] Through univariate analysis, a robust correlation (r = 0.7) between both measurements (FT and DAP) was noted, closely mirroring the reported values in various studies such as Larrazet et al. (r = 0.75),[29] Georges et al. (r = 0.73) prior to the implementation of their dose reduction programme,[45] and Roongsangmanoon et al. (r = 0.71).[46] The current values were also in accordance with those of Brnić et al.[11] (r = 0.61) and Georges et al. (r = 0.62) after the implementation of their dose reduction programme.[45] As for NCF, a milder correlation with DAP (r = 0.40) was found, in contrast to the stronger correlation reported by Brnić et al. (r = 0.68).[11] The aforementioned coefficients remained consistent following the high-order (partial) correlation analysis. Mitigating FT has long been regarded as a fundamental strategy for enhancing radiation safety in cardiac catheterization labs.[47] Moreover, addressing important factors that may prolong FT can reduce the risk of clinical complications.[48]

In the presence of any of the above high radiation risk scenarios, it is imperative to conduct a comprehensive reassessment of adopting dose-reduction techniques before initiating the procedure.[35] Specifically, cost-free techniques such as fluoroscopy frame rate reduction, especially in longer or more complex procedures where this component constitutes a more substantial contribution to the total dose,[27] opting for selective fluoroscopic image storage instead of cineangiography, with the latter employed only when needed,[49] and utilizing less angulated projections during imaging whenever possible, particularly in high-BMI patients,[34] are prevalent for achieving dose reduction in PCI. A marked reduction in both DAP and patient's effective dose of ~39% was found during single-vessel PCI, after the implementation of a simple and cost-free dose-saving practice involved lowering of fluoroscopic frame rate from 15 to 7.5 frames per second and increased collimation.[50]

The influence of NS on DAP was also assessed by comparing the deployment of 1 stent vs 2 stents, considering their majority in the overall distribution of stents. Univariate analysis demonstrated that NS was related to DAP. Moreover, the current median DAP increased with NS (130.0 [IQR: 96.1 to 155.9] Gy·cm^2 for ≤ 1 stent vs 158.6 [IQR: 129.4 to 204.5] Gy·cm^2 for > 1 stent, $p < 0.0001$), which corresponded to the findings of Boland et al.[51] Note, however, that they did not explicitly report p-values for DAP differences between two groups of deployed stent number. In the present multilinear model, although there was a slight rise in DAP with the escalation of NS, this trend did not reach statistical significance. Furthermore, high-order (partial) correlation analysis revealed no significant association between DAP and NS. Notably, Koh et al.[34] observed incremental increases in DAP with multiple stent implantation ($p < 0.05$), yet they did not include the comparison of 1 stent vs 2 stents in their analysis. Similarly to NS, UAT was correlated with DAP by univariate analysis, but this relationship was not statistical significant by multivariable analysis. It is highly likely that this finding may have been affected by insufficient statistical power, given the low representation of PCIs involving these technologies in the total cohort (4.5%). Undoubtedly, a larger dataset would have been required to assess a solid significance for these procedures.

In the current work, age, catheterization access route, artery type, operator and indication for PCI did not demonstrate a significant trend in the preliminary univariate analysis and, therefore, were not included in the multilinear model. Specifically, no significant association between DAP and access route was found, aligning with the results of Kuipers et al.[30] and Delewi et al.,[31] but contradicting the conclusions of other researchers[29,32,40] who observed higher DAP in one of the two routes. Over the years, controversial results have been reported regarding the elevated exposure rates typically linked to one specific access route over another, and as of now, a consensus on this issue remains elusive. However, taking into account our findings and the clinical superiority of the radial route,[52] it's highly unlikely that we would change our current practices in favor of the femoral route.

No correlation between DAP and operator was also found. Interestingly, procedures performed by operator A were related to longer cineangiography time (CT) and shorter FT compared to those performed by B (mean CT [1.3 ± 0.4] min for A vs [0.8 ± 0.2] min for B, $p < 0.0001$, and median FT 9.0 [IQR: 7.2 to 11.5] min for A vs 10.8 [IQR: 8.0 to 13.7] min for B, $p < 0.001$). Consequently, a noteworthy contrast in DAP derived from cineangiography emerged between the two operators (median 71.1 [IQR: 53.7 to 90.3] Gy·cm^2 for A vs 46.3 [IQR: 35.0 to 58.3] Gy·cm^2 for B, $p < 0.0001$), whereas the scenario reversed when examining DAP stemming from fluoroscopy (median 62.7 [IQR: 45.8 to 87.0] Gy·cm^2 for A vs 85.4 [IQR: 60.0 to 112.0] Gy·cm^2 for B, $p < 0.0001$). Additionally, BMI of patients who underwent PCIs performed by the two operators were not

statistically significantly different (median 28.4 [IQR: 25.9 to 31.2] kg/m^2 for A vs 27.8 [IQR: 25.6 to 31.1] kg/m^2 for B, p = 0.50). Moreover, the percentages of simple and complex in relation to total procedures were nearly identical between operators (79.56% simple and 20.44% complex for A vs 79.60% simple and 20.40% complex for B), both of whom possessed an equivalent level of experience. Therefore, the above finding could be explained by the compensatory effect between the differences in the utility of cineangiography and fluoroscopy mode among operators, ultimately resulting in no significant differences in total DAP.

Certain authors[30,31] have reported an association between DAP and lesion location, while others[43,51,53] have reported the opposite, which is consistent with present findings. Given the complexities of coronary lesions and the difficulties in vascular access in elderly patients, the influence of age on DAP was also investigated and no significant correlation between them was found, in agreement with Faroux et al.[32] and Ureyenet al.[54] In contrast, the multivariate analyses of Delewi et al.[31] and Koh et al.[34] unveiled a modest association between these two variables. This study also revealed no significant correlation between DAP and the indication for PCI, whether comparing other indication to STEMI or other indication to NSTEMI cases, which did not coincide with the findings of Stocker et al.[35] It's noteworthy, however, that they opted not to include indications for PCI among the clinically significant predictors, attributing this decision to the relatively minor impact of this variable on DAP as compared to other influencing factors.

The present analysis has several limitations. Firstly, the retrospective design of the study imposes constraints on conclusions regarding causality. Secondly, this is a single-center survey focused on single-vessel PCIs, and therefore, findings may not be extentable to other centers or multiple-vessel procedures. Unfortunately, we did not monitor technical factors that could potentially impact radiation dose, such as field of view, collimation, source-to-image distance and angulations, rendering us unable to incorporate them into the statistical analysis. Finally, radiation exposure was approximated by DAP. However, a more direct quantification of patient and operator doses could have been achieved through thermoluminescence or film dosimetry.

Conclusion

In conclusion, the present DAP values exceeded the majority of proposed national and international DRLs, highlighting the necessity for a comprehensive investigation and strongly suggesting an opportunity for improvement in our practices. Therefore, it was crucial to identify clinically relevant and independent predictors of elevated DAP. Utilizing a multivariate model, several key determinants of DAP during single-vessel PCI were identified, demonstrating that higher BMI, male gender, procedural complexity, ad-hoc PCIs and FT were associated with the highest increase in DAP. In the presence of these high radiation risk scenarios, clinicians must implement pre-procedure dose planning by meticulously reviewing all available dose-reduction techniques and incorporating them into practice.

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