Radiation Protection Dosimetry (2021), Vol. 194, No. 1, pp. 18–26
Advance Access publication 6 May 2021
doi:10.1093/rpd/ncab065

INCREASED EXPOSURE TO X-RAYS DURING CORONARY ANGIOGRAPHY AND PERCUTANEOUS CORONARY INTERVENTIONS ASSOCIATED WITH FRACTIONAL FLOW RESERVE MEASUREMENT AND ENDOCORONARY IMAGING TECHNIQUES

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Received 9 November 2020; revised 9 March 2021; editorial decision 8 April 2021; accepted 8 April 2021

Growing use of fractional flow reserve (FFR) and intracoronary imaging techniques by optical coherence tomography or intravascular ultrasound has raised concerns about additional exposure during coronary angiography and percutaneous coronary interventions (PCIs). Using data from the prospective CRAC-France PCI Prospective Multicentre registry, we sought to evaluate the effect of these new techniques on the radiation dose to patients undergoing coronary procedures. Data on Kerma Area Product (P_{KA}), total air kerma (KA_r) and fluoroscopy time from 42 182 coronary procedures were retrospectively compared, using multivariable linear regression, according to whether they included FFR and intracoronary imaging. In coronary angiography, FFR was associated with longer fluoroscopy time and higher P_{KA} (21.0 vs. 18.9 Gy.cm^2) and KA_r (372 vs. 299 mGy) (all $p < 0.001$). Intracoronary imaging was associated with longer fluoroscopy time, higher contrast volume (both $p < 0.001$), lower P_{KA} (18.3 vs. 19.0 Gy.cm^2, $p = 0.02$) and similar KA_r. In PCI, FFR was associated with a moderate increase in KA_r (682 vs. 626 mGy, $p < 0.01$) but not P_{KA} (35.9 vs. 33.7 Gy.cm^2, $p = 0.34$). For intracoronary imaging, there were no differences between groups, except for contrast volume. Increased patient exposure associated with FFR and intracoronary imaging is moderate in diagnostic coronary angiography and minimal or none in PCI, provided optimization techniques are used. It should not be a limitation on the use of these techniques given the important additional information they provide.

INTRODUCTION

Exposure to x-rays during diagnostic coronary angiography and percutaneous coronary interventions (PCIs) is associated with potential risk for both patients and operators[1–4]. Factors associated with a higher patient exposure include age, obesity, diabetes mellitus, severity of coronary artery disease and increasing complexity of PCIs[2–5]. Conversely, radiation protection training for operators, evaluation of practices with the use of optimization tools and renewal of radiological equipment have led to a reduction in x-ray doses in interventional cardiology[5–8].

Over the past decade, fractional flow reserve (FFR) has become the standard for identifying hemodynamically significant coronary lesions and for clinical decision-making about percutaneous coronary revascularization[9]. Intravascular ultrasound and optical coherence tomography are new techniques of intracoronary imaging that provide additional valuable information to coronary angiography, improve the evaluation of atherosclerotic or thrombotic lesions and are useful for guiding complex PCI procedures[10, 11].

Both FFR and intracoronary imaging techniques require the use of specific equipment such as pressure guidewires and/or endovascular probes, and additional injections that are associated with longer fluoroscopy time, additional cinegraphy runs and therefore a higher use of x-rays. Nevertheless, the intention is not to impose or suggest dose limits for procedures that are medically justified.

Little is known about the level of increased exposure to x-rays associated with FFR and intracoronary imaging[12, 13], use of which is gradually rising. The purpose of this study was to evaluate the effect of FFR and endocoronary imaging techniques on

radiation doses and contrast volume received by patients in a large series of unselected consecutive coronary angiographies and PCIs.

METHODS

Study design

The CRAC-France PCI Prospective Multicentre registry[14], started on 1 January 2014, includes all patients undergoing coronary angiography or PCI at an interventional cardiology centre in the Centre-Val-de-Loire region in central France. The Centre-Val-de-Loire region covers an area of 39 151 km^2 with 2.5 million inhabitants and 38 private and public hospitals. The registry is registered on clinicaltrials.org (NCT02778724). Data are collected prospectively by cardiologists during routine coronary angiographies and PCIs, using electronic reporting software (CardioReport®; CVX Medical, Croissy-Beaubourg, France). Data are anonymized before automatic transfer to the database.

Data collection and analysis

This prespecified analysis was conducted retrospectively using prospectively collected data. It included all consecutive coronary procedures performed between 1 January 2014 and 30 June 2018, regardless of indication. Data on PCIs performed immediately after the coronary angiography during the same procedure and PCIs performed during a separate procedure were pooled for analysis. Procedures were divided according to whether they included FFR measurement (+ or −) or endocoronary imaging (+ or −).

Radiation dose metrics

Data were collected on total air kerma at interventional reference point (KA_r; expressed in mGy), kerma area product (P_{KA}; $Gy.cm^2$) (also known as 'dose area product'), fluoroscopy time, P_{KA}/fluoroscopy time ratio and total volume of contrast media. Radiation parameters were compared between groups and against the national diagnostic reference and guide levels[15]. Reference and guide levels are defined as the rounded value of the 75th percentile and the median (50th percentile), respectively, of the distribution for each parameter[16]. For coronary angiography, the reference and guide levels were 6 and 4 min, respectively, for fluoroscopy time, and 38 and 21 $Gy.cm^2$, respectively, for P_{KA}. For PCI, reference and guide levels were 15 and 10 min, respectively, for fluoroscopy time, and 80 and 45 $Gy.cm^2$, respectively, for P_{KA}. As no official reference and guide levels were provided for KA_r, the values of 500 and 300 mGy for coronary angiography and 1300 and 750 mGy for PCI, corresponding to the 75th percentile and the median of KA_r in the nationwide RAYACT-2 study[16], were used as reference and guide levels, respectively. Finally, the rate of coronary angiography and PCI delivering a $P_{KA} > 500$ $Gy.cm^2$ or a $KA_r > 5000$ mGy value, above which the risk of radiation-induced skin lesions is increased, was calculated[2, 4, 5].

X-ray equipment

The radiological equipment used included 12 cardiovascular imaging systems from 3 different manufacturers (2 centers with 3 catheterization laboratories and 3 centers with 2). The equipment was the same through the study period in three centers and was renewed in the other two centers in 2015 and 2018. In accordance with the national quality control protocol established in 2005, all x-ray equipment in France is checked annually to ensure compliance with technical requirements and tolerances on the patients' dosimetry and the image quality. This includes an assessment of high-contrast spatial resolution under different magnification modes, maximum permissible entrance patient dose and displaying precision of installed P_{KA} measuring devices and accuracy of x-ray generator parameters (kV and mA reproducibility). No specific or complementary quality control checks were therefore required for the study.

Ethical considerations

The study was conducted according to French regulations (Advisory Committee on Information Processing in Material Research in the Field of Health no. 13.245). The French Persons Protection Committee (IRB00003888) approved the study protocol (no. 15-231). All patients were informed of the aims of the survey. All patients gave informed consent to participate.

Statistical analyses

Descriptive statistics are summarized as medians and quartiles or mean ± SD, where appropriate, for continuous variables, and as numbers and percentages for categorical variables. Radiation dose metrics were analyzed separately for coronary angiographies and PCIs. Univariate comparisons of radiation dose metrics and baseline characteristics of patients and procedures were performed using the χ^2 test or Fisher's exact test for qualitative data and the non-parametric U-Mann–Whitney test or analysis of variance for continuous data, as appropriate. Multivariable linear regression was performed utilizing factors that were statistically significantly different at baseline between groups and known predictors of radiation dose, which

include age, sex, body mass index, radial access, diabetes, renal failure and extent of coronary disease (for diagnostic coronary angiography) or number of treated lesions and the number of implanted stents (for PCI).

Because P_{KA}, KA_r and fluoroscopy time are log-normally distributed, multivariable adjusted analyses were performed by linear regression models on log-transformed values. Statistical analyses were performed using SPSS statistical software version 12.0, and R software, version i3863.6.2. Tests were two-sided. A p-value <0.05 was considered statistically significant.

RESULTS

A total of 59 171 coronary procedures were performed at 5 centers during the study period, of which 42 182 (18 881 coronary angiographies and 23 301 PCIs) included information on FFR and intracoronary imaging (Flow chart in Supplementary Figure 1). One center was excluded because of incomplete data. FFR was performed in 2194 procedures (5.2%) and intracoronary imaging in 411 (1%).

Baseline characteristics

FFR was done more frequently during coronary angiography and intracoronary imaging mainly during PCI (Table 1). Compared with the FFR− group, patients in the FFR+ group were younger, more frequently had single- or two-vessel disease and single-vessel PCI and presented more often with an acute coronary syndrome. However, FFR was rarely performed during emergency procedures. A largely similar pattern was observed for the use of intracoronary imaging.

FFR and patient exposure

In coronary angiography, FFR was associated with longer fluoroscopy time and higher KA_r and P_{KA} (all $p < 0.001$). The P_{KA}/fluoroscopy time ratio was also 55% higher, indicating that the increase in P_{KA} was not exclusively due to the increase in fluoroscopy time related to FFR (Table 2 and Figure 1). Differences in dose metrics between FFR+ and FFR− groups remained significant after adjustment (all $p < 0.001$) (Supplementary Table 1).

In PCI, FFR was associated with a moderate but significant increase in fluoroscopy time and KA_r but not in P_{KA}. The difference between groups for KA_r was no longer significant after adjustment on age, sex, body mass index, radial access, diabetes, renal failure and extent of coronary disease, and only differences in fluoroscopy time remained significant (Supplementary Table 2).

The percentages of procedures with dose metrics exceeding reference levels were higher in the FFR+ versus FFR− group for coronary angiographies but were not different for PCIs (Table 2). Only 0.3% of PCIs in the FFR+ group delivered an $KA_r > 5000$ mGy versus 0.5% in the FFR− group (non-significant difference). No coronary angiography associated with FFR delivered a $P_{KA} > 500$ Gy.cm^2 or $KA_r > 5000$ mGy.

Intracoronary imaging and patient exposure

In coronary angiography, intracoronary imaging by ultrasound or optical coherence tomography was associated with a longer fluoroscopy time and higher contrast volume (Table 3 and Figure 1). P_{KA} was slightly lower in the group who had intracoronary imaging and KA_r did not differ significantly between groups. In multivariable analysis, the difference in KA_r became statistically significant, although clinically negligible (adjusted mean ± standard error of mean: 454 ± 32 mGy in the intracoronary imaging+ group vs. 402 ± 2 mGy in the intracoronary imaging− group) (Supplementary Table 3).

In PCIs, there were no significant differences between the two groups before and after adjustment. Only contrast volume was higher in the intracoronary imaging+ group (160 vs. 140 ml, $p < 0.001$).

FFR or intracoronary imaging, dose metrics and extent of coronary disease

The increase in P_{KA} associated with FFR measurement was homogeneous in diagnostic coronary angiography regardless of the extent of coronary disease (Figure 2) but was not observed in multivessel PCI (Figure 3). No significant differences were found for intracoronary imaging.

DISCUSSION

The results of this study, drawn from a large series of unselected interventional coronary procedures, showed that the use of FFR was associated with an increase in radiation dose and volume of contrast medium when performed during coronary angiography, and to a lesser extent during PCI. Intracoronary imaging techniques were also associated with a moderate but significant additional radiation dose in coronary angiography only. The overall patient exposure remained low, and almost no procedures delivered an $KA_r > 5000$ mGy.

FFR and radiation dose

According to American and European guidelines, use of FFR is recommended to assess angiographic

Table 1. Baseline characteristics according to procedures performed with or without FFR or intracoronary imaging by ultrasound or optical coherence tomography.

	FFR			Intracoronary imaging		
	Yes (N = 2194)	No (N = 39 988)	p value	Yes (N = 411)	No (N = 41 771)	p value
Diagnostic coronary angiography	1308 (59.6)	17 573 (43.9)	<0.0001	101 (24.6)	18 780 (45.0)	<0.0001
PCI	886 (40.4)	22 415 (56.1)		310 (75.4)	22 991 (55.0)	
Ad-hoc PCI	649/886 (73.3)	16 447/22 415 (73.4)	0.93	218/310 (70.3)	16 878/22 991 (73.4)	0.22
Age, year	68 (60–75)	70 (61–78)	<0.0001	63 (52–73)	70 (61–78)	<0.0001
Male sex	1685/2194 (76.8)	30 305/39 988 (75.8)	0.28	300/411 (73.0)	31 690/41 764 (75.9)	0.17
BMI, kg/m^2	27.2 (24.6–30.3)	27.0 (24.3–30.1)	0.07	26.8 (24.6–29.7)	27.55 (24.3–30.1)	0.17
BMI >30 kg/m^2	584/2191 (26.7)	10 215/39 905 (25.6)	0.27	90/410 (22.0)	10 709/41 686 (25.7)	0.08
Diabetes	631/2193 (28.8)	11 437/39 956 (28.6)	0.88	88/411 (21.4)	11 980/41 738 (28.7)	0.001
Renal failure	32/2081 (1.5)	837/37 590 (2.2)	0.04	1/377 (0.2)	868/39 294 (2.2)	0.01
Dyslipidemia	1216/2181 (55.8)	21 142/39 334 (53.8)	0.06	212/406 (52.2)	22 416/41 109 (53.9)	0.50
Hypertension	1301/2189 (59.4)	23 887/39 848 (60.0)	0.63	198/411 (48.2)	24 990/41 626 (60.0)	<0.0001
Emergency procedure	10/2194 (0.5)	3715/39 972 (9.3)	<0.0001	20/411 (4.9)	3705/41 755 (8.9)	0.004
Left ventriculography	192/2194 (8.8)	3558/39 988 (8.9)	0.81	37/411 (9.0)	3713/41 771 (8.9)	0.93
Coronary graft opacification	93/2193 (4.2)	3389/39 974 (8.5)	<0.0001	25/411 (6.1)	3457/41 756 (8.3)	0.10
Arterial approach			<0.0001			0.28
Radial	2092/2194(95.4)	37 141/39 970 (92.9)		377/411 (91.7)	38 856/41 753 (93.1)	
Femoral	84/2194 (3.8)	2599/39 970 (6.5)		29/411 (7.1)	2654/41 753 (6.4)	
Humeral	12/2194 (0.6)	197/39 970 (0.5)		5/411 (1.2)	204/41 753 (0.5)	
Clinical presentation						
Chronic coronary syndrome	546/2194 (24.9)	15 507/39 988 (38.9)	<0.0001	170/411 (41.4)	15 883/41 771 (38.0)	0.16
Acute coronary syndrome	1465/2194 (66.8)	20 698/39 988 (51.8)	<0.0001	232/411 (56.5)	21 931/41 771 (52.5)	0.11
Other	183/2194 (8.3)	3783/39 988 (9.5)	0.08	9/411 (2.2)	3957/41 771 (9.5)	<0.0001
Extent of coronary artery disease						
No or non-significant lesion	10/2192 (0.4)	196/39 913 (0.4)	0.81	5/408 (1.2)	201/41 697 (0.5)	0.051[a]
Single-vessel disease	898/2192 (41.0)	14 503/39 913 (36.3)	<0.0001	183/408 (44.9)	15 218/41 697 (36.5)	0.0005
Two-vessel disease	795/2192 (36.3)	13 184/39 913 (33.0)	0.001	144/408 (35.3)	13 835/41 697 (33.2)	0.36
Three-vessel disease	489/2192 (22.3)	12 030/39 913 (30.1)	<0.0001	76/408 (18.6)	12 443/41 697 (29.8)	<0.0001
PCI						
Number of treated lesions per PCI	1.5 ± 0.8	1.4 ± 0.7	<0.0001	1.4 ± 0.8	1.4 ± 0.7	0.29
Single-vessel PCI	699/886 (78.9)	19 284/22 415 (86.0)	<0.0001	247/310 (79.7)	19 736/22 991(85.8)	0.002
Multi-vessel PCI	187/886 (21.1)	3131/22 415 (14.0)		63/310 (20.3)	3255/22 991 (14.2)	
PCI with stent implantation	869/886 (98.1)	20 997/22 413(93.7)	<0.0001	271/310 (87.4)	21 595/22 989 (93.9)	<0.0001
PCI with DES implantation	766/886 (86.5)	17 433/22 410 (77.8)	<0.0001	209/310 (67.4)	17 990/22 986 (78.3)	<0.0001
Number of implanted stents per PCI	1.6 ± 0.9	1.5 ± 1.0	<0.0001	1.4 ± 1.0	1.5 ± 1.0	0.003
Total length of implanted stents mm	26 (18–39)	23 (15–36)	<0.0001	23 (15–32)	23 (15–36)	0.005

BMI: body mass index; DES: drug-eluting stent. Data are number (%) or median (interquartile range) unless otherwise stated (mean ± standard deviation). For qualitative data, differences between denominators and heading counts indicate the number of missing values.

intermediate coronary lesions without evidence of ischemia in non-invasive testing (European Society of Cardiology class I, level A) and can be useful for guiding PCI in stable ischemic patients (American College of Cardiology/American Heart association class IIa, A) or in patients with multi vessel disease (European Society of Cardiology class IIa, B)[17, 18]. Although FFR is not as widely used as expected[19, 20], the high level of recommendations together with the widespread reimbursement of the dedicated material has led to an increase in its use, reaching >10% of procedures in the USA and some western

Table 2. Parameters of patient exposure in diagnostic and interventional coronary procedures performed with and without FFR measurement.

	Diagnostic coronary angiography			PCIs		
	FFR (N = 1308)	No FFR (N = 17 573)	p value	FFR (N = 886)	No FFR (N = 22 415)	p value
P_{KA}, Gy.cm^2	21.0 (12.0–35.0)	18.9 (11.1–31.9)	<0.001	35.9 (20.2–59.9)	33.7 (19.1–58.3)	0.34
P_{KA} > reference levels	287/1307 (22.0)	3210/17 430 (18.4)	0.002	133/883 (15.1)	3286/22 275 (14.8)	0.80
P_{KA} > guide levels	657/1307 (50.3)	7780/17 430 (44.6)	<0.001	331/883 (37.5)	8069/22 275 (36.2)	0.45
P_{KA} > 500 Gy.cm^2	0/1307 (0.0)	0/17 430 (0.0)	—	0/883 (0.0)	7/22 275 (0.03)	0.76[a]
KA_r, mGy	372.0 (213.0–616.5)	299.0 (179.0–500.0)	<0.001	682.0 (392.0–1194.5)	626.0 (356.0–1099.0)	0.008
KA_r > reference level	457/1307 (35.0)	4380/17 460 (25.1)	<0.001	181/880 (20.6)	4224/22 311 (18.9)	0.23
KA_r > guide levels	783/1307 (59.9)	8708/17 460 (49.9)	<0.001	405/880 (46.0)	9224/22 311 (41.3)	0.006
KA_r > 5000 mGy	0/1307 (0.0)	2/17 460 (0.01)	0.87[a]	3/880 (0.3)	110/22 311 (0.5)	0.53
Fluoroscopy time, min	5.8 (3.9–8.1)	3.0 (1.9–5.0)	<0.001	10.4 (6.9–14.6)	8.6 (5.5–14.0)	<0.001
Fluoroscopy time > reference level	624/1307 (47.7)	3265/17 529 (18.6)	<0.001	210/885 (23.7)	4903/22 381 (21.9)	0.20
Fluoroscopy time > guide levels	952/1307 (72.8)	5930/17 529 (33.8)	<0.001	462/885 (52.2)	9280/22 381 (41.5)	<0.001
Fluoroscopy time > 60 min	0/1307 (0.0)	0/17 529 (0.0)	—	1/885 (0.1)	233/22 381 (1.0)	0.001[a]
Ratio P_{KA}/fluoroscopy time	3.8 (2.2–6.0)	5.9 (3.4–10.4)	<0.001	3.4 (2.2–5.2)	3.8 (2.4–6.0)	<0.001
Contrast volume, ml	95 (72–120)	70 (54–95)	<0.001	150 (115–200)	139 (100–180)	<0.001

KA_r: reference air kerma; $P_{KA:}$ kerma area product. Data are number (%) or median (interquartile range).
[a]Fisher's exact test.

European countries[20]. In addition, the indications for FFR, limited mainly to stable patients, are likely to expand to patients with acute coronary syndromes[19]. It is therefore important to assess the expected increase in patient exposure linked to extension of the FFR indications. In this study, FFR combined with coronary angiography was associated with a 2-fold increase in fluoroscopy time, a 20% increase in KA_r (an indicator of the entrance skin dose), but only a 10% increase in global radiation dose, as assessed by P_{KA}. This is lower than the 30% increase of effective dose estimate reported in 200 procedures where radiation dose was measured immediately after coronary angiography, before and after FFR measurement[12]. In PCI, the increase in KA_r associated with FFR was only 8% and the additional P_{KA} was not significant.

The moderate increase in exposure associated with FFR may be counterbalanced by its benefits. First, the use of FFR is likely to avoid inappropriate PCIs that would have been decided on the basis of the angiogram alone. Thus, FFR-guided PCI resulted in a 6% reduction in the number of PCIs performed compared with the angiography-guided strategy, with an increase in non-irradiating surgical and medical treatments in one study[21] although its effect was neutral in another[22]. Moreover, as FFR is a surrogate for non-invasive testing, increased exposure related to FFR, estimated at 4 mSv[12], has to be balanced against the average effective radiation dose received during myocardial perfusion imaging (around 10–15 mSv) or the assessment of computed tomography-derived FFR (3 mSv), and dynamic myocardial computed tomography perfusion (5 mSv) by computed tomography coronary angiography[23]. Although FFR modestly increases patient exposure, it could paradoxically contribute to justification, the second cornerstone of radiation protection along with optimization.

Intracoronary imaging and radiation dose

Although recommendations for intracoronary ultrasound or optical coherence tomography have a lower level than those for FFR[17, 18], the use of these intracoronary imaging techniques has also increased, reported in 3.5% of diagnostic coronary angiographies and 6.6% of PCIs in the USA[24]. In a small series of coronary angiographies, intracoronary ultrasound resulted in a longer fluoroscopy time, optical coherence tomography had a modest effect on contrast volume but neither method had a detectable effect on the radiation dose[15]. When intracoronary imaging was performed in our study, the volume of contrast medium increased (13% for PCI and 57% for coronary angiography), the fluoroscopy time increased in coronary angiography only (58%) but the KA_r did not vary and the P_{KA} was lower, possibly due to a reduction in the number of cinegraphy runs.

The different effects of FFR and intracoronary imaging on exposure during coronary angiography (modest positive effect) and PCI (minimal or no effect) can be explained by the fact that both techniques require use of a larger catheter and placement of an intracoronary wire through the lesion

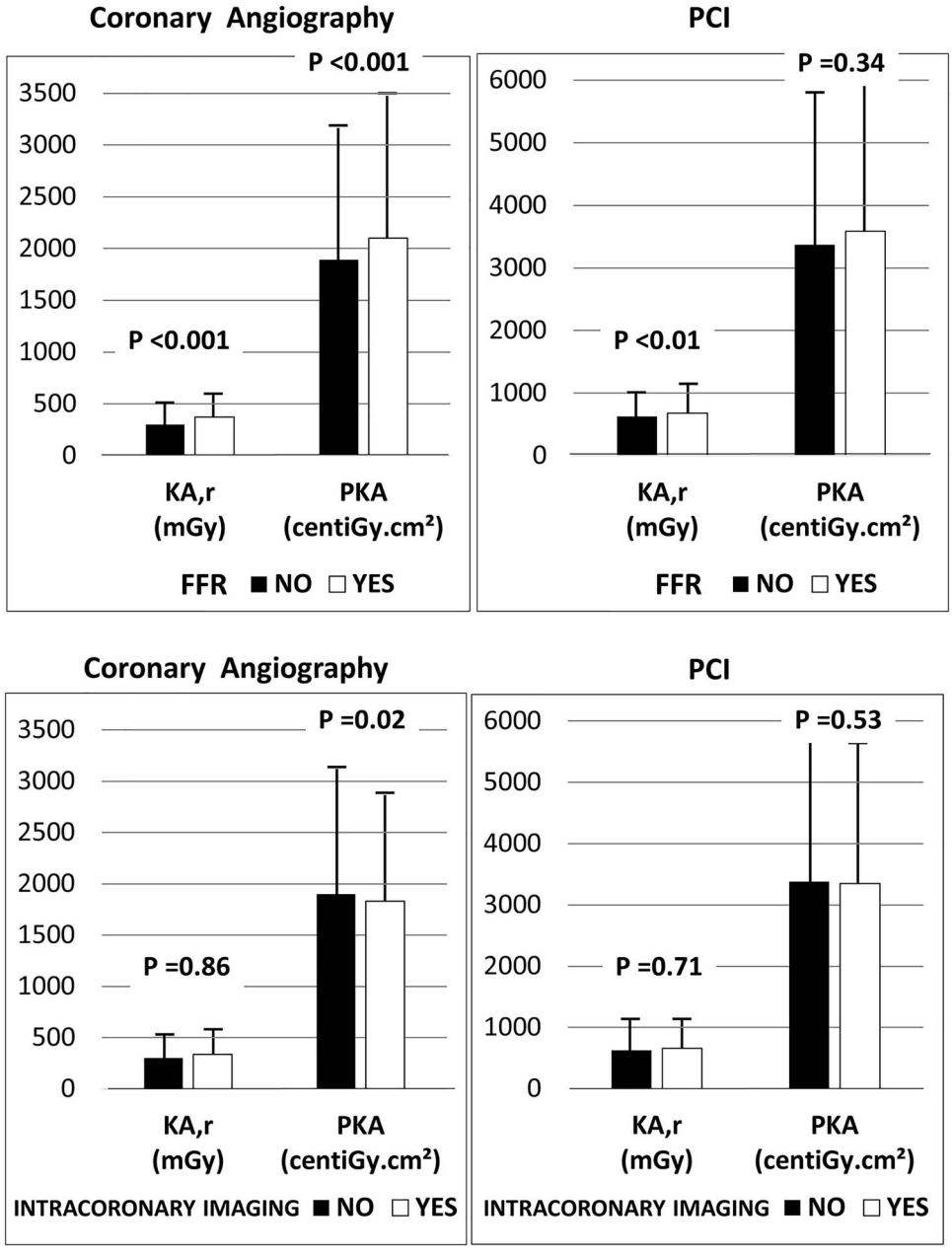

Figure 1: Effect of the use of FFR and intracoronary imaging by ultrasound or optical coherence tomography on patient dose metrics in diagnostic coronary angiography and percutaneous interventions (PCI). KA_r: total Air Kerma in mGy; P_{KA}: kerma area product in Gy.cm^2. Values are medians and third quartiles.

being evaluated. These extra steps require additional x-rays in coronary angiography, whereas they are systematically performed during PCI, irrespective of the use of FFR and intracoronary imaging.

Table 3. Parameters of patient exposure in diagnostic and interventional coronary procedures performed with or without intracoronary imaging by ultrasound or optical coherence tomography.

	Diagnostic coronary angiography			PCIs		
	Intracoronary imaging			Intracoronary imaging		
	Yes (N = 101)	No (N = 18 780)	p value	Yes (N = 310)	No (N = 22 991)	p value
P_{KA}, Gy.cm^2	18.3 (10.1–28.2)	19.0 (11.2–32.2)	0.02	33.5 (17.9–56.8)	33.8 (19.2–58.4)	0.53
P_{KA} > reference level	14/101 (13.9)	3483/18 636 (18.7)	0.21	36/309 (11.7)	3383/22 849 (14.8)	0.12
P_{KA} > guide level	44/101 (43.6)	8393/18 636 (45.0)	0.77	109/309 (35.3)	8291/22 849 (36.3)	0.71
P_{KA} > 500 Gy.cm^2	0/101 (0.0)	0/18 636 (0.0)	—	0/309 (0.0)	7/22 849 (0.0)	0.91[a]
KA_r, mGy	337.0 (204.0–521.0)	302.0 (181.0–509.0)	0.86	659.0 (363.0–1100.0)	627.0 (357.0–1102.0)	0.71
KA_r > reference level	26/101 (25.7)	7811/18 666 (25.8)	0.99	57/309 (19.0)	4348/22 882 (19.0)	0.81
KA_r > guide level	59/101 (58.4)	9432/18 666 (50.5)	0.12	138/309 (44.7)	9491/22 882 (41.5)	0.26
KA_r > 5000 mGy	0/101 (0.0)	2/18 666 (0.0)	0.99[a]	0/309 (0.0)	113/22 957 (0.5)	0.42[a]
Fluoroscopy time, min	4.9 (3.2–7.6)	3.1 (2.0–5.3)	<0.001	9.3 (5.7–14.8)	8.7 (5.5–14.0)	0.91
Fluoroscopy time > reference level	40/101 (39.6)	3849/18 735 (20.5)	<0.001	75/309 (24.3)	5038/22 957 (21.9)	0.33
Fluoroscopy time > guide level	67/101 (66.3)	6815/18 735 (36.4)	<0.001	145/309 (46.9)	9597/22 957 (41.8)	0.07
Fluoroscopy time > 60 min	0/101 (0.0)	0/18 735 (0.0)	—	2/309 (0.6)	232/22 957 (1.0)	0.77[a]
Ratio P_{KA}/fluoroscopy time	3.1 (2.1–5.2)	5.7 (3.3–10.1)	<0.001	3.6 (2.2–5.5)	3.8 (2.3–6.0)	0.15
Contrast volume, ml	110 (90–150)	70 (55–97)	<0.001	160 (120–210)	140 (100–180)	<0.001

Other abbreviations: same as Table 2. Data are number (%) or median (interquartile range).
[a]Fisher's exact test.

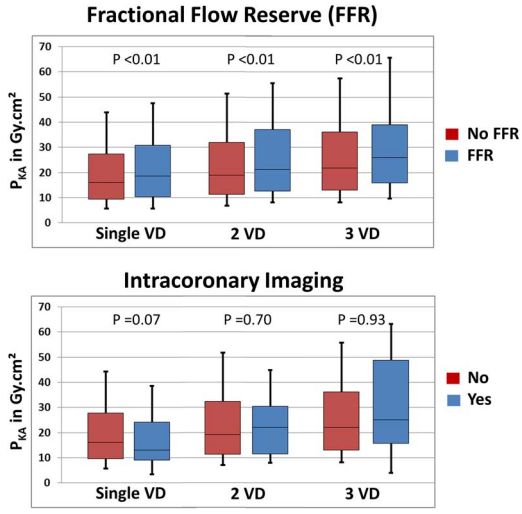

Figure 2: Effect of FFR measurement and intracoronary imaging on the kerma area product, according to the extent of coronary disease in diagnostic coronary angiography. P_{KA}: kerma area product in Gy.cm^2; VD: vessel disease. Box plots indicate the median and the first and third quartiles, the whiskers indicate the 10th and 90th percentiles of the values of kerma area product.

Patient overall exposure

The overall level of patient exposure was very low in the present study. The median P_{KA} associated with FFR in coronary angiography was three times lower in our study than in that by Ntalianis *et al*.[12] (using a commonly accepted KAP-to-effective dose conversion factor of 0.20[25], the reported 'effective dose' of 15 mSv approximately corresponds to a P_{KA} of about 75 Gy.cm^2). Similarly, the mean ± SD KA_r reported by De la Garza-Salazar *et al*. for coronary angiographies and PCIs performed with and without FFR and intracoronary imaging was 1549 mGy (1693.8 ± 1670.1 mGy in 799 males and 1130.2 ± 1171.4 mGy in 274 females)[13] compared with 331 ± 310 mGy for coronary angiography and 881 ± 844 mGy for PCI in the present study. The low level of exposure in our study is due to the extensive use of optimization techniques in the centers (low frame rates of 7.5 images/s in fluoroscopy, large fields of view, collimation and optimization of source/patient/detector distances). This explains why almost no procedures exceeded the KA_r value associated with a risk of deterministic effects, and that comparisons with national reference and guide levels were favorable for procedures including FFR and intracoronary imaging.

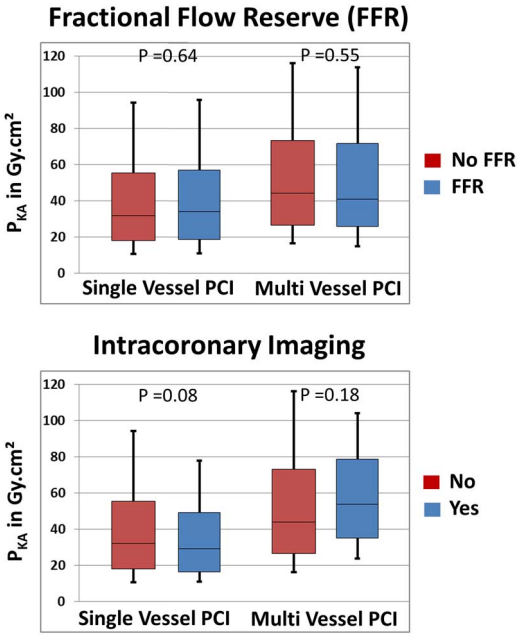

Figure 3: Effect of FFR measurement and intracoronary imaging on the kerma area product, according to the number of vessels treated during PCI. P_{KA}: kerma area product in Gy.cm^2. Box plots indicate the median and the first and third quartiles, the whiskers indicate the 10th and 90th percentiles of the values of kerma area product.

Study limitations

Although data collection was prospective, the analyses were done retrospectively, and biases may have occurred. First, data on FFR and intracoronary imaging were missing for 29% of procedures. However, almost all missing procedures were in coronary angiographies with no coronary lesion and without FFR or intracoronary imaging. Second, whereas x-ray equipment is submitted for annual quality controls, the overall uncertainty of P_{KA} values has been estimated at about 5%. Third, the study measured the radiation dose from individual coronary procedures and not the cumulative dose received by patients undergoing repeated procedures. Finally, comparison of radiation dose between coronary procedures with and without FFR was global, and we did not measure P_{KA} and fluoroscopy time immediately before and after the FFR measurement, as done by Ntalianis *et al.*[12]. No data on occupational dosimetry were available.

CONCLUSIONS

The results of this observational study, conducted in a large population, showed that FFR increased the radiation dose significantly in patients undergoing coronary angiography and modestly in PCI. Intracoronary imaging by ultrasound of optical coherence tomography had a very limited effect on exposure during coronary angiography and none in PCI. Both diagnostic and interventional coronary procedures associated with FFR and/or intracoronary imaging can be performed with low doses of radiation, provided that optimization techniques are used. The increase in exposure associated with functional assessment of coronary stenoses by FFR and intracoronary imaging appears acceptable given the important additional information they provide to the understanding of coronary disease, to decision-making support, and to therapeutic perspectives.

SUPPLEMENTARY DATA

Supplementary materials are available at *Radiation Protection Dosimetry* online.

ACKNOWLEDGEMENTS

The authors thank all interventional cardiologists, our clinical research assistants especially Christophe Laure, Jeanne Hohweyer, Carole Bellanger, Amelie Guillet, Lucile Fatien and our data manager Isabelle Goussard. We thank Sophie Rushton-Smith, PhD, for editorial assistance.

FUNDING

The CRAC-France PCI registry is supported by the regional health agency of Centre-Val-de-Loire (2015/OSMS/OS/15) and French the Ministry of Health. The present work was also supported by the Centre Hospitalier de Versailles. Unrestricted additional funding was provided by: AstraZeneca, Medtronic, Boston Scientific, Abbot, Biosensor, Terumo, Biotronik, Lilly Daichii Sankyo, Hexacath and Braun. The sponsors were not involved in the design, study progression, collection, management, data analyses or interpretations of the results and had no role in the preparation, review or approval of the manuscript.

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