Analysis of factors that affect radiation dose level during interventional cardiology procedures using logistic regression

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Received 28 July 2022; accepted 6 September 2022

Interventional cardiology procedures (ICP) are considered some of the main medical procedures in which patients are exposed to high doses of radiation. The aim of this study was to examine how to control the level of radiation exposure and to analyze and study the factors affecting the increase in radiation exposure from the specified level using a regression method. The results correctly predicted that in 80.0 %, 90.5 %, and 95.2% of the cases, there were routine dose area product (DAP) levels, and in 64.3%, 33.3%, and 77.8% of cases, there were high levels of DAP, giving an overall percentage, correct prediction rate of 72.45%, 73.35%, and 90.0%, for coronary angiography (CA), percutaneous coronary intervention (PCI), and combined CA with PCI (CA/PCI), respectively. All the factors studied in this research, namely voltage (kV), current (mA). Fluoroscopy Time (FT) and Body Mass Index (BMI), have a significant relationship with the DAP level. We concluded that regression analysis is a reliable method for evaluating the user protocol in a center or hospital and identifying variables that have an effect on the dose area product level in interventional cardiology.

Keywords: Interventional cardiology; fluoroscopy; logistic regression.

DOI: https://doi.org/10.31349/RevMexFis.69.031101

1. Introduction

Interventional cardiology procedures (ICP) are some of the major medical examination methods applied for the detection of cardiovascular diseases under fluoroscopic X-ray guidance to obtain images of the heart chambers, valves, and surrounding blood vessels [1]. The most frequently reported cardiac procedures by interventional fluoroscopy are coronary angiography (CA), percutaneous coronary intervention (PCI), and combined CA with PCI (CA/PCI) [2]. Due to the use of X-rays in interventional cardiac procedures, it is considered one of the main medical procedures in which patients are exposed to high doses of radiation. X-rays are ionizing radiation and pose a significant risk, with the main radiation-induced side effects being being skin injury (deterministic effect or tissue reaction) and increased cancer risk (stochastic effect) [3]. Therefore, more preventive measures and studies are needed to reduce the radiation dose. The radiation dose of the patient during interventional cardiology is influenced by three types of factors. First, the technical factors affecting the radiation dose (X-ray beam quality, X-ray geometry, X-ray beam limitation devices, and fluoroscopic and acquisition imaging dose rate settings). Second are procedure-related factors, which include the increase in the treatment of complex lesions, such as chronic total occlusions, because of improvements in techniques and PCI equipment. The third is the group of factors that are patient-related (body mass index (BMI), comorbidities, and seriousness of coronary artery disease) [4,5].

In general, for radiation protection and development of quality assurance programs, reference levels (RLs) were introduced by the International Commission on Radiological Protection. Establishing RLs for interventional cardiology is challenging because there are many factors influencing these procedures that lead to a wide dose distribution [6]. In interventional cardiology (IC), several research studies have focused on the dose area product for the establishment of reference levels and dose optimization [7,8]. However, literature data reveal that the most commonly studied parameters for cardiac interventions are BMI, fluoroscopy time (FT), peak skin dose, and dose area product (DAP) for each procedure [2-10].

The aim of this study was to examine how to control the level of radiation exposure, to analyze and study the factors affecting the increase in radiation exposure from the specified level, and to estimate the incidence of high radiation dose procedures using a logistic regression method.

2. Methods and materials

2.1. Logistic Regression

Logistic regression is a reliable method of identifying which variables have an impact on a topic of interest. The process of performing a regression allows one to confidently determine which factors matter most and which can be ignored. Binary logistic regression is used to estimate the association of one or more independent (predictor) variables with a binary dependent (outcome) variable. A binary (or dichotomous) variable is a categorical variable that can only take two different values or levels. The model usually has two types of objectives: predictive or explanatory. In a model with predictive objectives, we aim to establish a parsimonious model, *i.e.*, a model involving the least number of variables that best explains the dependent variable. In the case of a model with explanatory objectives, we aim to study the causal relationship between a 'cause' variable and an 'effect' variable. Given a set of values of the independent variables, we wish to estimate the probability that the event of interest will occur and evaluate the influence each independent variable has upon the response in the form of an odds ratio (OR). The form for predicted probabilities is expressed as a natural logarithm (ln) of the odds ratio [11].

$$\ln\left[\frac{P(Y)}{1-P(Y)}\right]=\beta_0+\beta_1X_1+\beta_2X_2+\ldots+\beta_kX_k, \quad (1)$$

$$\left[\frac{P(Y)}{1-P(Y)}\right]=e^{\beta_0+\beta_1X_1+\beta_2X_2+\ldots+\beta_kX_k}, \quad (2)$$

$$[P(Y)]=\frac{e^{\beta_0+\beta_1X_1+\beta_2X_2+\ldots+\beta_kX_k}}{1+e^{\beta_0+\beta_1X_1+\beta_2X_2+\ldots+\beta_kX_k}}, \quad (3)$$

where, $\ln[P(Y)/(1-P(Y))]$ is the log (odds) of the outcomes, Y is the dichotomous outcome; $X_1, X_2, \ldots\ldots., X_k$ are the predictor variables, $\beta_1, \beta_2, \ldots., \beta_k$ are the regression (model) coefficients, and β_0 is the intercept. In Eq. 3, the logistic regression model directly relates the probability of Y to the predictor variables. When an independent variable X_k increases by one unit (X_k+1), with all other factors remaining constant, the odds of the dependent variable increase by a factor exp (β_k), which is called the OR and ranges from zero (0) to positive infinity. It indicates the relative amount by which the odds of the dependent variable increase (OR > 1) or decrease (OR < 1) when the value of the corresponding independent variable increases by one (1) unit [12]. The goodness-of-fit for the Logistic Regression (LR) model can be assessed in several ways. First, the overall model (relationship between all of the independent variables and dependent variable) is assessed. Second, the significance of each of the independent variables also needs to be assessed. Third, the predictive accuracy or discriminating ability of the model need to be evaluated, and finally, the model needs to be validated [13].

2.2. Data collection

The data from CA, PCI, and combined CA and PCI (CA/PCI) performed from 1 January to 31 August 2021 were collected from the Erbil Heart Center in the Kurdistan region in Iraq. For each procedure, the following data were collected: patient characteristics (age, sex, weight, and length to calculate BMI), exposure factors kV, mAs, and FT, and dosimetry indicators. Clinical data and technical factors were gathered from 29 coronary angiography (CA), 30 percutaneous transluminal intervention (PCI), and 30 double set-up (CA/PCI) procedures; all performed using the femoral approach. The data were gathered using a stratified random sampling method. This center has 10 cardiologists, 10 nurses, and 10 radiology technicians, with three active to angiography systems angiography rooms. In room 1, a GE Innova 2100 C-arm fluoroscope system 1316440G2283 model is set up, and room 2 is geared with Philips C-arm fluoroscope system 722064 185 and 105935 181 models.

2.3. Statistical analysis

Model construction: A binary logistic regression model (BLRM), a statistical approach to predict the presence of a DAP based on the available variables (Kv, mA, FT, and BMI), has been successfully used to predict the presence of a DAP level. It is known that DAP is related to the risk of exposure to radiation, which is widely used in the establishment of RL. DAP is the binary outcome variable used in the analysis. High DAP levels are assigned the value of 1, and routine DAP levels are assigned the value of 0. The BLRM has the following form:

$$\begin{aligned}Y=\ln[\text{odds}]&=\beta_{Kv}\,Kv+\beta_{mA}\,mA\\&+\beta_{FT}\,FT+\beta_{BMI}\,BMI\end{aligned} \quad (4)$$

In Eq. (4), the variable Y is the log (natural) of the odds of the event under consideration. In our case, the event will be the occurrence of a high DAP procedure. The $\boldsymbol{\beta}$s are the coefficients of the regression calculated by the model of predictor variables kV, mA, FT, and BMI. The regression method was chosen with a free intercept. The justification for this is that the Automatic exposure control (AEC) compensates by keeping the quantity of radiation. The DAP values for 89 patients were dichotomized into three groups, which are CA, PCI, and CA/PCI, for each group divided into two subgroups; for CA, the DAP ≤ 35 Gy.cm^2 and >35 Gy.cm^2, for PCI, the DAP ≤ 85 Gy.cm^2, and >85 Gy.cm^2, for CA/PCI, the DAP $\leq$ 130 Gy.cm^2 and $>$130 Gy.cm^2, respectively. The first subgroup is considered the routine radiation dose procedure, and the second is considered the high radiation dose procedure. The choice of level of DAP was based on the European Society of Vascular Interventional Radiology [7,10].

3. Results

Table I shows a summary of the 89 patients' data in three groups of CA, PCI, and CA/PCI and their associated radiation dose metric with exposure factors. Figure 1 shows the scatter plots matrix, showing DAP as a function of kV, mA, FT, and BMI, respectively. Figure 2 demonstrates the scatter plots of DAP for CA, PCI, CA/PCI with the level of DRLs of the European Society of Interventional Cardiology. Figure 3 boxplots explain the four predicting variables kV, mA, FT, and BMI distribution for the two dependent variable categories of DAP: DAP >35 Gy.cm^2 and DAP ≤ 35 Gy.cm^2 for CA, DAP >85 Gy.cm^2 and DAP ≤ 85 Gy.cm^2 for PCI, and DAP >130 Gy.cm^2 and DAP ≤ 130 Gy.cm^2 for CA/PCI.

The binary regression analysis was conducted to investigate whether kV, mA, FT, and BMI factors predict DAP

TABLE I. Sample size and mean, SD, Max. and Min. for patient characteristics for three group CA, PCI, and CA/PCI, and their associated radiation dose metric with exposure factors.

	Sample size		**BMI (kg/m^2)**	kV	**mA**	**FT**	**DAP (Gy.cm^2)**
CA	29	Mean	26.741	80.482	13.975	3.500	44.274
		S.D	3.746	17.795	3.362	2.341	38.534
		Max.	33.306	120	18.7	12	148
		Min.	15.241	53	5.9	1.08	4.510
PCI	30	Mean	28.038	78.900	15.926	10.182	69.779
		S.D	3.417	16.649	3.049	5.931	30.257
		Max.	34.131	120	19.5	24.800	148
		Min.	15.241	45	8.6	2	4.510
CA/PCI	30	Mean	28.646	82.466	14.4	8.181	86.224
		S.D	3.589	18.574	3.268	4.815	59.837
		Max.	35.651	120	18.7	19.400	241.410
		Min.	23.437	54	7	1.100	28.100

TABLE II. Classification table for CA, PCI, and CA/PCI.

Observed			Predicted		
			DAP.Classes		Percentage Correct
			≤ 35	> 35	
CA	DAP.Classes	≤ 35	14	2	87.5
		> 35	8	5	38.5
		Overall Percentage			65.5
			DAP.Classes		
			≤ 85	> 85	
PCI	DAP.Classes	≤ 85	20	2	90.9
		> 85	5	3	37.5
		Overall Percentage			76.7
			DAP.Classes		
			≤ 130	> 130	
CA/PCI	DAP Classes	≤ 130	20	1	95.2
		> 130	2	7	77.8
		Overall Percentage			90.0

levels. The Hosmer-Lemeshow goodness-of-fit was not significant ($P > 0.05$), indicating that the model was correctly specified Table II. The model correctly predicted 80.0%, 90.5%, and 95.2% of cases where there were routine DAP levels and 64.3%, 33.3%, and 77.8% of cases where there was a high level of DAP, giving an overall percentage correct prediction rate of 72.45%, 73.35%, and 90.0% for CA, PCI, and CA/PCI, respectively. The model's results showed that independent variables (kV, mA, FT, and BMI) were found to be significant for all three groups: CA, PCI, and CA/PCI. As shown in Table III, the obtained LRM with four predictors (variables) is given by Eq. (5) below:

for CA

$$[Y = \ln[\text{odds}] = 0.020 \text{ kV} - 0.50 \text{ mA} - 0.125 FT - 0.011 BMI]$$

for PCI

$$[Y = \ln[\text{odds}] = 0.016\text{kV} - 0.211\text{mA} + 0.084\ FT + 0.007\ BMI]$$

for CA/PCI

$$[Y = \ln[\text{odds}] = 0.0109 \text{ kV} - 0.021 \text{ mA} + 0.989\ FT - 0.188\ BMI]. \tag{5}$$

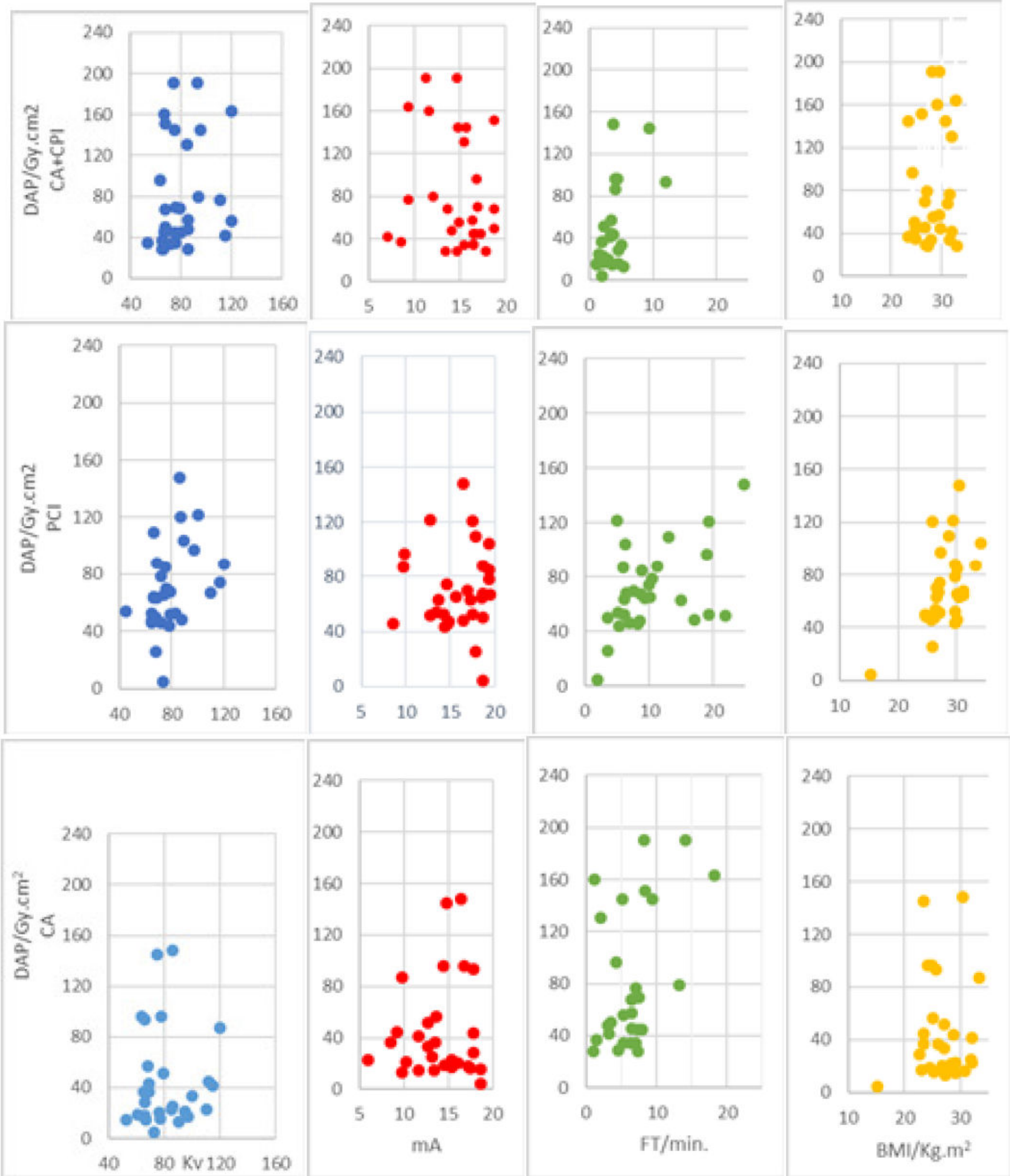

FIGURE 1. Scatter plots matrix showing DAP as function of Kv, mA, FT, and BMI, respectively, for CA, PCI, and CA/PCI.

When a logistic regression is calculated, as in Eq. (5) and Table III for CA, the regression coefficients ($\beta_{Kv} = 0.02$, $\beta_{mA} = -0.125$, $\beta_{FT} = 0.500$, and $\beta_{BMI} = -0.011$) are the estimated increase in the log odds of the DAP per unit increase in the value of the kV, and FT; also the estimated increase in the log odds of the DAP per unit, decrease in the value of the mA and BMI. And we can say that the increase of one unit of kV, mA, FT, and BMI will be reflected in the DAP increase by 0.2%, -12.5%, 50.0%, and -1.1%, respectively. In other words, the exponential function of the regression coefficient ($e^{\beta_{Kv}} = 1.021$, $e^{\beta_{mA}} = 0.882$, $e^{\beta_{FT}} = 1.649$, and $e^{\beta_{BMI}} = 0.989$) are the odds ratios associated with a one-unit increase in the Kv, mA, FT, and BMI, respectively. However, for PCI, the regression coefficients ($\beta_{Kv} = 0.016$, $\beta_{mA} = -0.211, \beta_{FT} = 0.084$ and $\beta_{BMI} = 0.007$) are the estimated increase in the log odds of the DAP per unit increase in the value of the kV, FT, and BMI, and were decreased in the value of the mA. Fur-

TABLE III. Results of the logistic regression analysis for all the variables that may be related to the occurrence of high dose area product for CA, PCI, and CA/PCI procedures.

		β	S.E.	Wald	Exp(β)	95% C.I. for EXP(β)	
						Lower	Upper
CA							
Step 1[a]	Kv	0.020	0.024	0.501	1.021	0.962	1.061
	FT	0.500	0.296	2.859	1.649	0.966	4.303
	mA	-0.125	0.110	1.297	0.882	0.686	1.077
	BMI (kg/m^2)	-0.011	0.098	0.012	0.989	0.789	1.167
PCI							
Step 1[a]	Kv	0.016	0.026	0.358	1.016	0.963	1.060
	FT	0.084	0.073	1.328	1.088	0.935	1.227
	mA	-0.211	0.132	2.533	0.810	0.672	1.078
	BMI (kg/m^2)	0.007	0.106	0.004	1.007	0.832	1.219
CA/PCI							
Step 1[a]	Kv	0.0109	0.081	0.638	1.011	0.799	1.099
	FT	0.030	0.028	0.511	1.030	0.593	1.791
	mA	-0.021	0.087	0.327	0.979	1.035	6.978
	BMI (kg/m^2)	-0.188	0.217	0.751	0.829	0.542	1.268

a. Variable(s) entered on step 1: Kv, mA, FT, BMI (kg/m^2).

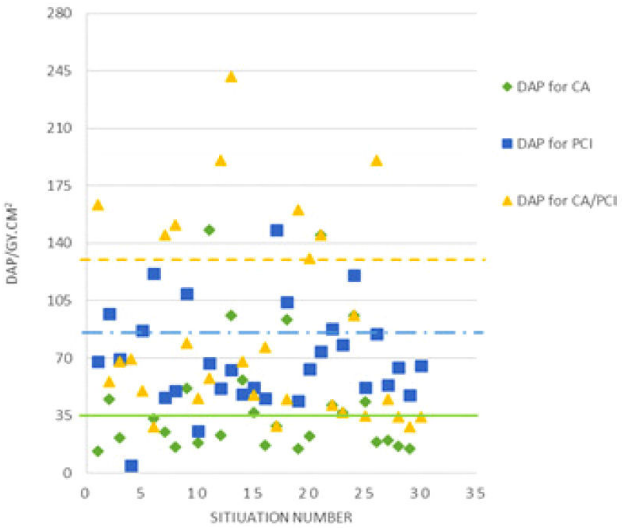

FIGURE 2. Scatter plots matrix showing DAP Level, the green is for the procedures with DAP $>$35Gy cm^2 and DAP $\leq$35 Gy cm^2. The blue is for the procedures with DAP $>$85 Gy cm^2 and DAP$\leq$80Gy.cm^2. The yellow is for the procedures with DAP $>$130 Gy cm^2 and DAP $\leq$130 Gy.cm^2.

thermore, we can say that an increase of one unit of kV, mA, FT, and BMI will be reflected in the DAP increase by 1.6%, -21.1%, 8.4%, and 0.7%, respectively.

In other words, the exponential function of the regression coefficient ($e^{\beta_{Kv}} = 1.016, e^{\beta_{mA}} = 0.810$, $e^{\beta_{FT}} = 1.088$, and $e^{\beta_{BMI}} = 1.007$), are the odds ratios associated with a one unit increase in the kV, mA, FT, and BMI, respectively. Finally, for CA/PCI, the regression coefficients ($\beta_{Kv} = 0.0109$, $\beta_{mA} = -0.021$, $\beta_{FT} = 0.030$, and $\beta_{BMI} = -0.188$) are the estimated increases in the log odds of the DAP per unit increases in the value of the kV, mA, FT, and BMI, respectively. We can say that the increase in one unit of kV, mA, FT, and BMI will be reflected in the DAP increase by 1.09%, -2.1%, 3.0%, and -18.8%, respectively. In other words, the exponential function of the regression coefficient ($e^{\beta_{Kv}} = 1.011$, $e^{\beta_{mA}} = 0.979$, $e^{\beta_{FT}} = 1.030$, and $e^{\beta_{BMI}} = 0.829$) are the odds ratios associated with a one unit increase in the kV, mA, FT, and BMI, respectively.

4. Discussion

The scatter plots matrix in Fig. 1; showing DAP as a function of kV, mA, FT, and BMI, respectively. We note that the scatter plot for kV and FT are strong, positive association because as kV and FT increases, so the DAP increased, but we note that the scatter plot for mA and BMI are strong, negative association, because in general, as mA and BMI increase, their DAP decreases. According to the results of the binary regression model, all the factors studied in this research, namely kV, mA, FT, and BMI, have a significant relationship with the DAP levels and confidently determine this result, which agrees with those published by others [2,4,5,11]. However, when reviewing the various studies on patient dosimetry, there appears to be a considerable variation in the radiation doses received by patients, as shown in Table IV. As there are a number of possible explanations, it is necessary to establish such a model to explain the radiation doses received by patients during interventional cardiology procedures and

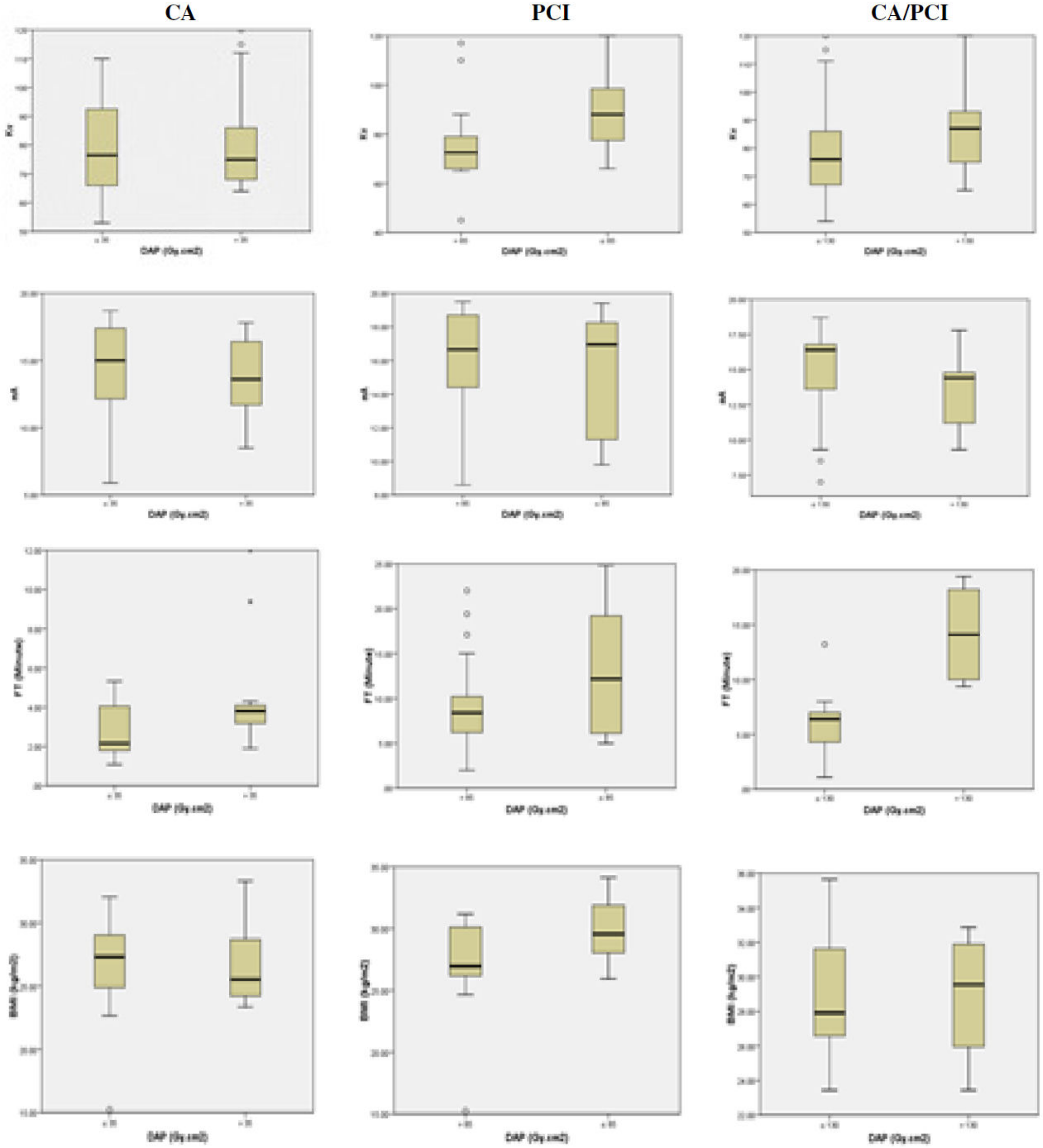

FIGURE 3. Boxplots showing the four predicting variables kV, mA, FT and BMI distribution for the two dependent variable categories of DAP; DPA >35Gy cm^2 and DAP ≤ 35 Gy cm^2 for CA,DPA >85 Gy cm^2 and DAP$\leq$85Gy for PCI, and DPA >130 Gy cm^2 and DAP ≤ 35 Gy.cm^2.

TABLE IV. DAP (Gy.cm2) comparisons with values published in the literature.

DAP Gy.cm^2			Ref.
CA	**PCI**	**CA/PCA**	
39.9	78.3	109.3	[2]
87	91		[6]
35	85	130	[8]
83	193	199	[14]
45	86	96	[15]
43.72	38.77		[16]
44.274	69.779	86.224	This study

to detect the reason why the patient received a high dose and higher than the permissible dose level. When coefficient β of the variable is positive, we obtain OR > 1, and it therefore corresponds to a risk factor. If the value β is negative, OR will be < 1, and the variable therefore corresponds to a protective factor [12,13]. According to this, we concluded that for CA, the odds of $(\text{patients that } DAP \leq 35/\text{patients that } DAP > 35)$ increase if kV and FT increase by one unit and decrease if mA and BMI decrease by one unit. This means that the number of patients with DAP >35 Gy.cm^2 can be reduced when kV and FT decrease and mA increases. However, we concluded for PCI that the odds of (patients that $DAP \leq 85$/patients that $DAP > 85$) increases if kV and FT increased by one unit, and decreased if mA and BMI decreased by one unit. This means that the number of patients with DAP >85 Gy.cm^2 can be reduced when kV and FT decrease and mA increase. For CA/PCI, the odds of (patients that $DAP \leq 130$/patients that $DAP > 130$) increases if kV and FT increased by one unit, and decreased if mA and BMI decreased by one unit. It means that the number of patients with DAP >130 Gy.cm^2 can be reduced when kV and FT decrease and mA increases. Finally, we can conclude that increased kV and FT are the two factors that help to increase the risk, and according to the model, decreased mA is a factor that helps in radiation protection. From this, we concluded that we can identify variables that have an effect on the DAP level in interventional cardiology.

5. Conclusion

We can conclude that according to the model, increased kV and FT are the two factors that increase the risk, while decreased mA is a factor that helps in radiation protection. From this, we can identify variables that have an effect on the DAP level in interventional cardiology. Also, we state that regression analysis is a reliable method for evaluating user protocols in a center or hospital. We can also identify the most critical factors and the factors that can be disregarded. Thus, we conclude that the regression analysis method can be used in quality assurance and driving diagnostic reference levels and dose optimization.

Acknowledgments

The authors would like to thank Sallahddin University for their support in the current work.And the authors give thanks to the Surgeries Hospital Specialist - Heart Center and express sincere thanks to Prof. Dr. Wasfi Kahwachi, Tishk International University for encouragement and helpful suggestions during this research work.

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