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Abstract

Interventional cardiology (IC) has grown rapidly with an annual workload of 15 577 therapeutic procedures in Europe according to a 2006 IAEA data collection (1). Although these procedures provide significant benefits to the patient compared to surgical methods, concern has grown about radiation exposure and more specifically, doses to the skin following these types of procedure. Consequently, prior knowledge of the factors that influence the peak skin dose (PSD) in order to optimise practices is of outmost importance for patient radiation protection.

In the VERIDIC (Validation and Estimation of Radiation skIn Dose in Interventional Cardiology) project, medical practices for high-dose, cardiac procedures and the resulting skin doses werere analysed. Through investigating the relations between procedure parameters and skin dose, skin dose reduction strategies were defined. Reference and alert levels in terms of DAP, AK and PSD were established.

In order to do so, two subtasks were defined. In the first subtask, data collection was conducted by project partners in 8 countries (Belgium, Croatia, France, Greece, Ireland, Italy, Serbia, Switzerland), 12 hospitals and 22 IC rooms. In the second subtask, the influence of clinical procedure parameters on the patient exposure were investigated by performing univariate and multivariate statistical analysis on R software. Technical parameters were extracted from provided RDSR using Python code and the influence of technical parameters on patient exposure was studied using univariate and multivariate analysis on R software. Based on the multivariate results, a priori and a posteriori models for estimating PSD as well as recommendations for patient dose optimisation were derived.

Three types of IC procedures were identified for data collection: PCI (Percutaneous Coronary Intervention), CTO (Chronic Total Occlusion Percutaneous Coronary Intervention) and TAVI (Trans catheter Aortic Valve Implantation) as these therapeutic procedures are associated with non-negligible doses to the patient. A comprehensive questionnaire was jointly developed by experienced participating partners. It includes 62 clinical parameters divided into 10 subsections as well as dosimetric information. The questionnaire was filled for each procedure. For the hospitals and rooms in which it was available, the Radiation Dose Structured Reports (RDSR) for each patient was collected. RDSR was also used with Python code to extract technical parameters. Univariate and multivariate statistical analysis was performed using clinical determinants and extracted technical parameters; DRL were suggested and predictive models were derived. Overall, technical factors were found to be more influential on skin dose than clinical factors. For PCI, fluoroscopy time, tube voltage and current as well as distance source to detector were major factors increasing PSD. For CTO, age, BMI, sex, number of fluoro/cine acquisitions as well as sheath size were determinant factors for an increase in PSD. For TAVI, sex, age, fluoroscopy time and stationary acquisition (cine mode) were most prominent in depicting an increase in PSD. Frequency of high dose procedures was determined over 3-6 months in participating sites and accounted for 2.65 % of total procedures having an AK between 3 and 5 Gy and 0.75 % having a PSD between 3 and 5 Gy.

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List of acronyms

AM: Acute Marginal Branch

BMI: Body-Mass Index

CABG: Coronary Artery Bypass Graft Surgery

COPD: Chronic Obstructive Pulmonary Disease

CTO: Chronic Total Occlusion

Cx: Left Circumflex Artery

DCM: DICOM defined code

DICOM: digital imaging and communications in medicine

FOV: Field Of View

HBP: High Blood Pressure

IC: Interventional Cardiology

ICRP: International Commission on Radiological Protection

ICRU: International commission on radiation units and measurements

DAP: Dose-Area Product

AK: cumulative Air Kerma at interventional reference point

kVp: kilovoltage peAk

LAD: Left Anterior Descending coronary artery

LM: Left Main

MI: Myocardial Infection

PCI: Percutaneous Coronary Intervention

POBA: Plain Old Balloon Angioplasty

PSD: Peak Skin Dose

RCA: Right Coronary Artery

RDSR: Radiation Dose Structured Report

WP: Work Package

1 Investigation of skin dose determinants and optimisation of medical practice

1.1 General framework

In recent years, the number of interventional cardiology (IC) procedures have increased, as it limits hospitalization duration and is a good substitute for invasive surgery (2-4). As more complex procedures become technically possible, patients may be exposed to high doses to the skin resulting in tissue reactions following single or multiple procedures. Side effects of radiation include hair loss, skin damage (related to total Kerma) and risk for development of neoplasia (related to total Dose Area Product) (5). Three types of IC procedures are chosen within this project: PCI (Percutaneous Coronary Intervention), CTO (Chronic Total Occlusion Percutaneous Coronary Intervention) and TAVI (Trans catheter Aortic Valve Implantation). PCI is a therapeutic procedure performed on the coronary arteries and/or coronary artery graft. CTO is a subspecialty procedure of PCI used to treat patients with chronic total occlusion (CTO), or complete blockages, of the coronary arteries. TAVI is a therapeutic procedure performed for the treatment of symptomatic aortic stenosis in patients who cannot undergo conventional surgical procedure.

Several software tools have been developed to assess the Peak Skin Dose (PSD) which patient is receiving during these procedures. VERIDIC project is aimed to evaluate these tools form different perspectives, as outlined in project work packages. WP1 dealt with harmonization of these software tools whereas WP2 developed a comprehensive quality assurance programme and validation tools for the softwares. WP3's aim was to investigate clinical and technical parameters that have an influence on patient's dose through an extensive data collection in 12 hospitals and 22 rooms which encompasses all 4 vendors (Canon, GE, Philips and Siemens)

1.1.1 Description of work achieved in WP3

In WP3 a data collection was done in by project partners from 8 countries (Belgium, Croatia, France, Greece, Ireland, Italy, Serbia, Switzerland), in 12 different hospitals and 22 IC rooms for three types of cardiology procedures (PCI, CTO and TAVI) through a questionnaire. RDSR were collected in sites where they existed. Data collection was approved through each country institutional ethical board committee.

Two different sub-tasks were carried out during the considered reporting period:

- Data collection through a questionnaire (clinical and dosimetry parameters) as well as technical parameters collected from available RDSR/Excel dose reports
- Statistical analysis (univariate and multivariate analysis) on the collected data in order to define optimization of practice

1.1.2 Data Collection

Development of a questionnaire

The questionnaire was developed on an Excel sheet and included 12 different sections with 62 parameters:

- Inclusion
- Risk factors
- Medical history
- Operator experience
- Vessels treated
- Approach
- Lesion Description
- Techniques
- Wire complications
- Stents or Valves
- Dosimetry
- Interventional cardiology room equipment

A separate sheet for each type of procedure (PCI/CTO and TAVI) was created and some sections were adapted to the specificity of the particular procedure such as the section Stents for PCI/CTO procedures that is replaced by Valves for TAVI procedures. Different clinical parameters taken into account in the questionnaire are described in Table 1.

Table 1 Different sections of the Excel questionnaire with clinical parameters

Inclusion	**Risk Factors**	**Medical History**	**Operator**	**Vessels treated**	**Approach**	**Lesion Description**	**Techniques**	**Wire Complications**	**Stents (Valves)**
Age	*HBP*	*COPD*	Operator Experience	Number of treated vessels	*Femoral*	*RCA*	Contrast agent type	*Dissection*	*Number of stents*
Sex	*Diabetes*	*Previous Stroke*		Number of stented vessels	*Radial*	*LAD*	Contrast agent quantity	*Coronary ostium dissection*	*Stent Length*
Height	*Dyslipedemia*	*Previous MI*			*Brachial*	*Cx*	*Rotablator*	*Perforation*	*Total Stent Length*
Weight	*Smoking*	*Previous PCI*			*Size 4/5/6/7/8F*	*Left Main*	*Cutting balloon*	*Pericardiocentesis*	*Number of valves*
BMI	*Renal Failure*	*Previous CABG*			*Sheathless*	*Marginal*	*Laser*	Stent on percutaneous approach	Valve type
	Peripheral arterial disease	Number of diseased vessels			Subclavian (TAVI)	*Bifurcation*	*POBA*		
		Number of previous attempts			Carotid (TAVI)	*Proximal to Lesion Stenosis (only for PCI)*	Antegrade		

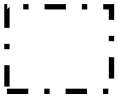
					Transapical (TAVI)	*Tortuosity*	Retrograde		
						Calcified	Bilateral (CART)		
						Proximal to CTO lesion	Septal		
						J-CTO score	Epicardial		
							Previous antero/ retro failed same session		

Common variables for PCI, CTO and TAVI procedures

Common variables for PCI and CTO procedures

Common variables for PCI and CTO procedures

Specific Variables for TAVI procedures



Specific Variables for PCI procedures

All the items of the questionnaires were developed with the help of cardiology registrar/cardiologists to take into account all parameters that have a role in procedures' complexity.

Most questionnaire items were binary responses (Y/N) except when numerical values were needed such as age, BMI, number of stent, length of stent etc. The majority of clinical parameters were found in end of treatment reports.

J-CTO score was defined according to the scale defined in Table 2 following Morino et al. publication (6):

Table 2: J-CTO score scale

J-CTO score	
0	No tortuosity, no calcification and no previous attempt
1	Tortuosity OR Calcification OR Previous attempt
2	Any 2 of the 3 criteria Tortuosity/Calcification/Previous attempt
3	Tortuosity and Calcification and Previous attempt

Operator experience was divided in 3 levels: level 1 for less than 5 years' experience, level 2 for 5-10 years' experience and level 3 for more than 10 years 'experience.

The dosimetry section includes comprehensive dosimetry information about the procedure that can be found either on the DACS (Dose Archiving and Communication System) or on the equipment console itself (total DAP, total AK, total fluoroscopy time etc.) as illustrated in Table 3.

Interventional cardiology equipment parameters include manufacturer name and type/model of unit. Quality Assurance (QA) results were also mentioned to assure that equipment was well maintained and that the accuracy of the DAP meter was within acceptable limits according to local QA protocols as mentioned in Table 3.

Table 3: Collected parameters on dosimetry and interventional cardiology room equipment

Dosimetry	**Interventional cardiology room Equipment**	**QA**	**Protocol used**
Total DAP	Room ID	DAP accuracy	Name of the protocol
DAP fluoro	Manufacturer	AK accuracy	
DAP cine	Type		
Total AK	Year manufactured		
AK fluoro	Detector type		
AK cine	Detector size		
PSD (Peak Skin Dose)			
Fluoroscopy time			
Procedure time			

On the clinical side, 62 clinical parameters were collected that are of interest when describing the complexity of the procedure.

Questionnaires were filled for a total of 962 procedures in 8 countries (Belgium, Croatia, France, Greece, Ireland, Italy, Serbia, Switzerland), 12 hospitals and 22 fluoroscopic systems supplied by 4 manufacturers. Patient identities were preserved according to local ethical regulations in each country and the study was approved by Mondor Institutional Review Board (00011558) as the statistical analysis of data was done in APHP-Bicêtre.

Table 4 summarizes the number of procedures per site and per equipment. All sites except D-site 1 had DR detector systems and all of equipment were manufactured between 2005-2016. Data on 534 PCI 219 CTO and 209 TAVI procedures were collected.

Table 4: Summary of equipment and number of procedures per country site

Country code	Manufacturer	Model	Year	Number of PCI	Number of CTO	Number of TAVI
A	Philips	Allura Clarity FD10	2008	28	8	52
		Allura Clarity FD10	2008	22	3	
B	GE	Innova 2100IQ	2012	44		
		Innova 2100IQ	2012	13		
C	Canon	Infinix 8000 D biplan	2017	31	10	2
	Siemens	Artis Zee	2011	28	3	29
D-site 1	Siemens	AXIOM ARTIS dBA	2006	65		
D-site 2	Philips	ALLURA	2010	16		12
D-site 3	Philips	PHILIPS ALLURA XPER FD10	2011	37		15
E-site 1	Philips	Allura Xper FD10	2016	18		
		Azurion 7 M12 Clarity IQ	2017	33		
E-site 2	Siemens	Artis Zee Floor	2014	2	2	
		Axiom Artis dFc	2005	31	28	
E-site 3	GE	Innova 520	2014	29	17	17
		Innova 520	2018	33	19	31
	Siemens	Axiom Artis Q Zen	2013	5	11	
		Axiom Artis Q Zen	2013	6		
F	Siemens	Axiom Artis dFA	2008	21	17	
		Axiom Artis dFA	2008	16	7	
		Axiom Artis zee Floor	2016	4	8	
G	Siemens	ARTIS zee	N/A	52	51	51
H	Philips	Allura Xper	2009		35	
Total Number				534	219	209

Image quality

In order to verify the harmonisation of image quality among partners, image quality evaluation was performed in some participating hospitals. Initially, seven countries were supposed to contribute to this exercise by providing, for a selected number of local interventional centres, 5 diagnostic procedures (coronarographies) scored according to a set of predefined quality criteria. In total, 11 hospitals were identified as potentially being able to provide data and being ready to assess coronarography images as planned in WP3. Unfortunately, for several feasibility reasons, the actual number of collected IC procedures was much less important than the announced one leading to a reduced sample of scored examinations as shown in Table 5.

Table 5: Expected and actual sample size and mean number of IC gathered by each room for image quality evaluation

	Initial Number	Actual Number
Countries	8	4
Nb of IC centers	12	6
Nb of IC rooms	22	6
Nb of IC procedures by centre	5	7,8
Total (examinations)	110	47

On average, image quality was scored on more than 7 procedures per partner site using overall criteria (mostly related to technical component of the procedure) as well as specific criteria for the visualization of the RCA and LAD (mostly expressing the degree of visibility of anatomical details) .

Despite the reduced IC procedures sample size, some interesting results were found. The overall image quality assessed according to the compliance with criteria such as arms superimposition, full opacification of the vessel lumen, panning and collimation showed two different categories of centres. Those (A and C) where the criteria were 100% time fulfilled, meaning an “optimal” way of performing all the procedures i.e. no arms superimposition, a full opacification of the vessel lumen, no panning, images collimated as adequately as possible; and those where the procedures were far from being “optimal” as illustrated in figure 1.

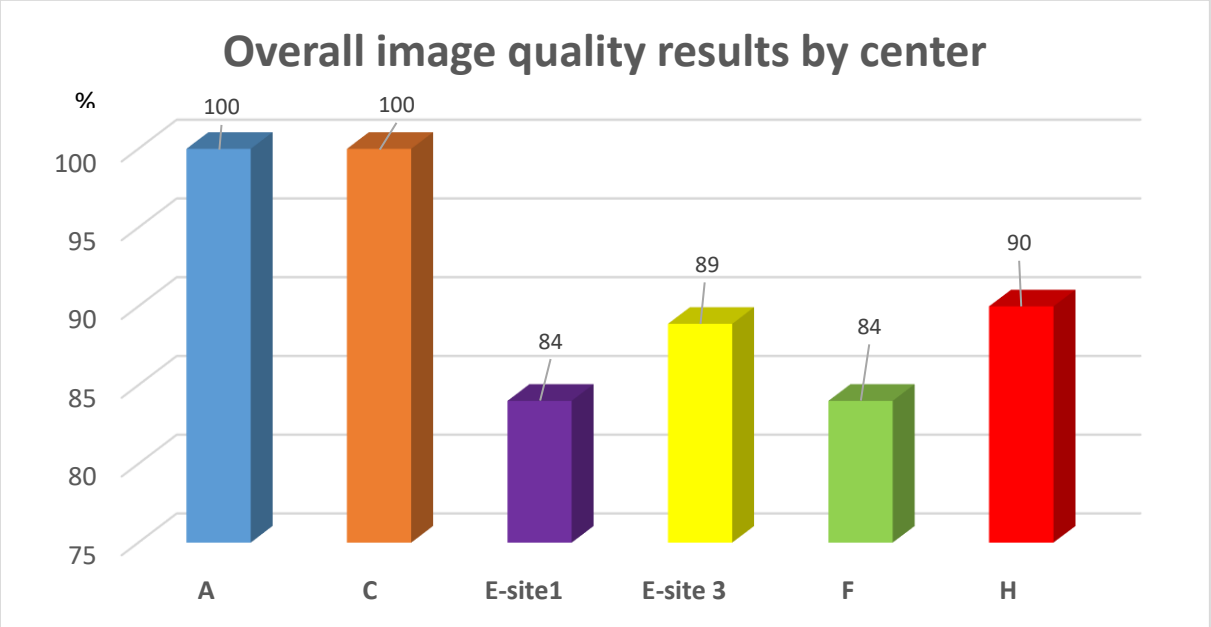


Figure 1: Overall image quality results by center

When combining all centers together and looking at the overall image criteria results, one may estimate the degree of fulfilment of each criterion and therefore appreciate the overall relevance of the selected criteria to "gauge" the quality of the procedure (figure 2).

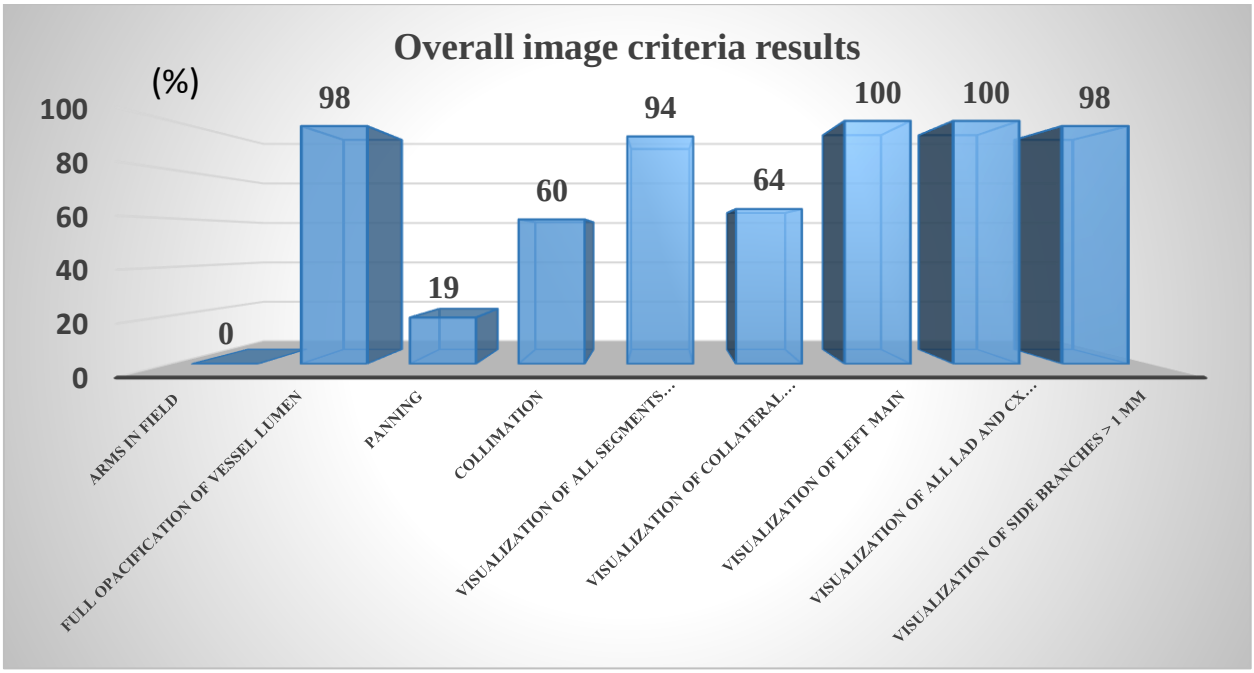


Figure 2: Overall image criteria results

Depending on the criterion considered, the fulfilment rate varied from 0 to 100%.

The criterion "arms in the field", that can be considered as a relevant indicator of the radiological practice, received the lowest possible score, showing from radiation protection point of view, that all procedures were correctly performed without directly exposing patient's arms to the primary beam.

Score values given to more anatomical details visibility related criteria were less homogeneous indicating for instance the difficulty of visualizing very tiny structures such as collaterals (seen in 64% of procedures) despite the high score (98%) of "full opacification of the vessel lumen" criterion.

At least, more than 1 procedure out of 2 included one or few images which were collimated thus dealing with a field of view restricted to the region of interest as clearly recommended by the cardiology code of good practice.

As for “panning”, a technique that should as much as possible be avoided, almost 20 % of procedures showed during a given x-ray projection such a moving images.

RDSR collection and Python code

For the cathlabs in which it was available (408 procedures / 962 collected) 42 % of the total number of procedures, RDSR was collected. A multi-manufacturer adaptable Python code was developed in order to extract technical information that was of interest to relate to dose received by the patient. For each X-ray event, the technical parameter associated was extracted (Table 6).

Table 6: Technical parameters extraction

Technical parameters extracted from all RDSR
Tube voltage (kV)
Tube current (mA)
Collimated Field Area (mm^2)
Source to detector distance (mm)
Field Of View (mm)
Table height (mm)
Contribution in % of fluoroscopy
Primary angle (degree)
Secondary angle (degree)
Number of fluoro acquisitions
Number of cine acquisitions
Patient thickness (mm)*
Pulse rate (pps)

*Only three sites had patient thickness in RDSR for PCI pr

Each procedure was associated with a series of x-ray events. Therefore, the mean value of tube voltage, tube current, source to detector distance and table height were computed. In order to compute fluoroscopy contribution in percentage, the AK associated to fluoroscopy was divided by total AK. Primary angles were associated to the following angulation according to their contribution to total AK:

Angle (°)	
[-180,-67.5[	RLAT
[-67.5, -22.5]	RAO
[-22.5, 22.5]	PA
]22.5 + 67.5]	LAO
]67.5, 180]	LLAT

The median patient thickness for PA angulation was calculated for each patient according to the values provided in RDSR.

Among the 408 procedures with RDSR, Peak Skin Dose was calculated for 383 procedures using different online/ offline software's as illustrated in Table 7:

- RDM for GE and Siemens RDSR (RDM is not validated for Philips or Canon/Toshiba equipment)
- Radimetrics for Philips
- Dose Tracking System (DTS) for Canon procedures
- SkinCare (developed under the PhD project of Marko Karijnovic-Vinca Institute of Nuclear Science)
- For some procedures that had no RDSR a PSD was provided on Siemens DICOM images.

An extended description of the software products is available in the first deliverable of the present project (7).

Table 7: Distribution of Online/Offline software PSD calculation per type of procedure

PSD calculation		
PCI	170	71 RDM 50 Radimetrics 31 Canon (Online) 18 Siemens (Online)
CTO	106	47 RDM 11 Radimetrics 10 Canon (Online) 3 Siemens (Online) 35 SkinCare
TAVI	117	45 RDM 52 Radimetrics 2 Canon (Online) 18 Siemens (Online)

The uncertainty associated with PSD calculations of CareMonitor, DTS and RDM 3D was evaluated on compatible angiographic systems as part of VERIDIC activities. Tests were performed for different thicknesses of PMMA phantom and simple projections on a Rando Alderson phantom; in addition, software accuracy was evaluated for three clinical procedures on a Rando Alderson phantom. Detailed resuts can be found in the third project deliverable (8). Accuracy of CareMonitor on a Siemens system and DTS on a Canon system was on average 82% and 80% over the three clinical procedures and within 28% and 28%, respectively; whereas RDM 3D accuracy on a Siemens and a GE system was on average 98% and 142%, and within 9% and 51%, respectively. Radimetrics accuracy could not be tested.

The different sites for which PSD was available is described in Table 8 including manufacturer, model, year of manufacturing as well as the number of PCI, CTO and TAVI for each site.

Table 8: Number of procedures per site and model for PSD

Country code	Manufacturer	Model	Year	Number of PCI	Number of CTO	Number of TAVI
A	Philips	Allura Clarity FD10	2008	28	8	52
		Allura Clarity FD10	2008	22	3	
C	Canon	Infinix 8000 D biplan	2017	31	9	2
	Siemens	Artis Zee	2011	18	3	18
E-site 3	GE	Innova 520	2014	29	17	15
		Innova 520	2018	33	19	30

	Siemens	Axiom Artis Q Zen	2013	4	11	
		Axiom Artis Q Zen	2013	5		
	Philips	Allura Xper	2009		35	
Total Number				170	105	117

Collection of dose reports over 3-6 months

In order to estimate the frequency of high dose procedures, Excel dose reports/RDSR for all cardiac procedures during a timeline of 3-6 months in the majority of the participating sites were collected. Nine sites out of twelve could provide such reports and those accounted for 11 712 procedures with Total DAP, 11 218 procedures with Total AK. Only 3 076 procedures with PSD were available for two sites as they provided RDSR or Excel dose reports with PSD value from Dosewatch.

According to ICRP 118, total AK tissue reactions (deterministic effects) appear at the threshold of 2 Gy (early transient erythema) (9). Damage from that point on will become more severe to attain acute ulceration of the skin. Thresholds for patients follow-up as defined in Society of Interventional Radiology Guidelines are 3 Gy for Peak Skin Dose, 5 Gy for Air Kerma and 500 Gy cm2 for DAP (10). Therefore, based on this information, three threshold levels were defined in Veridic for total DAP, total AK and PSD as summarized in Table 9.

Table 9: Threshold levels for Total DAP, Total AK and PSD

Threshold levels	Total DAP (Gy cm^2)	Total AK (Gy)	PSD (Gy)
Level 1	200<DAP≤300	2<AK≤3	2<PSD ≤3
Level 2	300<DAP≤500	3<AK ≤5	3<PSD ≤5
Level 3	DAP>500	AK > 5	PSD > 5

A Python code was developed to extract Total AK, and Total DAP from RDSR/Excel dose reports and assess the frequency of each threshold values for the collected dosimetry data.

2 Statistical Analysis of collected data

R version 3.5.0. was used to analyze the data and perform statistical analysis. Median and range (minimum to maximum) were used to summarize continuous variables while categorical variables were summarized using count and percentage. A two-sided p-value with alpha ≤ 0.05 was used as level of significance. For each procedure (PCI, CTO and TAVI), the overall mean of Total DAP, Total AK, Fluoroscopy time and PSD, was compared to the mean of each site by one-sample t-tests, after verification of validity assumptions.

2.1 Dosimetry data comparisons between sites

Dosimetry data was compared for each type of procedure between the different sites participating in the data collection. Mean value for each site (all rooms per site) was compared to the mean value of all sites for Air Kerma, DAP, Fluoroscopy time and Peak Skin Dose. ***Significant differences (p-value < 0.05) between sites for each dosimetry parameter is illustrated with a star.***

The highest variability of data between sites was observed for PCI (Figure 3). PCI was the type of procedure that had the highest number of sites and total number of procedures. Variations in PCI procedures depend on the clinical condition for each individual patient and are not standardized procedures (4; 10). Moreover, the classification of PCI procedure varies and it is possible that for some sites these procedures were mixed (CA followed by PCI) which would explain the high variability of data (elective PCI procedures versus CA followed by PCI procedures) as CA followed by PCI procedures could result in higher dose. Also, for one site, total obstruction that is less than 3 months old could be accounted as PCI and not CTO which is not the case for all sites.

Air Kerma had over 200% variation for site G compared to the mean value for all sites as shown in Figure 3. DAP had over 100 % variation for site G compared to the mean value for all sites. Site G was the only one with less experienced operators (15 procedures with <5 years experience operators and 62 with 5-10 years' experience operators) as well as with the highest percentage of cine when compared to other sites, which could explain the important differences. Total AK variation for PCI procedures as a function of Operator Experience is illustrated in Figure 6 as well as Table 10.

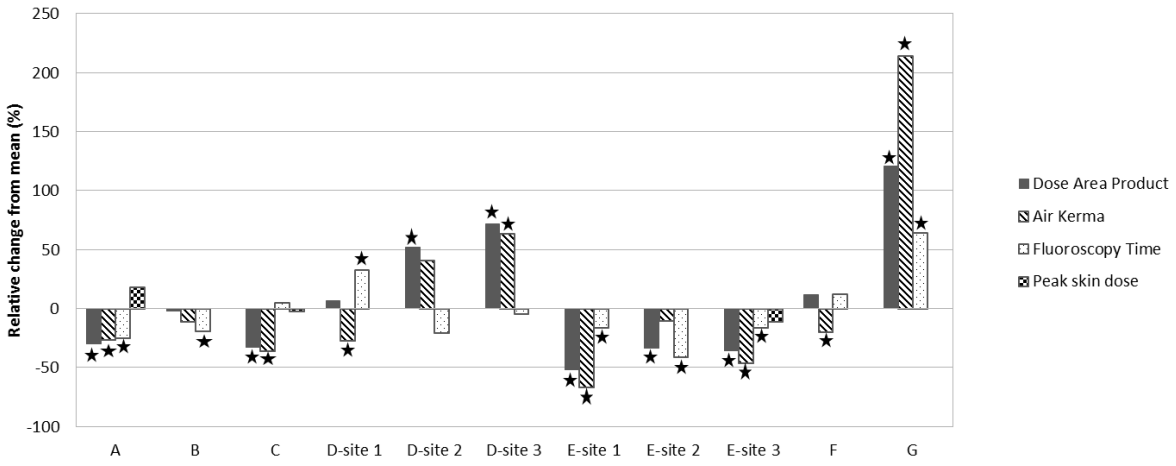


Figure 3: Comparisons to the mean value of all sites for Dose Area Product, Air Kerma, Fluoroscopy Time and Peak Skin Dose per site for PCI **Significant difference between means*

For CTOs in figure 4, site G had the highest air kerma variation with more than 60% and the highest total AK variation with more than 35% when compared to the mean value of all sites. This can be explained by operators' experience as for CTOs, 98% of site G operators had 5-10 years' experience when compared to 87.5% of operators in other sites with more than 10 years' experience. Fluroscopy time was the highest for site C with 80% increase compared to the mean of all sites.

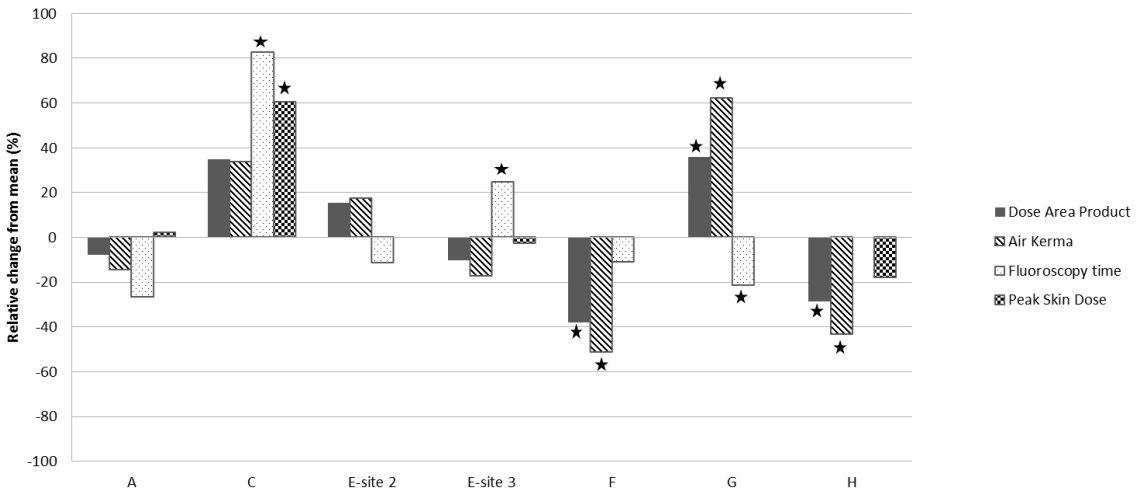


Figure 4: Comparisons to the mean value of all sites for Dose Area Product, Air Kerma, Peak Skin Dose and Fluoroscopy Time per site for CTO procedures **Significant difference between means*

For TAVIs in figure 5, D-site 2 had the highest variation of total AK with more than 120% and G-site the highest variation of Air Kerma with more than 55% when compared to the mean values of all sites. This variation could be explained by the fact that TAVI is a new procedure associated with a learning curve for some unexperienced sites (such as D-site 2) compared to more experienced sites (site A, E site 3).

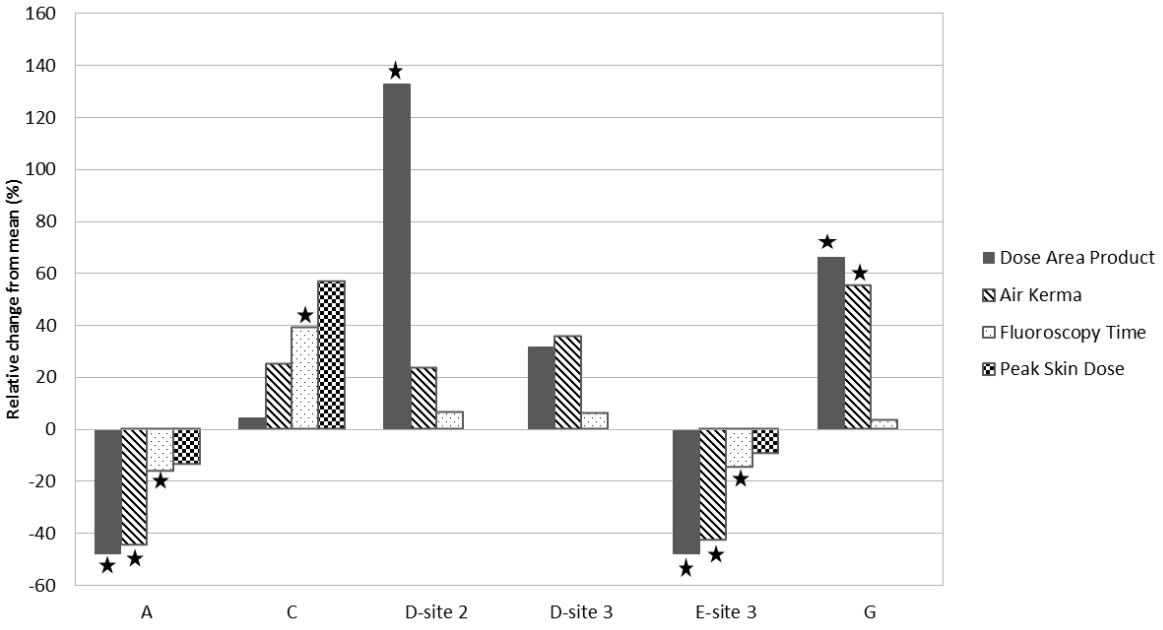


Figure 5: Comparisons to the mean value of all sites for Dose Area Product, Air Kerma, Peak Skin Dose and Fluoroscopy Time per site for TAVI **Significant difference between means*

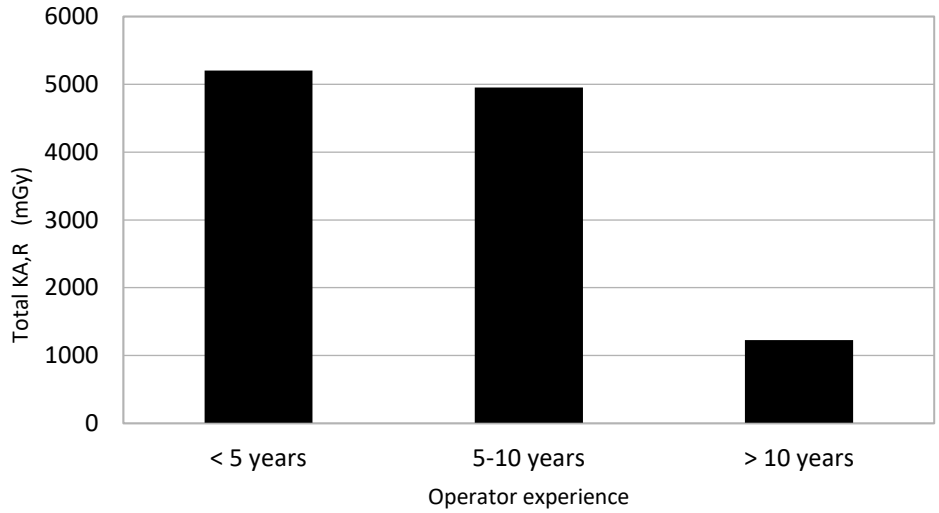


Figure 6: Total AK variation as a function of Operator Experience for PCI procedures

Table 10: Operator Experience and Total AK for PCI procedures

	PCI	
	Total AK	
Operator experience	**N**	**Median**
< 5 years	15	5205
5-10 years	62	4954
> 10 years	424	1226

2.2 Dosimetry data comparisons between procedures

Mean values of dosimetry data (Total AK ,Total DAP, PSD) as well as fluoroscopy time were compared for each of the three types of procedures. Mean total AK, total DAP, PSD and fluoroscopy time were highest for CTO procedures according to figures 7-10 when compared to PCI or TAVI procedures.

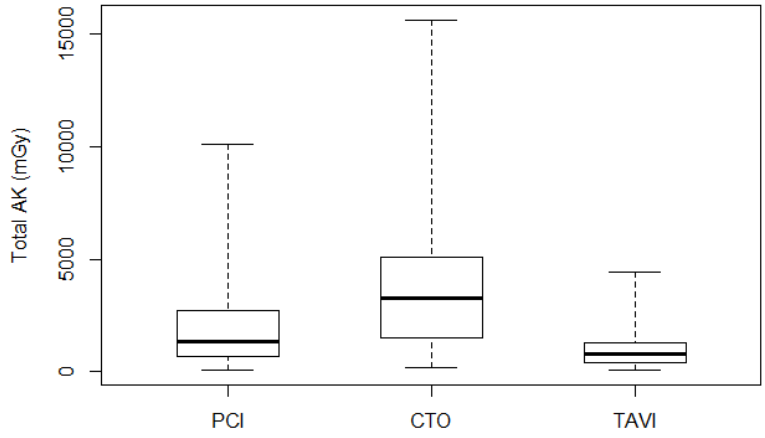


Figure 7: Comparisons of total air kerma for all three procedures' type

Results are expressed as median, 25th percentile, 75th percentile, minimum, maximum values of the distribution.

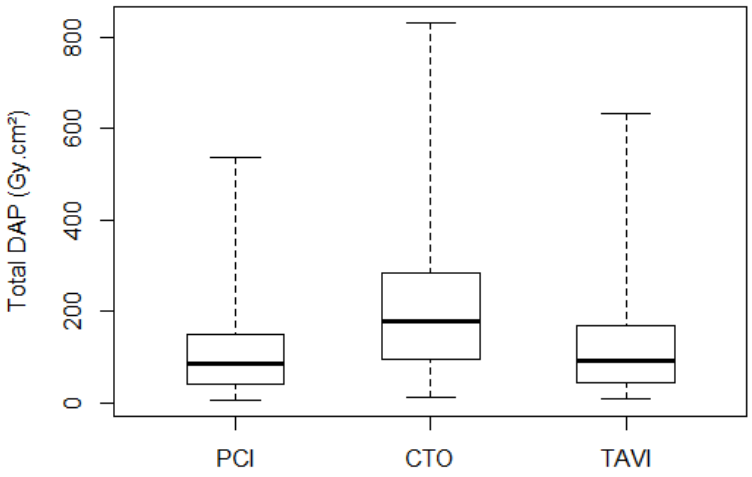


Figure 8: Comparisons of total DAP for all three procedures' type

Results are expressed as median, 25th percentile, 75th percentile, minimum, maximum values of the distribution.

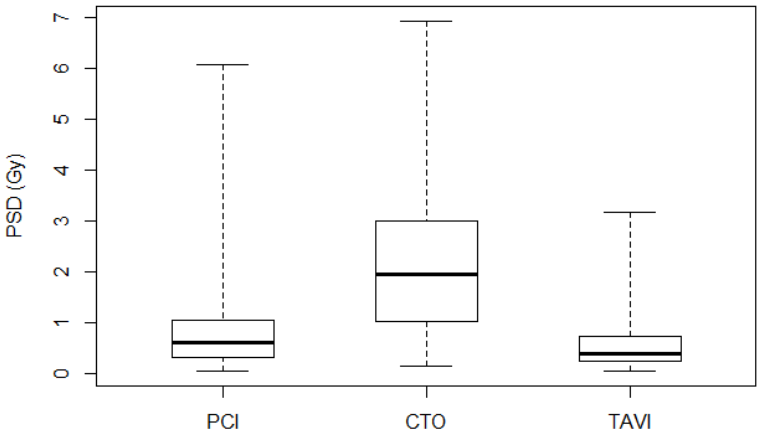


Figure 9: Comparisons of PSD for all three procedures' type

Results are expressed as median, 25th percentile, 75th percentile, minimum, maximum values of the distribution.

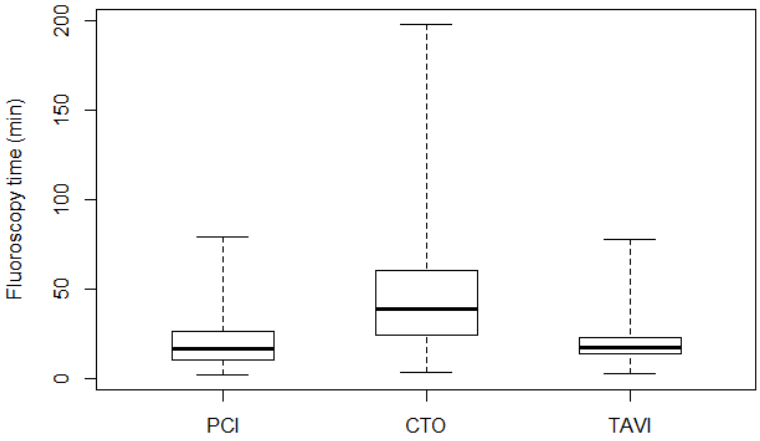


Figure 10: Comparisons of Fluoroscopy Time for all three procedures' type

Results are expressed as median, 25th percentile, 75th percentile, minimum, maximum values of the distribution.

Table 11: Results of statistical analysis comparing Mean Total AK and PSD for three types of procedure

	Total AK (mGy)					PSD (mGy)		
	Mean for all sites	**p-value vs CTO**	**p-value vs TAVI**			**Mean for all sites**	**p-value vs CTO**	**p-value vs TAVI**
PCI	2030	$< 10^{-3}$	$< 10^{-3}$		**PCI**	826	$< 10^{-3}$	$< 10^{-3}$
CTO	3605				**CTO**	2167		
TAVI	985	$< 10^{-3}$			**TAVI**	556	$< 10^{-3}$	

Mean total AK and PSD were compared two by two for each type of procedures (PCI vs CTO, PCI vs TAVI and TAVI vs CTO) in Table 11. Significant differences were found between the mean values of total AK and PSD, which indicates that those three types of procedures are distinct in terms of dosimetrical impact.

Total AK was found to be in the vast majority of the cases overestimating PSD. For PCI , CTO and TAVI total AK was higher than PSD in 91%, 79% and 75 % of the total number of procedures respectively which shows that total AK as a dosimetric parameter is not sufficient alone to predict PSD. It should also be noted that some uncertainty exists in the determination of PSD depending on the software used which in some cases might incur a better prediction of total AK for PSD than calculated PSD itself.

All patient quantitative and clinical binary/qualitative characteristics for the different types of procedures are summarized in the tables below. Quantitative characteristics are reported as median, range (min-max) as well as a percentage of not available characteristics. Clinical Binary/Qualitative Characteristics are expressed as number of subjects as well as percentage of not available characteristics. Variables with less than 10 subjects per category which are highlighted in dark grey were not analysed.

2.3 Collected Procedures Characteristics

Collected quantitative and qualitative characteristics of each procedure type are summarized in the following sections 2.3.1-2.3.3.

2.3.1 PCI Characteristics

The quantitative and qualitative characteristics of the collected PCI procedures are summarized in the tables 12-13.

Table 12: PCI Quantitative Characteristics

Quantitative Characteristics	Median (Min-Max)	% NA
Age (year)	69 (22-96)	0
Height (cm)	172 (148-198)	9.9
Weight (kg)	81 (39-160)	8.1
BMI (kg/m²)	27 (16-45.9)	9.9
Contrast Agent Quantity (mL)	190 (0-965)	18.0
Total Stent Length (mm)	33 (3-172)	4.5
Fluoroscopy Time	17 (2-79)	0.2
Fluoroscopy Contribution (%)	56 (1-100)	5.6
Total Procedure Time (min)	67 (15-230)	39.5
Tube Voltage (kV)	90 (71-117)	11.6
Tube Current (mAs)	288 (118-435)	11.6
Distance source to Detector (mm)	1120 (878-1209)	16.3
Table Height (mm)	947 (843-1040)	57.1
Number of fluoro acquisitions	61 (14-389)	11.6
Number of stationary acquisitions	18 (3-59)	11.6
15 pps contribution (%)	24 (0-100)	8.6
Angulation contribution (%) RAO LAO PA LLAT	 1 (0-76) 24 (0-99) 54 (0-100) 2 (0-80)	 28.8 28.8 28.8 28.8
Patient thickness (mm)	272 (131-417)	34.3
FOV (cm)	17 (12-20)	46.4

Table 13: PCI Qualitative Characteristics

Clinical Binary/Qualitative Characteristics	n (%)	NA in %
Male Sex	417 (78.1)	0
High Blood Pressure	340 (63.7)	7.9
Diabetes	154 (28.8)	9.0
Dyslipidemia	264 (49.4)	8.6
Smoking	196 (36.7)	8.1
Renal Failure	56 (10.5)	9.0
Peripheral artery disease	47 (8.8)	16.1
Previous Stroke	24 (4.5)	8.1
Previous MI	143 (26.8)	6.9
Previous PCI 1 ≥2	 150 (28.1) 26 (4.9)	 11.8
Previous CABG	26 (4.9)	1.3

Diseased vessels		
0	104 (19.5)	21.0
1	109 (20.4)	
2	101 (18.9)	
≥3	108 (20.2)	
Previous attempts		
0	366 (68.5)	26.8
≥1	25 (4.7)	
Treated Vessels		
1	380 (71.2)	0.6
≥2	151 (28.3)	
Stented Vessels		0.7
0	24 (4.5)	
1	391 (73.2)	
≥2	115 (21.5)	
Approach site		3.2
Femoral	62 (11.6)	
Radial	442 (82.8)	
Femoral + Radial	13 (2.4)	
Size		
4/5 F	44 (8.2)	0.2
6/7 F	489 (91.6)	
Lesion type		
RCA	213 (39.9)	0.4
LAD	284 (53.2)	1.7
Cx	161 (30.1)	2.6
Left Main	48 (9.0)	2.8
Marginal	39 (7.3)	7.7
Bifurcation	111 (20.8)	4.5
Contrast Agent type		12.5
Ionic	33 (6.2)	
Non Ionic	434 (81.3)	
POBA	156 (29.2)	0.2
Rotablator	13 (2.4)	4.5
Wire complications		
Dissection	19 (3.6)	0
Coronary ostium dissection	0 (0)	0
Perforation	3 (0.6)	0
Pericardio centesis	2 (0.4)	0
Number of stents		0.6
≤1	283 (53.0)	
2	134 (25.1)	
3	72 (13.5)	
≥4	42 (7.9)	
Technical Qualitative Characteristics	n (%)	NA in %
Equipment Year manufactured		
2005-2010	199 (37.3)	10.1
2011-2014	163 (30.5)	
2016-2018	118 (22.1)	
Manufacturer		1.5
Siemens	230 (43.1)	
GE	119 (22.3)	

Philips Canon	146 (27.3) 31 (5.8)	
Detector Size (cm) 18-25 30-48	 419 (78.5) 63 (11.8)	 9.7
Predominant Pulse Rate 15 pps 7.5 pps	 71 (30.5) 136 (58.4)	 11.2
Predominant Angulation LAO PA	 44 (18.9) 87 (37.3)	 43.8

PCI procedures were performed on 417 (78.1%) male patients and 117 (21.9%) female patients. The median age for those patients was 69 years old, median BMI was 27 and weight was 81. The median age of female patients (72) was 5 year older than of male patients (67). Male patients were heavier than female patients as 27.1 % of male patients had a BMI > 30 compared to 22.2 % of female patients although BMI and sex are distinct. The majority of patients (63.7%) had high blood pressure. 28% of the patients already had one previous PCI and 4.9% two or more. Stents were used for 95.5 % of the patients and 94.7% of the vessels were stented. The most common lesion type was LAD (53.2%) followed by RCA (39.9%) and Cx (30.1%). Very few wire complications (4.5%) were observed for those patients. Equipment used was representative of the 4 different existing manufacturers with a majority of Siemens equipment (43.1%). Fluoroscopic (vs acquisition) imaging mode accounted for 56.4 % contribution to the PSD. 7.5 pps was the predominant pulse rate for 58.4% of PCI procedures and most used angulations were PA and LAO with 37.3% and 18.9% contribution to PSD.

The distribution of total AK in PCI for males and females is illustrated in figure 11. The variation of PSD as a function of BMI was analysed. As presented in Figure 12, a Pearson correlation coefficient of 0.42 was found which indicates that BMI is not the only factor explaining PSD.

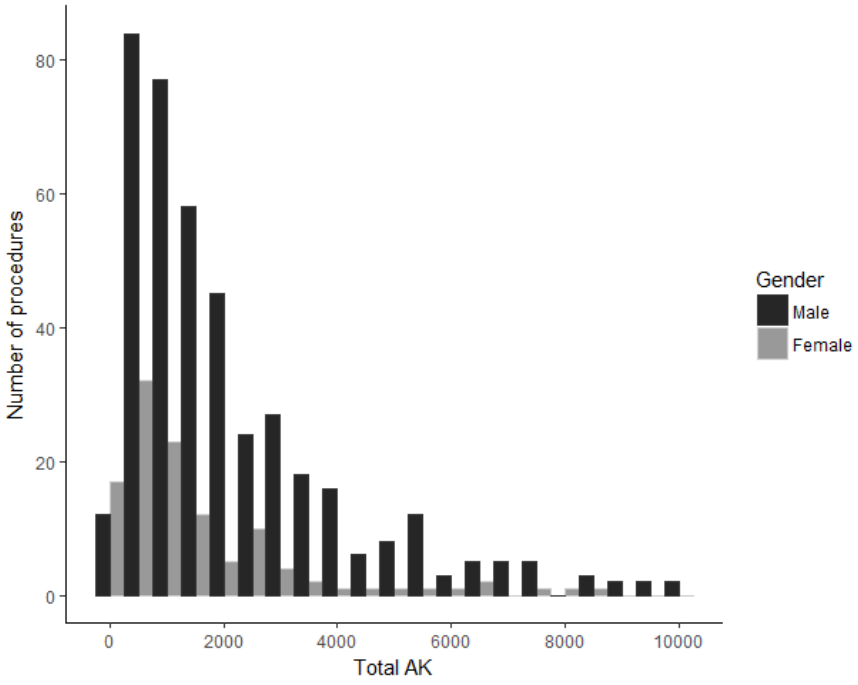


Figure 11: Distribution of Total AK per sex for PCI

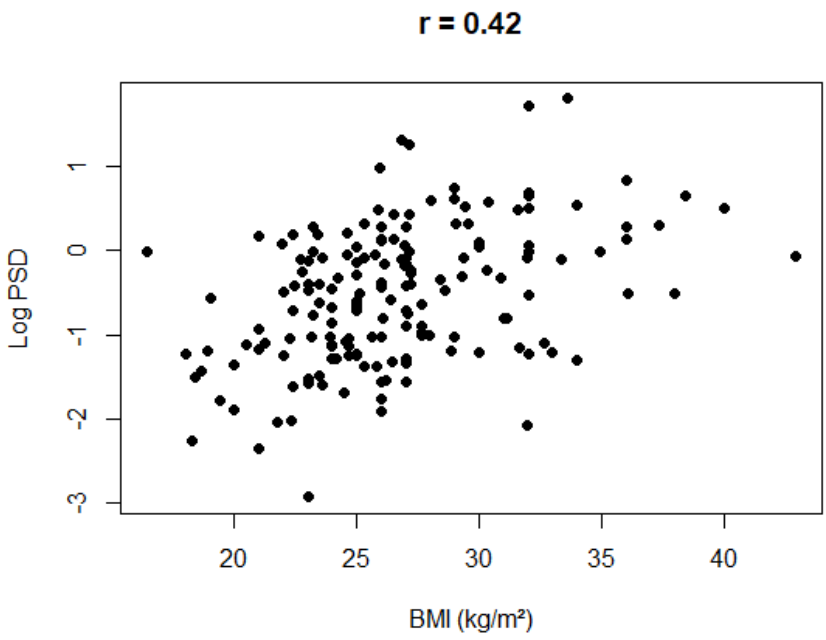


Figure 12: Correlation between log PSD and BMI

For the few sites in which patient thickness was available in the RDSR, the relationship with log PSD was studied. As expected patient median thickness taken for PA angulation had a higher Pearson correlation coefficient with log PSD than BMI with r =0.57, as presented in Figure 13.

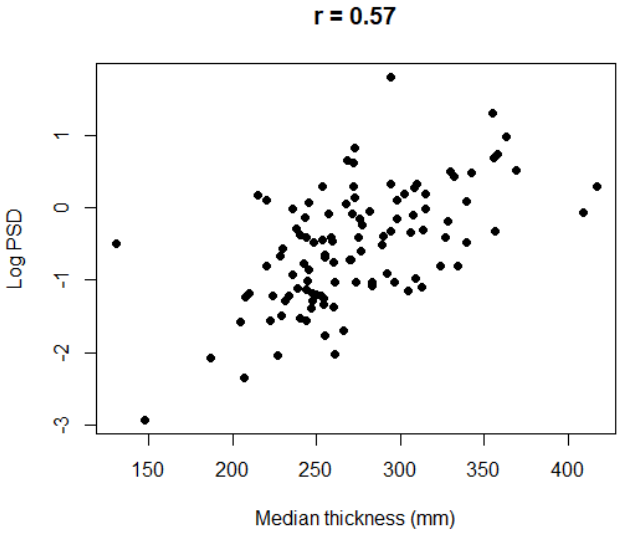


Figure 13: Correlation between log PSD and median patient thickness

Median tube potential in kV and median tube current in mAs were studied as a function of the three BMI classes in figures 14 and 15 respectively. BMI was classified by merging some categories of the World Health Organization classifications for sample size issues: <18.5-24.9, 25-29.9 and >30. As expected, tube potential and tube current increased steadily with BMI, as presented in Figures 14-15. The increase of tube potential was more pronounced which is in agreement with findings by Osei et al.

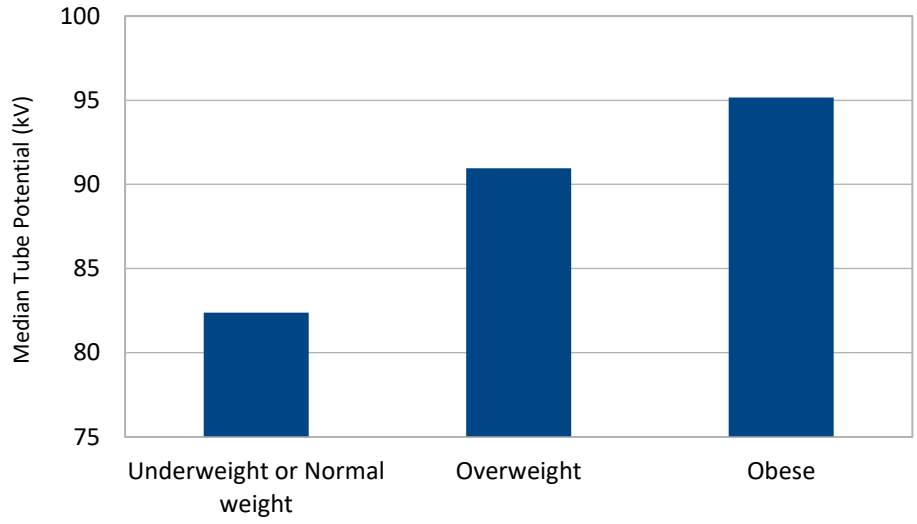


Figure 14: Tube Potential variation between different BMI classes

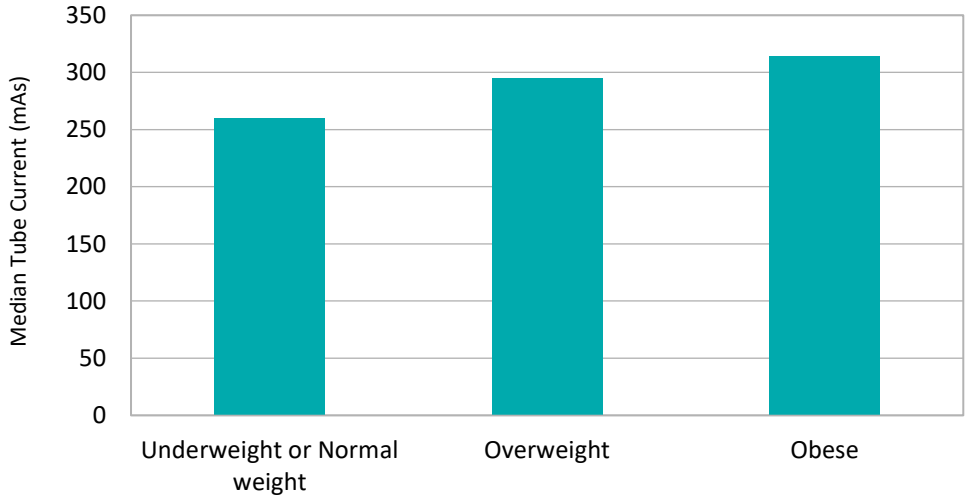


Figure 15: Tube Current variation between different BMI classes

2.3.2 CTO Characteristics

The qualitative and quantitative characteristics of the collected CTO procedures are summarized in the tables 14-15.

Table 14: CTO Quantitative Characteristics

Quantitative Characteristics	Median (Min-Max)	% NA
Age (year)	64 (31-87)	0
Height (cm)	174 (145-197)	0
Weight (kg)	85 (45-178)	0
BMI (kg/m²)	28 (16-63)	0
Contrast Agent Quantity (ml)	305 (68-870)	7.3
Total Stent Length (mm)	61 (0-181)	22.8
Fluoroscopy Time	39 (3-198)	16.0
Fluoroscopy Contribution (%)	66 (22-92)	39.7
Total Procedure Time (min)	109 (20-480)	15.1

Detector Size (mm)	21 (18-48)	23.3
Tube Voltage (kV)	93 (75-116)	2.8
Tube Current (mAs)	235 (121-413)	2.8
Distance source to Detector (mm)	1123 (960-1200)	3.8
Table Height (mm)	899 (868-946)	89.6
Number of fluoro acquisitions	110 (25-545)	2.8
Number of stationary acquisitions	25 (3-71)	2.8
15 pps contribution (%)	41 (0-100)	1.9
Angulation contribution (%) RAO LAO PA LLAT	 2.9 (0-70) 39 (0-95) 50 (1-100) 0 (0-36)	 13.2 13.2 13.2 13.2
Patient thickness (mm)	268 (186-378)	55.7
FOV (cm)	17 (13-20)	55.7

Table 15: CTO Qualitative Characteristics

Clinical Binary/Qualitative Characteristics	n (%)	NA in %
Male Sex	190 (86.8)	0
High Blood Pressure	172 (78.5)	0
Diabetes	70 (32.0)	0
Dyslipidemia	166 (75.8)	0
Smoking	132 (60.3)	0.5
Renal Failure	13 (5.9)	23.3
Peripheral artery disease	18 (8.2)	23.3
Previous Stroke	7 (3.2)	23.3
Previous MI	69 (31.5)	0
Previous PCI 1 ≥2	 83 (37.9) 35 (16)	 0
Previous CABG	10 (4.6)	0
Diseased vessels 0 1 2 ≥3	 39 (17.8) 73 (33.3) 53 (24.2) 54 (24.7)	0
Treated Vessels ≤1 ≥2	 194 (88.6) 24 (11.0)	 0.5
Stented Vessels 0 ≥1	 38 (17.4) 180 (82.2)	0.5
Approach site Femoral only Radial only Double Femoral Double Radial 2 sites Femoral + Radial or Femoral + Double Radial Brachial	 66 (30.1) 56 (25.6) 3 (1.4) 43 (19.6) 48 (21.9) 1 (0.5)	0.9
Size 4/5/6 F	 151 (68.9)	 0

7/8 F	68 (31.1)	
Lesion type At least one RCA At least one LAD At least one Cx	 134 (61.2) 67 (30.6) 29 (13.2)	0
Tortuosity 0 ≥1	 73 (33.3) 55 (25.1)	41.6
Calcified 0 1 ≥2	 97 (44.3) 41 (18.7) 49 (22.4)	14.6
Bifurcation	37 (16.9)	15.5
Proximal to CTO lesion	30 (13.7)	16.4
J-CTO score 0 1 ≥2	 64(29.2) 46 (21.0) 77 (35.2)	14.6
Techniques		
Antegrade	113 (51.6)	40.2
Retrograde	37 (16.9)	26.0
Bilateral	11 (5.0)	40.6
Previous anterograde failed same session	31 (14.2)	23.3
Previous retrograde failed same session	20 (9.1)	23.3
Septal	19 (8.7)	23.3
Epicardial	6 (2.7)	23.3
Wire complications Dissection Coronary ostium dissection Perforation Pericardio centesis	 12 (5.5) 2 (0.9) 5 (2.3) 4 (1.8)	0
Contrast Agent Type Ionic Non-ionic	 29 (13.2) 189 (86.3)	0.5
Rotablator or other device	6 (2.7)	0
Number of stents 0 1 2 ≥3	 50(22.8) 54(24.7) 55(25.1) 60 (27.4)	0
Equipment Year manufactured 2005-2010 2011-2014 2016-2018	 98 (44.7) 33 (15.1) 35 (16.0)	24.2
Manufacturer Siemens GE Philips Canon	 127 (58.0) 36 (16.4) 46 (21.0) 10 (4.6)	0
Predominant Pulse Rate		

10 pps 15 pps 7.5 pps	2 (1.9) 44(41.5) 58 (54.7)	1.9
Predominant Angulation LAO PA RAO PA + LAO PA + RAO LAO + LLAT PA + LAO + RAO	 35 (33.0) 36 (34.0) 2 (1.9) 2 (1.9) 4 (3.8) 2 (1.9) 1 (0.9)	12.3

CTO procedures were performed on 190 (86.8%) male patients and 29 (13.2%) female patients. The median age for those patients was 64 years old, median BMI was 28 and weight was 85 kg. The median age of female patients and male patients was equivalent (64 year old). 35.8% of males had a BMI>30 when compared to 41.4% of women which indicates that BMI and sex are distinct. The majority of patients had Dislipidemia (75.8%) and/or High Blood Pressure (78.5%). 60.3 % of the patients were smokers. Stents were used for 77.2 % of the patients and 82.2% of the vessels were stented. The majority of lesions had a J-CTO higher or equal to 2 (35.2%). The antegrade technique was mostly used (51.6%). The most common lesion type was RCA (61.2%) followed by LAD (30.6%). Few wire complications (10.5%) were observed for those patients. Equipment used was representative of the 4 different existent manufacturer with a majority of Siemens equipment (58%). Fluoroscopic (vs acquisition) imaging mode accounted for 65.6 % contribution to the PSD. 7.5 pps was the predominant pulse rate for 54.7% of CTO procedures and most used angulations were PA and LAO with 33% and 34% contribution to PSD.

The distribution of total AK in CTO for males and females is illustrated in figure 16. The variation of PSD as a function of BMI was analysed and a Pearson correlation coefficient of 0.15 was found which indicates that BMI is not the only factor explaining PSD as presented in figure 17.

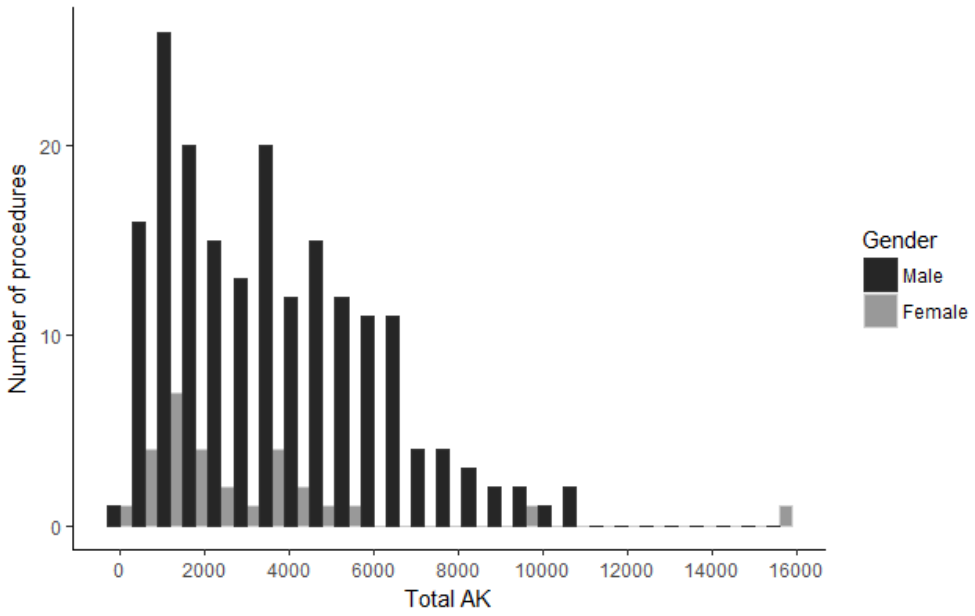


Figure 16: Distribution of Total AK per Sex for CTO procedures

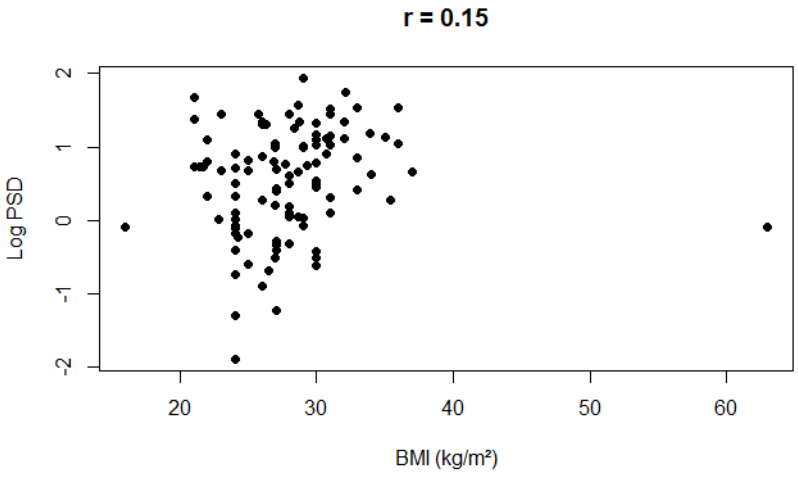


Figure 17: Correlation between Log PSD and BMI for CTO procedures

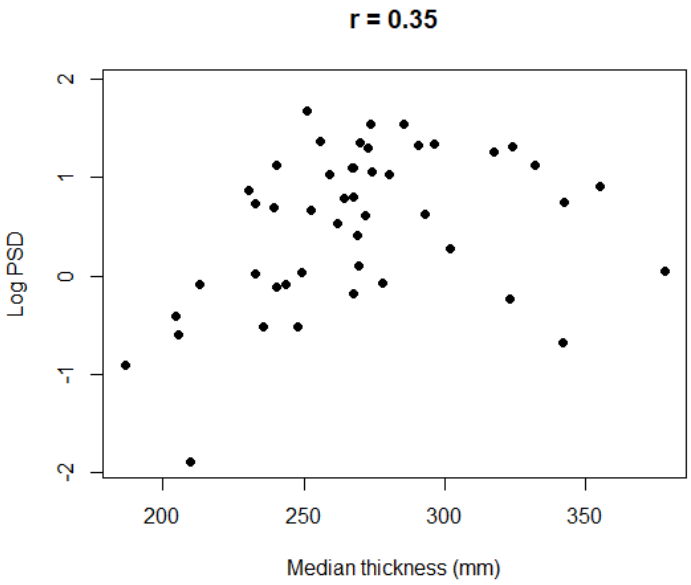


Figure 18: Correlation between Log PSD and Median Patient thickness for CTO procedures

As expected median patient thickness taken for PA angulation had a higher Pearson correlation coefficient with log PSD than BMI with r =0.35, as presented in Figure 18.

Median tube potential in kV and median tube current in mAs were studied as a function of the three BMI classes (Figures 19 and 20). The increase of tube potential was more pronounced. Tube current increase between underweight/normal weight BMI class and overweight BMI class but decreased for obese class most probably compensated by higher tube potential.

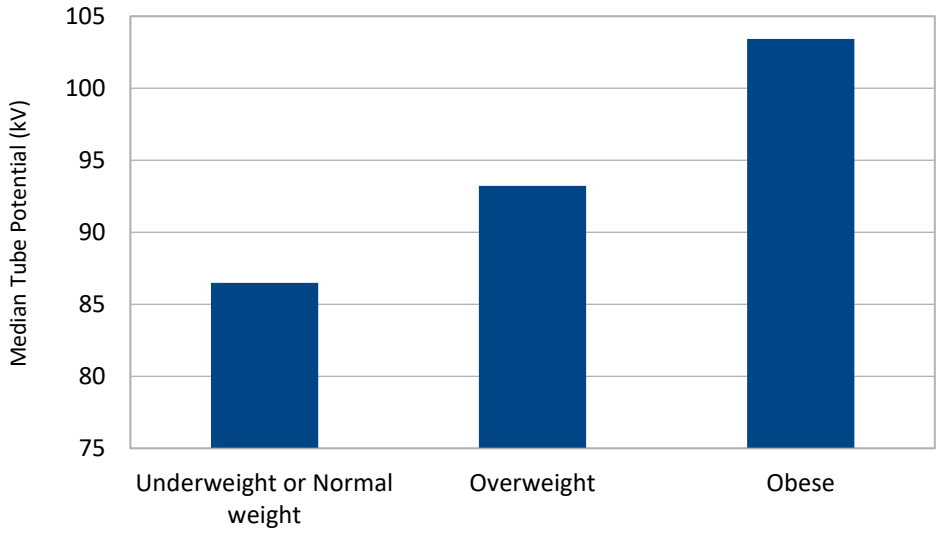


Figure 19: Variation of median tube potential according to BMI classes for CTO procedures

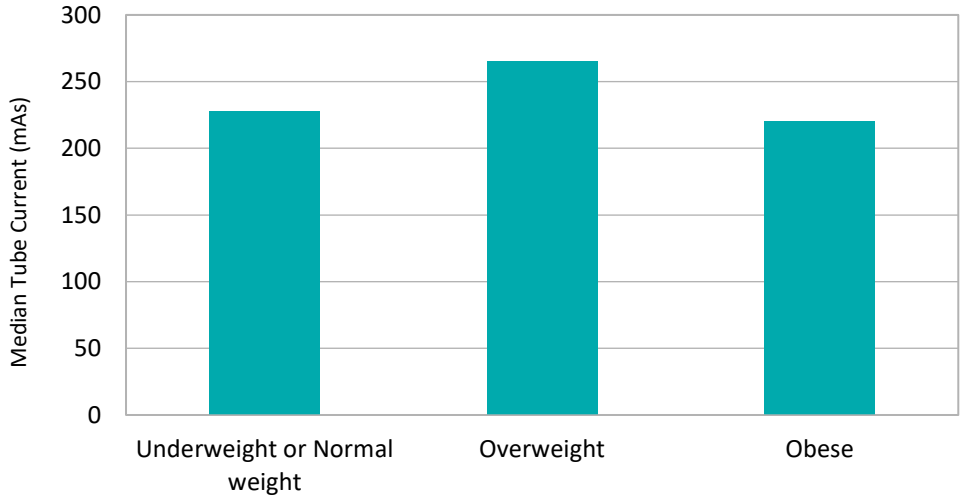


Figure 20: Variation of median tube current according to BMI classes for CTO procedures

Some supplementary analysis was done for the CTO procedures based on the special focus paper (11). In this paper, a review on CTO procedures is presented: safety, patient and equipment selection are defined in order to ensure a successful CTO programme establishment. Strategic decision-making is described as well as the most efficient way in dealing with complex CTO lesion.

From our database, the most common used sheath size were 6/7F. Double arterial access (femoral/radial) accounted for 22% of the total CTO procedures although in the paper dual arterial access is recommended. Only 17% of the procedures were done with a retrograde approach. 68% of the septal lesions were done in retrograde which is identified as ideal.

Age ≥ 65 years and lesion calcifications were identified as unfavourable factors. This was also observed in our dose comparison. Population with age ≥ 65 years and lesion calcifications had significant higher total AK and fluoroscopy time ($p < 10^{-3}$; p= 0.014 respectively) than population with age < 65 years and lesion calcifications.

Other comparisons including long occlusions compared to short ones and comparison of antegrade access with calcification/tortuosity compared to antegrade without calcification/tortuosity were not possible due to low sample size in each class.

2.3.3 TAVI Characteristics

The quantitative characteristics of the collected TAVI are summarized in table 16 whereas the qualitative characteristics are found in table 17.

Table 16: TAVI Quantitative Characteristics

Quantitative Characteristics	Median (Min-Max)	% NA
Age (year)	83 (66-100)	3.1
Height (cm)	164 (145-186)	0
Weight (kg)	70 (46-130)	0
BMI (kg/m²)	26 (18-44)	0
Contrast Agent Quantity (ml)	175 (0-570)	0
Fluoroscopy Time	16 (4-78)	0
Fluoroscopy Contribution (%)	62 (26-100)	34.0
Total Procedure Time (min)	100 (30-215)	36.9
Detector Size (mm)	20 (18-40)	24.4
Tube Voltage (kV)	80 (70-112)	4.6
Tube Current (mAs)	209 (107-349)	21.4
Distance source to Detector (mm)	970 (866-1129)	24.4
Table Height (mm)	857 (830-932)	58.8
Number of fluoro acquisitions	63(17-164)	24.4
Number of stationary acquisitions	9 (1-49)	24.4
15 pps contribution (%)	52 (0-100)	6.9
Angulation contribution (%) RAO LAO PA LLAT	 2 (0-33) 5 (0-81) 89 (15-100) 0	26.0
Patient thickness (mm)	249 (165-332)	25.2
FOV (mm)	18 (16-20)	24.4

Table 17: TAVI Qualitative Characteristics

Clinical Binary/Qualitative Characteristics	n (%)	NA in %
Male Sex	100 (47.8)	0
High Blood Pressure	156 (74.6)	7.7
Diabetes	49 (23.4)	8.6
Dyslipidemia	111 (53.1)	9.1
Smoking	36 (17.2)	7.7
Peripheral artery disease	38 (18.2)	33.0
Previous Stroke	15 (7.2)	7.7
Previous MI	9 (4.3)	7.7
Previous PCI ≥1	 30 (14.4)	 7.7
Previous CABG	28 (13.4)	7.7
Previous attempts 1	 9 (4.3)	7.7
Diseased vessels 0 ≥1	 94 (45) 49 (23.4)	31.6
Approach site Implant Femoral	 150 (71.8)	 5.7

Double Femoral Subclavian Carotid Transapical	44 (21.1) 3 (1.4) 0 0	
Site control Angio Radial	 64 (30.6)	 0
Size 5 F 6 F 7F 8F	 2 (1.0) 196 (93.8) 8 (3.8) 3 (1.4)	 0
Sheathless	0	0
Techniques		
Angio carrefour*	109 (52.2)	46.9
Angio ss claviere	3 (1.4)	44.5
Wire complications Dissection Coronary ostium dissection Perforation Pericardio centesis Stent on percutaneous approach	 3 (1.4) 0 2 (1.0) 0 3 (1.4)	 0 0 0 0 24.4
Contrast Agent Type Ionic Non-ionic	 0 208 (99.5)	 0.5
Number of valves 1 2	 157 (75.1) 1 (0.5)	 24.4
Equipment Year manufactured 2008 2011-2014 2016-2018	 52 (24.9) 73 (34.9) 33 (15.8)	24.4
Manufacturer Siemens GE Philips Canon	 80 (38.3) 48 (23.0) 79 (37.8) 2 (1.0)	 0
Detector Size (cm) 18-25 30-48	 117 (56.0) 41 (19.6)	 24.4
Predominant Pulse Rate 10 pps 15 pps 7.5 pps	 18 (15.4) 58 (49.6) 38 (32.5)	 2.6
Predominant Angulation LAO PA PA + LAO	 7 (6.0) 87 (74.4) 2 (1.7)	 17.1

*This parameter was not analysed as for only two patients angio carrefour was not used

TAVI procedures were performed on 109 (52.1 %) female patients and 100 (47.8%) male patients. The median age for those patients was 83 years old, median BMI was 26 and weight was 70 kg. The median age of female patients and male patients was equivalent (84 year old) as well as the distribution of BMI classes between females and males. The majority of patients had High Blood Pressure (74.6%) and/or Dyslipidemia

(53.1%). Only 17.2 % of the patients were smokers. 1 valve was used for 75.1% of the patients. Very few wire complications (3.4 %) were observed for those patients. Equipment used was representative of the 4 different existent manufacturers with a majority of Siemens equipment (38.3%) closely followed by Philips (37.8%). Fluoroscopic (vs acquisition) imaging mode accounted for 61.9 % contribution to the PSD. 15 pps was the predominant pulse rate for 49.6% of TAVI procedures and most used angulations was PA with 74.4% contribution to PSD.

The distribution of total AK in TAVI for males and females is illustrated in figure 21. The variation of PSD as a function of BMI was analysed in Figure 22 and a correlation factor of 0.50 was found which indicates that BMI is not the only factor explaining peak skin dose.

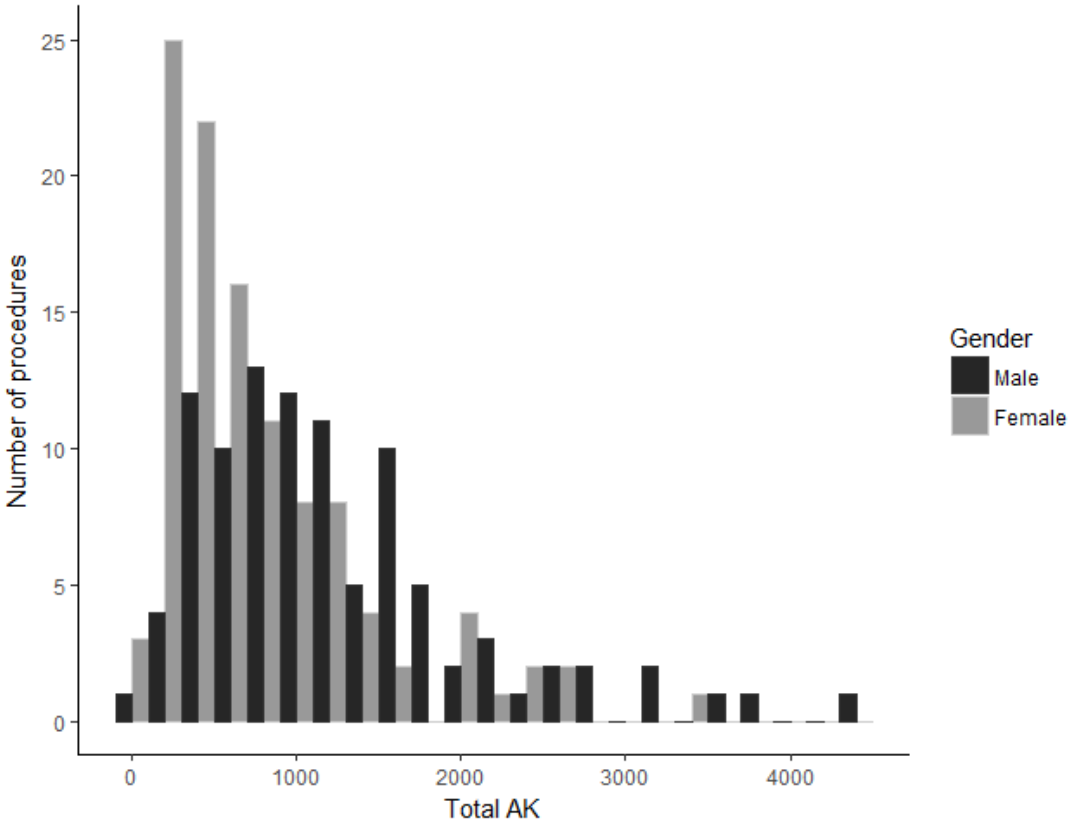


Figure 21: Distribution of Total AK per Sex for TAVI procedures

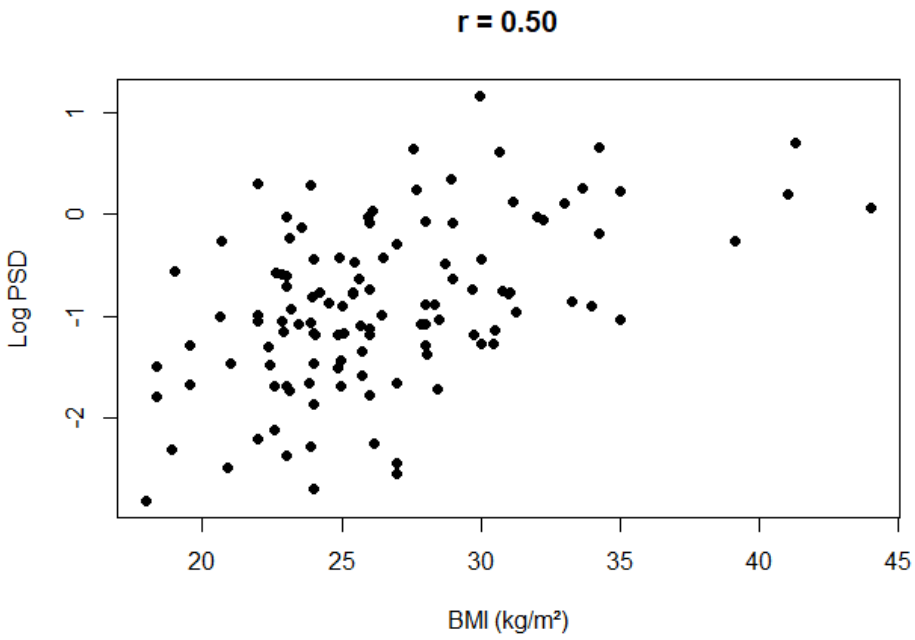


Figure 22: Correlation between Log PSD and BMI for TAVI procedures

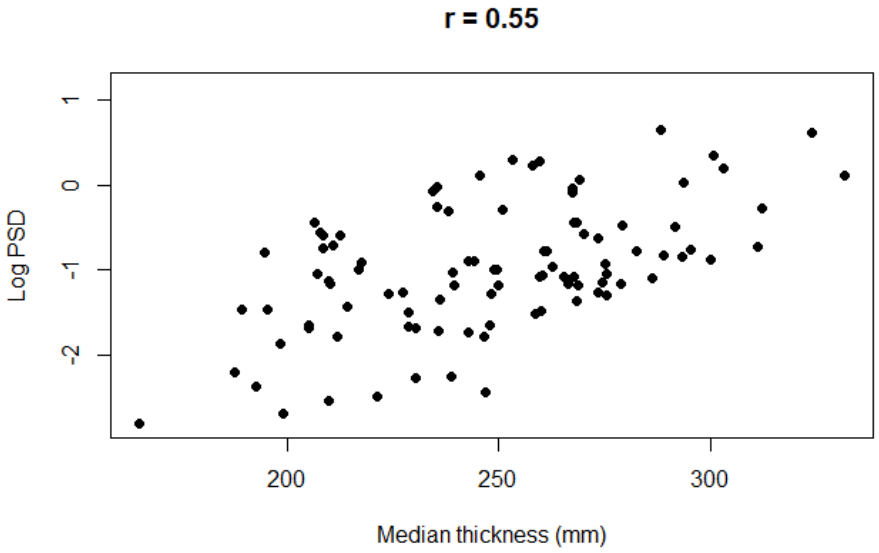


Figure 23: Correlation between Log PSD and median patient thickness for TAVI procedures

As expected patient median thickness taken for PA angulation had a higher Pearson correlation coefficient with log PSD than BMI with r =0.55, as presented in figure 23.

Median tube potential in kV and median tube current in mAs were studied as a function of the three BMI classes (figures 24 and 25). As expected, tube potential and tube current increased steadily with BMI. The increase of tube potential was more pronounced which is in agreement with findings by Osei et al (15).

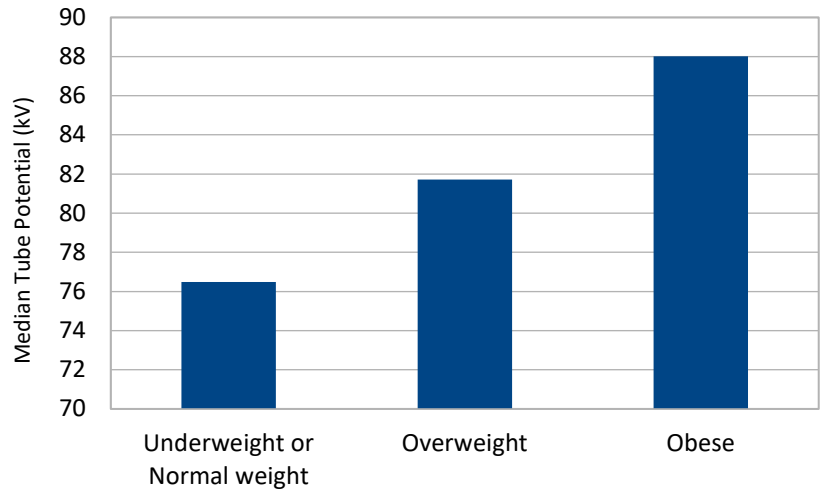


Figure 24: Variation of median tube potential according to BMI classes for TAVI procedures

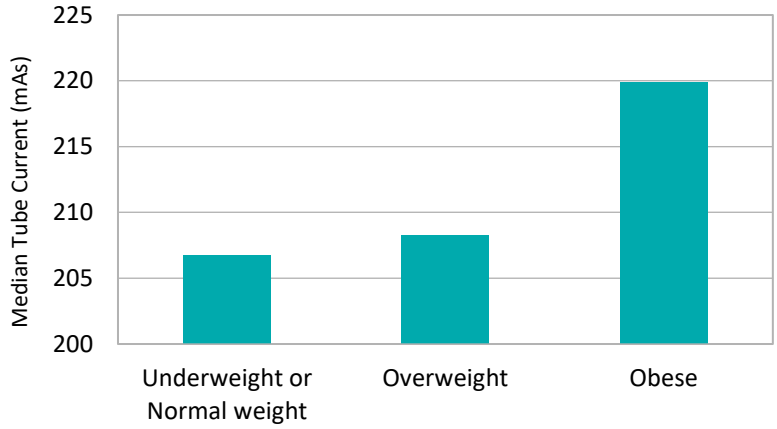


Figure 25: Variation of median tube potential current according to BMI classes for TAVI procedures

2.4 Determination of classical DRLs per procedure type

The median DAP, *AK* as well as fluoroscopy times for all sites and each individual site (all rooms) are summarized in tables 18-20 separately for each type of procedures PCI, CTO and TAVI. The 75th percentile is provided as a Diagnostic Reference Level (DRL) for all sites. A comparison with DRLs suggested in paper by Siiskonen et al (12) is provided. Total DAP, Total AK and PSD reference levels were determined by the 75th percentile of the medians of each site (all rooms included) as this is the recommended methodology for multicentre surveys (13). For categorical variables significantly associated in univariate analysis, dose reference levels for each category were determined in the same way.

Table 18: Median and 75th percentile for DAP and AK for PCI for each site compared to suggested DRL

Procedure	DAP (Gy cm^2) Median (Range) ***75th percentile***	Suggested DRL (12)	AK (mGy) Median (Range) ***75th percentile***	Suggested DRL (12)	Fluoroscopy Time (min) Median (Range)	Fluoroscopy Time (min) (15)
PCI-All sites	85 (6-538) ***125 99****	85	1364 (101-10129) ***2157 1580****	1200	17 (2-79)	13 (2-34)
A	60 (9-295)		1168 (164-5670)		13 (4-41)	
B	97 (13-500)		1637 (233-7412)		13 (2-74)	
C	57 (12-257)		991 (190-3925)		16 (5-79)	
D-site 1	93 (10-313)		1265 (127-4769)		23 (7-61)	
D-site 2	150 (49-336)		2677 (901-5374)		15 (5-30)	
D-site 3	190 (84-332)		3289 (1435-6293)		20 (5-43)	
E-site 1	43 (8-151)		482 (110-1915)		14 (4-59)	
E-site 2	50 (11-258)		1410 (203-5345)		9 (2-33)	
E-site 3	48 (6-538)		806 (101-6961)		14 (2-60)	
F	100 (20-382)		1293 (253-5262)		18 (8-66)	
G	219 (11-535)		6305 (2183-10129)		31 (8-62)	

***without site G**

Table 19: Median and 75th percentile for DAP and AK for CTO for each site compared to suggested DRL

Procedure	DAP (Gy cm^2) Median (Range) ***75th percentile***	Suggested DRL (12)	AK (mGy) Median (Range) ***75th percentile***	Suggested DRL (12)	Fluoroscopy Time (min) Median (Range)	Fluoroscopy Time (min) (15)
CTO- All sites	180 (13-832) ***239 207****	137	3292 (218-15634) ***4251 3682****	2020	39 (3-198)	
A	174 (65-413)		2796 (1215-6310)		28 (10-108)	
C	275 (81-578)		4525 (1143-9768)		84 (31-198)	
E-site 2	218 (27-681)		3977 (489-10637)		38 (3-105)	
E-site 3	147 (13-624)		2558 (218-9573.1)		48 (11-157)	
F	111 (21-430)		1414 (303-6234)		38 (10-117)	
G	260 (73-658)		5200 (3248-15634)		35 (14-80)	
H	108 (22-832)		1544 (286-5537)		*(one fluoroscopy time filled)	

***without site G**

Table 20: Median and 75th percentile for DAP and AK for TAVI for each site compared to suggested DRL

Procedure	DAP (Gy cm^2) Median (Range) ***75th percentile***	Suggested DRL (12)	AK (mGy) Median (Range) ***75th percentile***	Suggested DRL (12)	Fluoroscopy Time (min) Median (Range)	Fluoroscopy Time (min) (15)
TAVI- All sites	93 (9-634) ***174 142****	130	794 (67-4429) ***1216 1213****	1200	17 (2-78)	
A	46 (13-290)		373 (101-2454)		14 (7-75)	
C	107 (27-401)		863 (254-3701)		21 (13-78)	
D-site 2	245 (80-634)		1217 (413-2170)		22 (11-27)	
D-site 3	142 (42 -394)		1213 (430-3173)		22 (10-30)	
E-site 3	52 (9-187)		413 (67-1605)		16 (4-36)	
G	185 (39-594)		1236 (517-4429)		18 (2-51)	

***without site G**

For PCI and CTO in tables 18-19 the DRL obtained is higher than the one suggested in paper by Siiskonen et al. (5). For PCI procedures, this is due to the higher values obtained in site G (total AK and total DAP). A comparison between site G and other sites is provided. Site G had 79% of level 2 experience operators and 21% of level 1 experience operator when PCI procedures were performed which explains the higher values as other sites had experienced operators (89% of level 3) according to table 21. In fact, there is a clear decrease of total AK as operators have more years of experience (figure 26, table 22).

For CTO procedures, the complexity of the procedures in Veridic project could be different from the ones pooled in Siiskonen as only two sites with a sufficient amount of procedures were concerned in the paper (France and Sweden) as Ireland had only 5 procedures pooled. In fact, CTO procedure complexity can have a major impact on dose levels as illustrated by Maccia et al on the paediatric population (15). In addition, operator experience in CTO procedures was different between site G and other sites, which had a direct impact on total AK values. As illustrated in Table 22, procedures performed by experienced operators (more than 10 years' experience) resulted in a total AK reduced by half (2427 mGy) when compared to procedures' total AK performed by less than 10 years' experience operators (4467 mGy).

For TAVI procedures, the DRL obtained for total AK is comparable to the one suggested by Siiskonen et al (1216 vs 1200 mGy). For DAP, the DRL is higher (174 Gy cm^2) when compared to the one suggested by Siiskonen et al. which is due to the high value obtained for D-site 2. As other sites (D-site 3 and G site) have the same AK DRL with lower DAP DRL, it could indicate that D-site 2 did not limit the collimation to the minimum needed required visual fluoroscopy field. This assumption could not be checked, as RDSR were not provided for this site.

Table 21: Comparison of Operator Experience, treated vessels and approach between site G and other sites for PCI procedures

PCI		**Site G**		**Other sites**	
		N	%	N	%
Operator experience	**< 5 years**	**11**	**21.2**	**4**	**0.8**
	5-10 years	**41**	**78.6**	**23**	**4.8**
	> 10 years	0	0	427	88.6
	NA	0	0	28	5.8
Treated vessels	1	37	71.2	343	71.2
	2	15	28.8	111	23.0
	3	0	0	21	4.4
	4	0	0	4	0.8
	NA	0	0	3	0.6
		Site G		**Other sites**	
		N	%	N	%
Approach : site	Femoral	21	40.4	41	8.5
	Radial	28	53.9	414	85.9
	Femoral+Radial	3	5.8	10	2.1
	NA	0	0	17	3.5

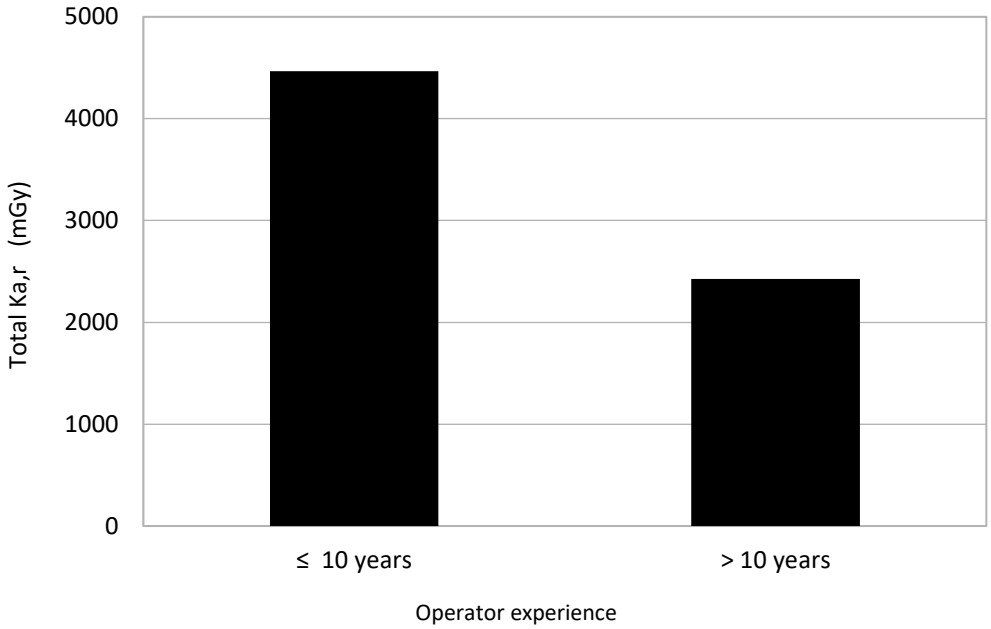


Figure 26: Comparison of total AK for different operator experience

Table 22: Distribution of Total AK for two different operator experience in CTO procedures

	Total AK	
Operator experience	**N**	**Median**
≤ 10 years	71	4467
> 10 years	147	2427

2.5 Univariate Analysis of clinical factors

Univariate analyses were performed with simple linear regression models, in which the dosimetry parameters: Total DAP, Total AK or PSD was log-transformed, to ensure the validity of the models. Results of univariate regressions were presented as exponentiated coefficients which can be interpreted as relative dose multiplier and their 95% confidence intervals. For instance, log (total DAP) = α + β*Previous MI and the exponentiated coefficients is exp(β). All relative dose multipliers are presented as exp(β).

2.5.1 Univariate Analysis of clinical factors for PCI procedures

Since Site G had a much higher total AK for PCI procedures (section 2.1), when compared to other sites and ultimately biased the results (univariate analysis was done including and excluding this site, which confirmed the bias), it was not taken into account in the univariate analysis for this parameter.

Total DAP univariate results are shown in the forest plots figures 27-28. Clinical and technical factors found in the questionnaire are shown in the first forest plot figure 27. ***Increasing BMI*** (25-30 kg/m²: 1.83; 95%CI: 1.54-2.18; > 30 kg/m²: 2.82; 95%CI: 2.33-3.42), ***Previous MI*** (1.22; 95%CI: 1.03-1.44), ***number of diseased*** (1 vessel: 1.43; 95%CI: 1.13-1.79; 2 vessels: 1.88 ; 95%CI : 1.48-2.38 ; ≥ 3 vessels: 1.94; 95%CI: 1.54-2.44) / ***treated*** (≥ 2 vessels: 1.42; 95%CI: 1.21-1.68) / ***stented*** (≥ 2 vessels: 1.58; 95%CI: 1.33-1.89) ***vessels***, ***femoral***

approach (1.36; 95%CI: 1.07-1.72), ***femoral + radial approach*** (2.13; 95%CI: 1.33-3.44), ***Cx lesion*** (1.32; 95%CI: 1.12-1.56), ***POBA*** (1.58; 95%CI:1.35-1.85), ***number of stents*** (2 stents: 1.62; 95%CI: 1.36-1.92; 3 stents: 1.92; 95%CI: 1.55-2.37; ≥4 stents: 2.45; 95%CI: 1.88-3.19), ***total stent length*** (> 33 mm: 1.69; 95%CI: 1.46-1.95), ***contrast agent quantity*** (1.0040; 95%CI: 1.0035-1.0044), ***fluoroscopy contribution*** (1.016; 95%CI: 1.012-1.020), ***fluoroscopy time*** (1.041; 95%CI: 1.036-1.046) and ***total procedure time*** (1.012; 95%CI: 1.009-1.014) were found to significantly increase total DAP. Female sex (0.61; 95%CI: 0.51-0.73), increasing age (0.994; 95%CI: 0.987-0.999), large detector size (0.62; 95%CI: 0.50-0.77) and recently manufactured equipment (0.57; 95%CI: 0.48-0.67) were found to decrease total DAP. Technical factors extracted from available RDSR are shown in the second forest plot figure 28. ***Patient thickness*** (250-300 mm: 1.69; 95%CI: 1.30-2.18; > 300 mm: 2.82; 95%CI: 2.11-3.77), ***tube voltage*** (1.05; 95%CI: 1.04-1.06),), ***tube current*** (1.002; 95%CI: 1.001-1.004), ***15 pps pulse rate contribution*** (1.003; 95%CI: 1.0002-1.005), ***number of stationary acquisitions*** (1.05; 95%CI: 1.04-1.05) as well as ***left lateral angulation*** (1.41; 95%CI: 1.03-1.93) were found to increase significantly total DAP. FOV (0.92; 95%CI: 0.86-0.98) was found to decrease significantly total DAP.

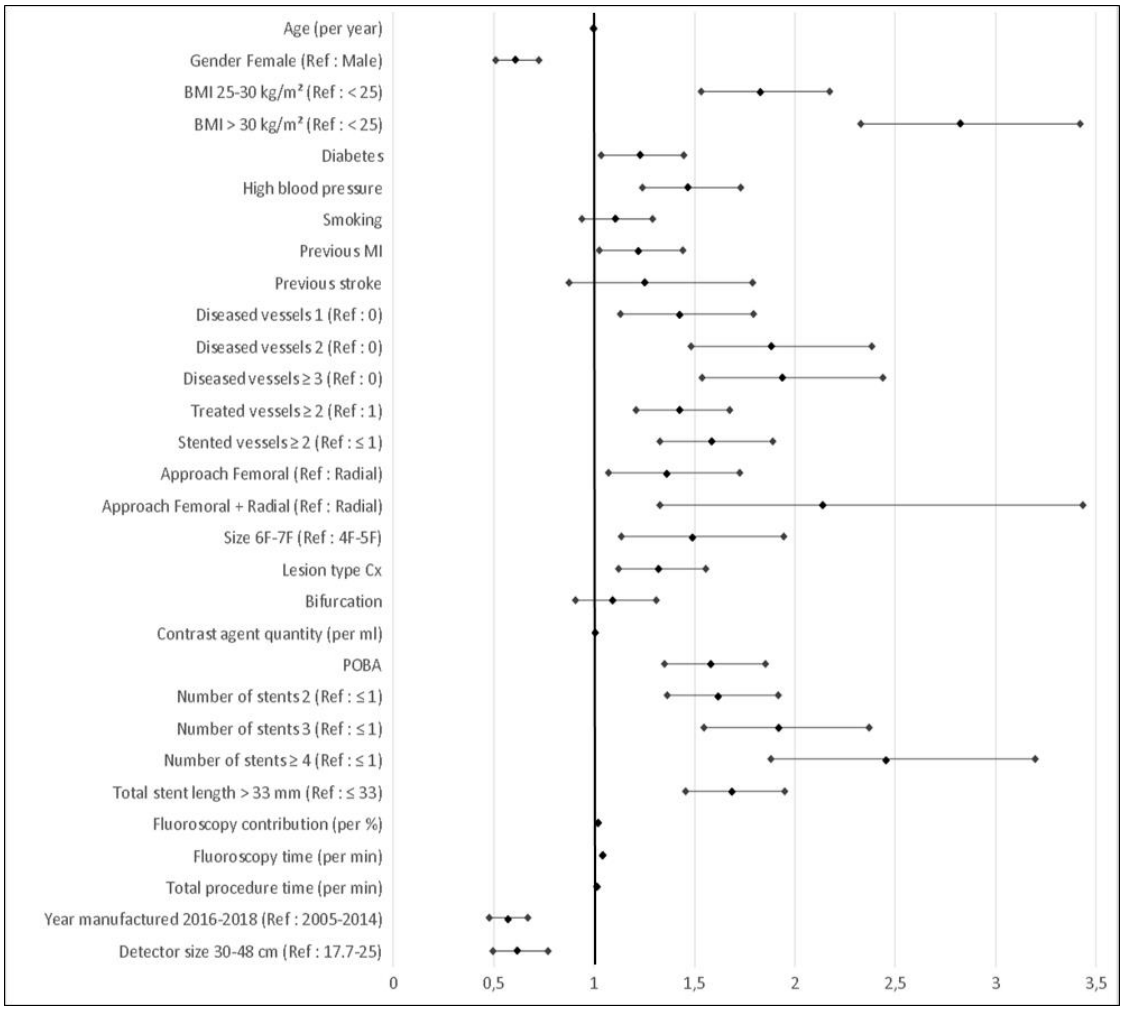


Figure 27: Forest plots univariate results for clinical and technical factors found in the Excel questionnaire for PCI procedures and total DAP *Diamonds represent exponentiated coefficients and error bars represent 95% confidence interval*

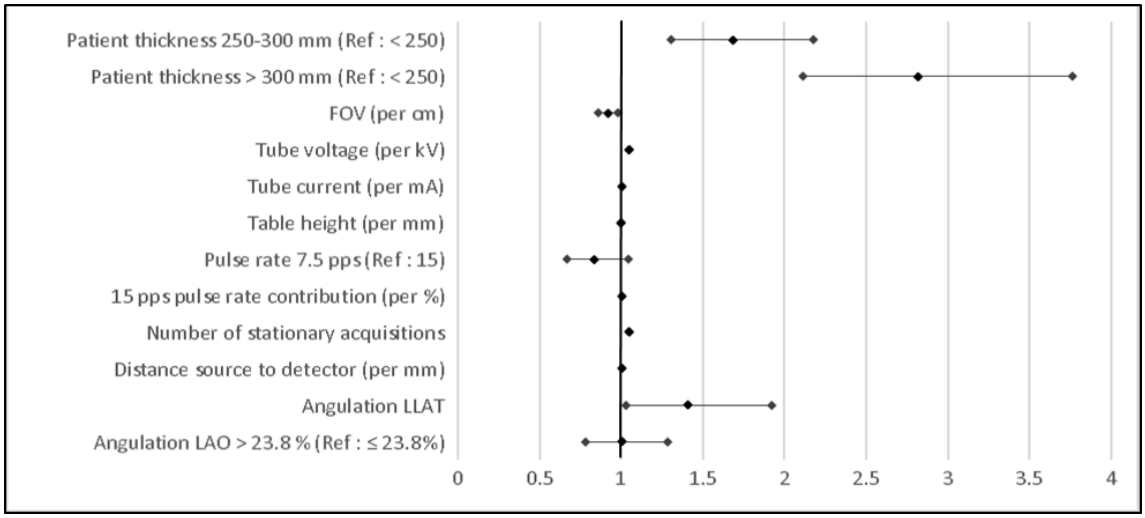


Figure 28: Forest plots univariate results for technical factors extracted from available RDSR for PCI procedures and total DAP *Diamonds represent exponentiated coefficients and error bars represent 95% confidence interval*

Total AK univariate results are shown in the forest plots figures 29-30. Clinical and technical factors found in the questionnaire are shown in the first forest plot, figure 29. ***Increasing BMI*** (25-30 kg/m²: 1.75; 95%CI: 1.45-2.10; > 30 kg/m²: 2.44; 95%CI: 1.99-3.01), ***Previous MI*** (1.41; 95%CI: 1.18-1.67), ***Previous stroke*** (1.47; 95%CI: 1.03-2.08), ***number of diseased*** (1 vessel: 1.46; 95%CI: 1.15-1.84; 2 **vessels**: 1.88; 95%CI: 1.47-2.41; ≥ 3 vessels: 2.04; 95%CI: 1.61-2.59) /***treated*** (≥ 2 vessels: 1.53; 95%CI: 1.29-1.81)/***stented vessels*** ((≥ 2 vessels: 1.60; 95%CI: 1.34-1.93), ***femoral + radial approach*** (1.99; 95%CI: 1.15-3.44), ***Cx lesion*** (1.34; 95%CI: 1.12-1.59), POBA (1.69; 95%CI: 1.44-1.98), ***number of stents*** (2 stents: 1.67; 95%CI: 1.40-2.00; 3 stents: 1.84; 95%CI: 1.46-2.32; ≥ 4 stents: 2.18; 95%CI: 1.63-2.90), ***total stent length*** (> 33 mm: 1.71; 95%CI: 1.47-1.99), ***fluoroscopy time*** (1.04; 95%CI: 1.03-1.04), ***bifurcation*** (1.37; 95%CI: 1.14-1.65), ***contrast agent quantity*** (1.005; 95%CI: 1.004-1.006), ***fluoroscopy contribution*** (1.010; 95%CI: 1.006-1.015) and ***total procedure time*** (1.008; 95%CI: 1.006-1.011) were found to significantly increase total AK . Female sex (0.59; 95%CI: 0.49-0.71), increasing age (0.991; 95%CI: 0.985-0.998), large detector size (0.54; 95%CI: 0.43-0.68) and recently manufactured equipment (0.49; 95%CI: 0.41-0.58) were found to decrease total AK . Technical factors extracted from available RDSR are shown in the second forest plot figure 30. ***Patient thickness*** (250-300 mm: 1.79; 95%CI: 1.35-2.37; > 300 mm: 3.46; 95%CI: 2.52-4.75), ***tube voltage*** (1.06; 95%CI: 1.05-1.07), ***tube current*** (1.003; 95%CI: 1.001-1.005), ***15 pps pulse rate contribution*** (1.005; 95%CI: 1.002-1.008), ***number of stationary acquisitions*** (1.05; 95%CI: 1.04-1.06), ***distance source to detector*** (1.004; 95%CI:1.002-1.006) as well as ***left lateral angulation*** (1.64; 95%CI:1.16-2.31) were found to increase significantly total AK . 7.5 pps when compared to 15 pps was found to decrease the dose (0.67; 95%CI: 0.53-0.86) which is in agreement with what is expected and what has been shown in the literature (17). Increasing FOV (0.87; 95%CI: 0.81-0.93) was found to decrease significantly total AK.

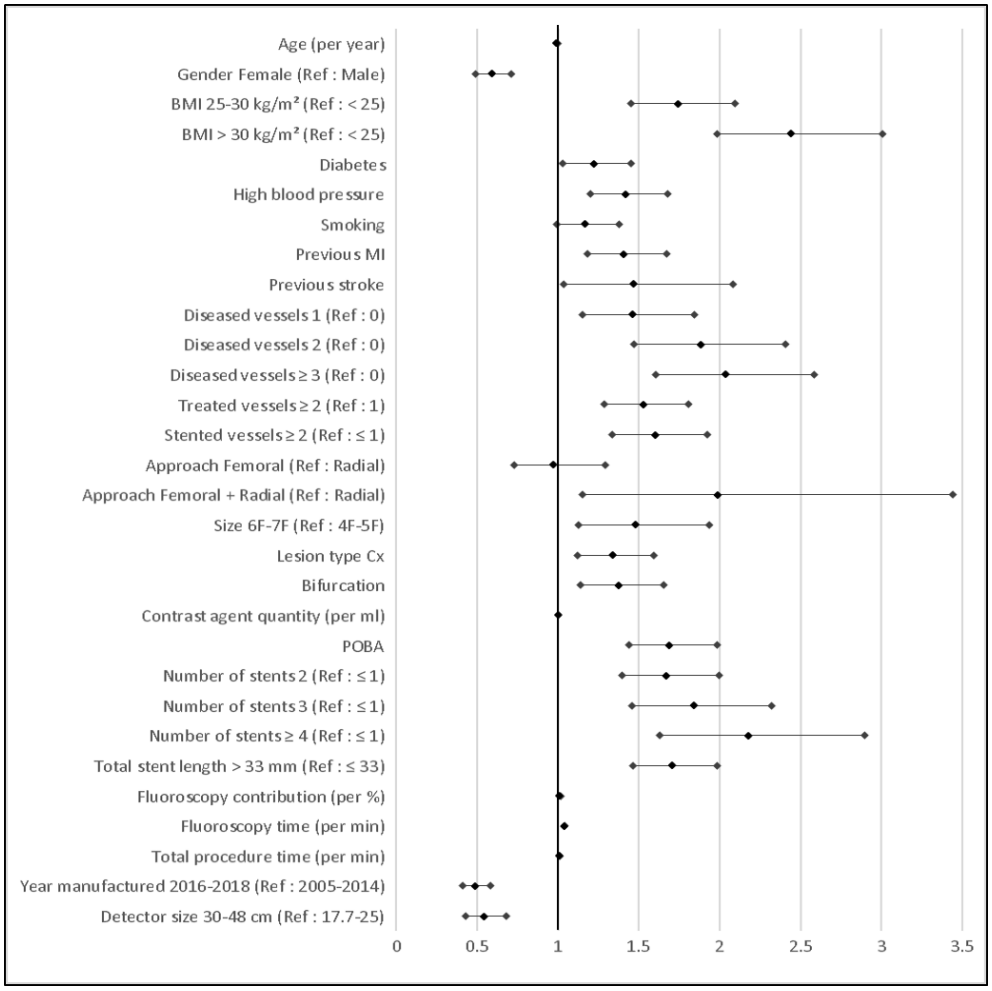


Figure 29: Forest plots univariate results for clinical and technical factors found in the Excel questionnaire for PCI procedures and total AK *Diamonds represent exponentiated coefficients and error bars represent 95% confidence interval*

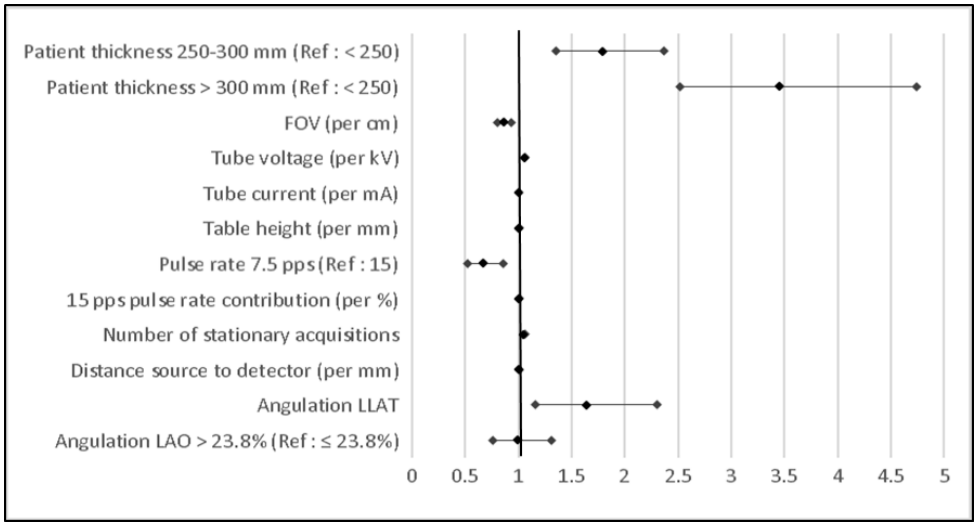


Figure 30: Forest plots univariate results for technical factors extracted from available RDSR for PCI procedures and total AK *Diamonds represent exponentiated coefficients and error bars represent 95% confidence interval*

PSD univariate results are shown in figure 31 and can be compared to the results of Fetterly et al (12). A significant increase of PSD was observed with an increase of BMI which has been also shown by Fetterly et al. Compared to male patients, a significant lower PSD was found in female patients (0.58; 95% CI: 0.44-0.75) which is close to the results of Fetterly et al (0.72; 95%CI: 0.68-0.75). Fetterly et al. could not show the influence of diabetes whereas in our case diabetes is predictive of increased dose (1.32; 95% CI: 1.02-1.70). Cx lesions were associated with increased PSD (1.37; 95% CI: 1.06-1.78) as shown in the paper by Fetterly et al. (1.14; 95% CI: 1.08-1.20).

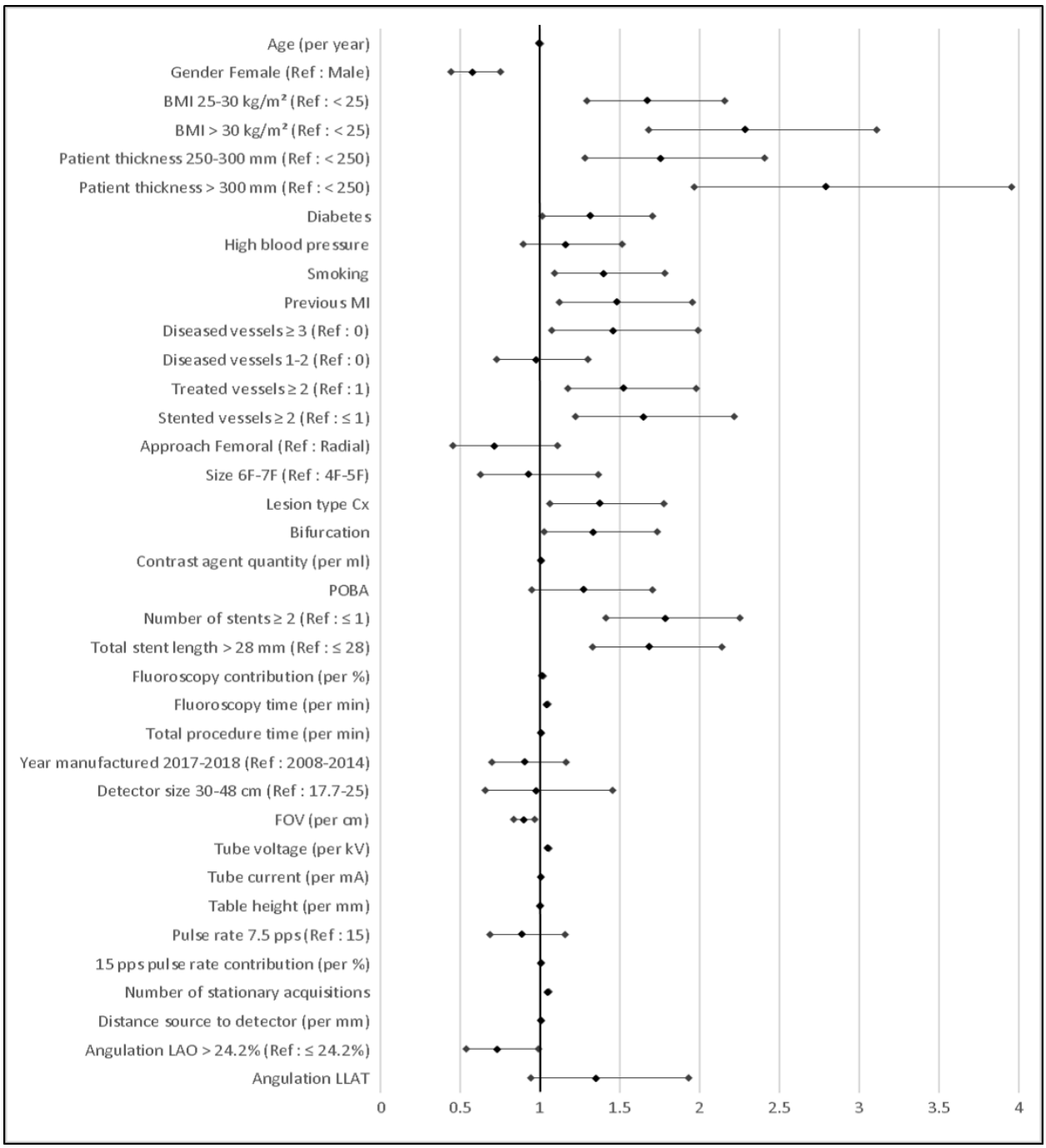


Figure 31: Forest plots univariate results for PCI procedures and PSD *Diamonds represent exponentiated coefficients and error bars represent 95% confidence interval*

2.5.2 Univariate Analysis of clinical factors for CTO procedures

Total DAP univariate results are shown in the forest plots figures 32-33. Clinical and technical factors found in the questionnaire are shown in the first forest plot figure 32. ***Increasing BMI*** (25-30 kg/m²: 1.61; 95%CI: 1.24-2.10; > 30 kg/m²: 1.85; 95%CI: 1.41-2.42), age > 64 years (1.27; 95%CI: 1.03-1.58), high blood pressure (1.45; 95%CI: 1.12-1.88) , ***diseased vessels*** (1.20; 95%CI: 1.10-1.30), ***retrograde approach*** (1.42; 95%CI: 1.05-1.94), ***contrast agent quantity*** (> 305 ml: 2.25; 95%CI: 1.85-2.72), ***wire complications*** (1.71, 95%CI: 1.20-2.45), ***total stent length*** (> 61 mm: 1.52; 95%CI: 1.19-1.95), a ***previous antero/retro failed in the same session*** (1.61; 95%CI: 1.20-2.15), ***fluoroscopy contribution*** (1.02; 95%CI: 1.01-1.03), ***fluoroscopy time*** (1.011; 95%CI: 1.008-1.014 and ***total procedure time*** (1.006; 95%CI: 1.004-1.007) were found to significantly increase total DAP. Female sex (0.67; 95%CI: 0.49-0.92) and operator experience > 10 years (0.72; 95%CI: 0.57-0.90) were found to decrease total DAP. Technical factors extracted from available RDSR are shown in the second forest plot figure 33. ***Patient thickness*** (≥ 250 mm: 2.40; 95%CI: 1.46-3.93), ***tube voltage*** (1.017; 95%CI: 1.002-1.033), ***number of stationary acquisitions*** (1.03; 95%CI: 1.02-1.05) as well as 7.5 pps (1.41; 95%CI: 1.02-1.95) were found to increase significantly total DAP. LAO angulation contribution (0.993; 95%CI: 0.988-0.998) was found to decrease significantly total DAP.

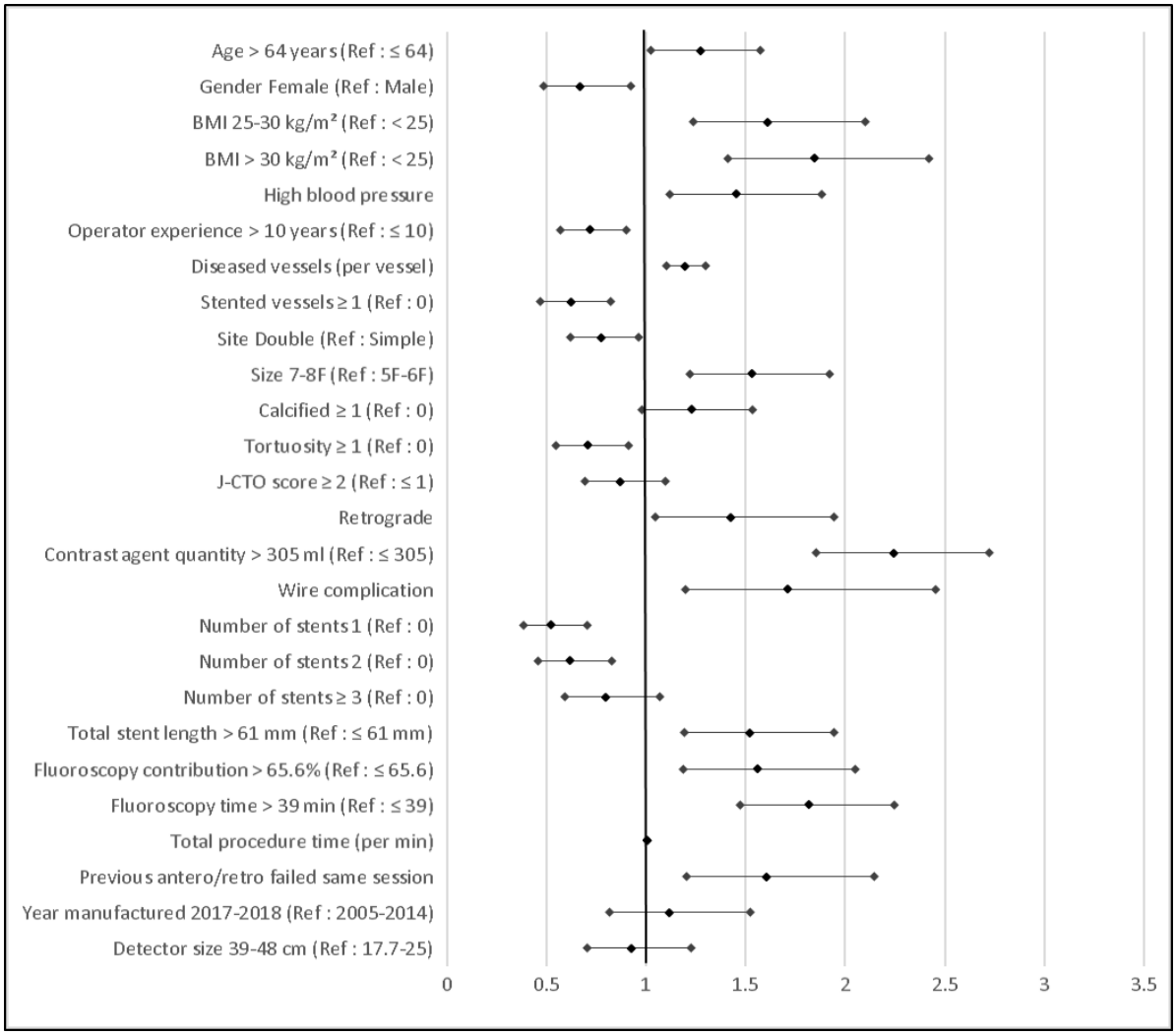


Figure 32: Forest plots univariate results for clinical and technical factors found in the Excel questionnaire for CTO procedures and total DAP *Diamonds represent exponentiated coefficients and error bars represent 95% confidence interval*

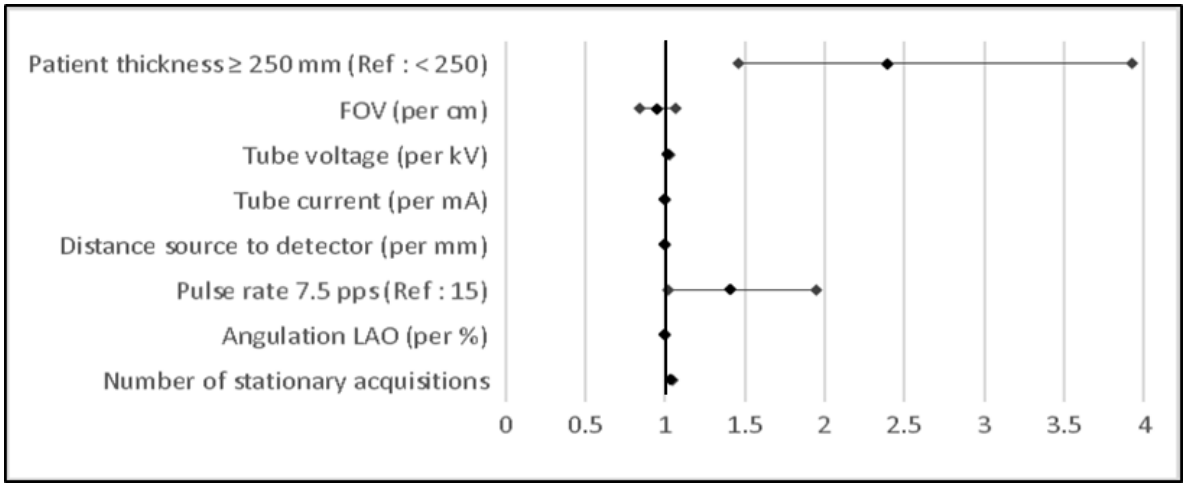


Figure 33: Forest plots univariate results for technical factors extracted from available RDSR for CTO procedures and total DAP *Diamonds represent exponentiated coefficients and error bars represent 95% confidence interval*

Total AK univariate results are shown in the forest plots figures 34-35. Clinical and technical factors found in the questionnaire are shown in figure 34**. *Age> 64 years*** (1.41; 95%CI: 1.13-1.75), ***increasing BMI*** (25-30 kg/m²: 1.59; 95%CI: 1.20-2.10; > 30 kg/m²: 1.84; 95%CI: 1.39-2.44), ***high blood pressure*** (1.38; 95%CI: 1.05-1.81), ***diseased vessels*** (1.24; 95%CI: 1.14-1.35), ***sheath size 7-8 F*** (1.59; 95%CI: 1.26-2.02), ***retrograde approach*** (1.57; 95%CI: 1.16-2.13), ***calcified lesions*** (1.50; 95%CI: 1.20-1.89), ***contrast agent quantity*** (> 305 ml: 2.48; 95%CI: 2.02-3.02), ***wire complications*** (1.88; 95%CI: 1.30-2.74), total stent length (> 61 mm: 1.68; 95%CI: 1.31-2.16), ***fluoroscopy time*** (> 39 min: 1.89; 95%CI: 1.52-2.36)/***contribution*** (> 65.6%: 1.43; 95%CI: 1.08-1.90),), ***total procedure time*** (1.005; 95%CI: 1.004-1.007) and a ***previous antero/retro failed in the same session*** (1.53; 95%CI: 1.15-2.05) were found to significantly increase total AK . Female sex (0.67; 95%CI: 0.48-0.93) and operator experience > 10 years (0.61; 95%CI: 0.48-0.77) were found to decrease total AK . Technical factors extracted from available RDSR are shown in figure 35. ***Patient thickness*** (≥ 250mm: 2.79; 95%CI: 1.84-4.24), ***tube voltage*** (1.02; 95%CI: 1.01-1.04), ***number of stationary acquisitions*** (1.04; 95%CI: 1.03-1.05) were found to increase significantly total AK . Surprisingly, LAO angulation contribution (0.992; 95%CI: 0.987-0.997) was found to decrease significantly total AK which is not in agreement with good practices that encourages the limitation of such angulation. By looking more into details, only one site (site A) did not show this tendency and a very high total AK value of 10 000 mGy in one hospital (E-site 3) with 2% LAO contribution could have biased this result.

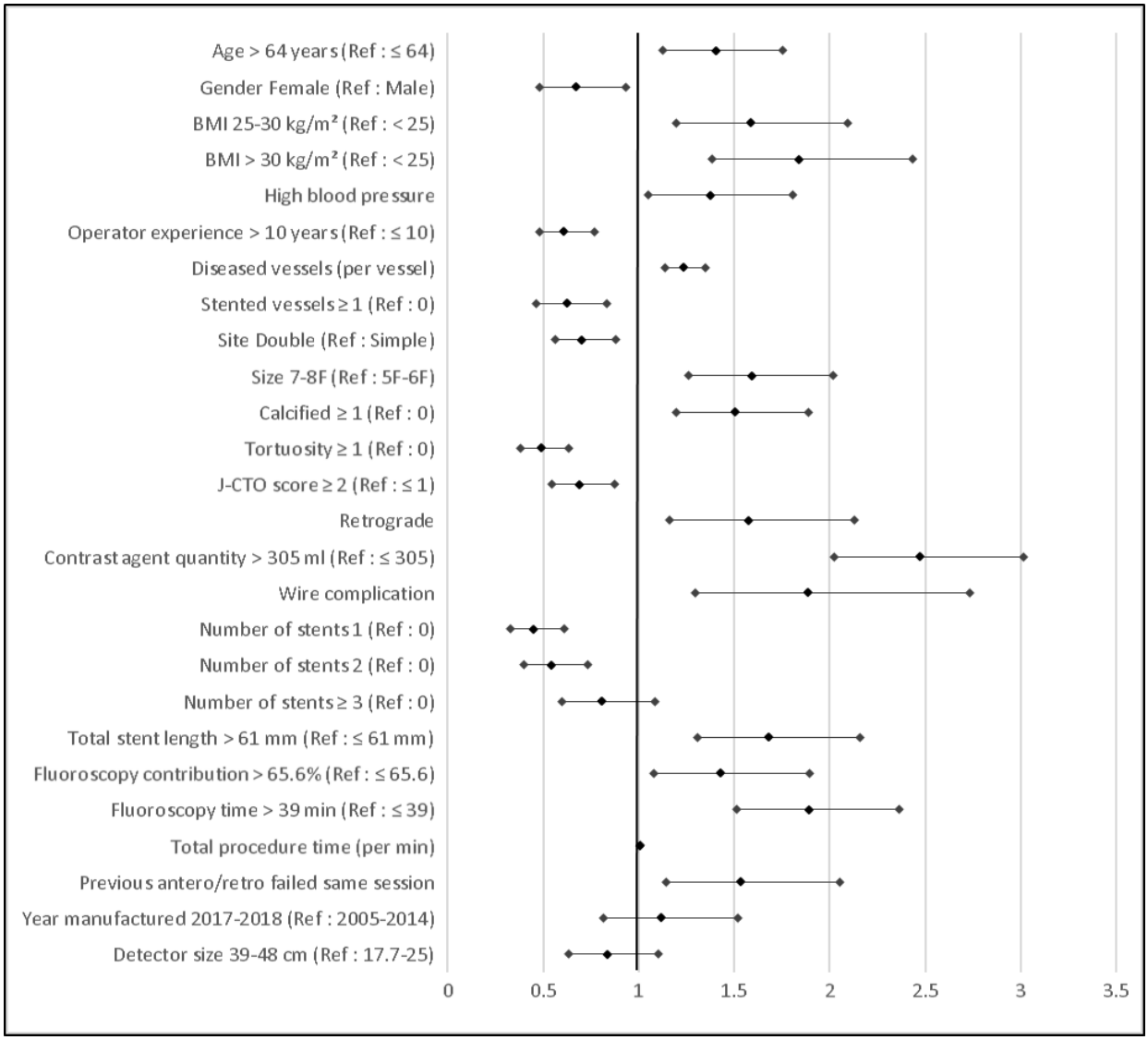


Figure 34: Forest plots univariate results for clinical and technical factors found in the Excel questionnaire for CTO procedures and total AK *Diamonds represent exponentiated coefficients and error bars represent 95% confidence interval*

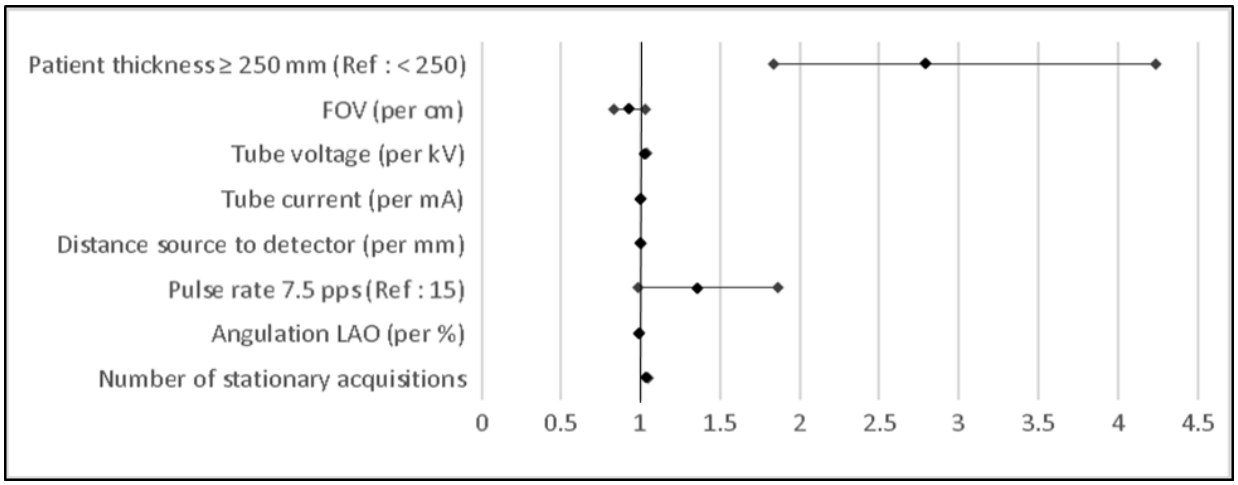


Figure 35: Forest plots univariate results for technical factors extracted from available RDSR for CTO procedures and total AK *Diamonds represent exponentiated coefficients and error bars represent 95% confidence interval*

For CTO as illustrated in Table 23, the fluoroscopy total time was found to be significantly higher for procedures with 7.5 pps (65.5 minutes for mean fluoroscopy time) compared to 15 pps procedures (33 minutes for means fluoroscopy time) which explains why 7.5 pps tends to increase total AK and total DAP instead of decreasing it in our database of collected CTO procedures as shown in forest plots figures 33 and 35.

Table 23: Comparison of fluoroscopy time per pulse rate for CTO procedures

	Fluoroscopy time					**p-value**
Pulse rate	**N**	**Mean**	**Median**	**Min**	**Max**	**0.008**
15	14	33	28	10	108	
7.5	54	656	59	11	198	

PSD univariate results are shown in the forest plot figure 36. A significant increase of PSD was observed with an increase of BMI (BMI > 30 kg/m²: 1.69; 95%CI: 1.16-2.44). Age was predictive of increased dose (1.02; 95% CI: 1.01-1.04). JCTO score ≥2 compared to the reference JCTO≤1 meant a relative increase of PSD (1.45; 95% CI: 1.03-2.04). A previous anterograde/retrograde technique that failed during the same session induced an increased dose (1.57;95%CI: 1.08-2.29).

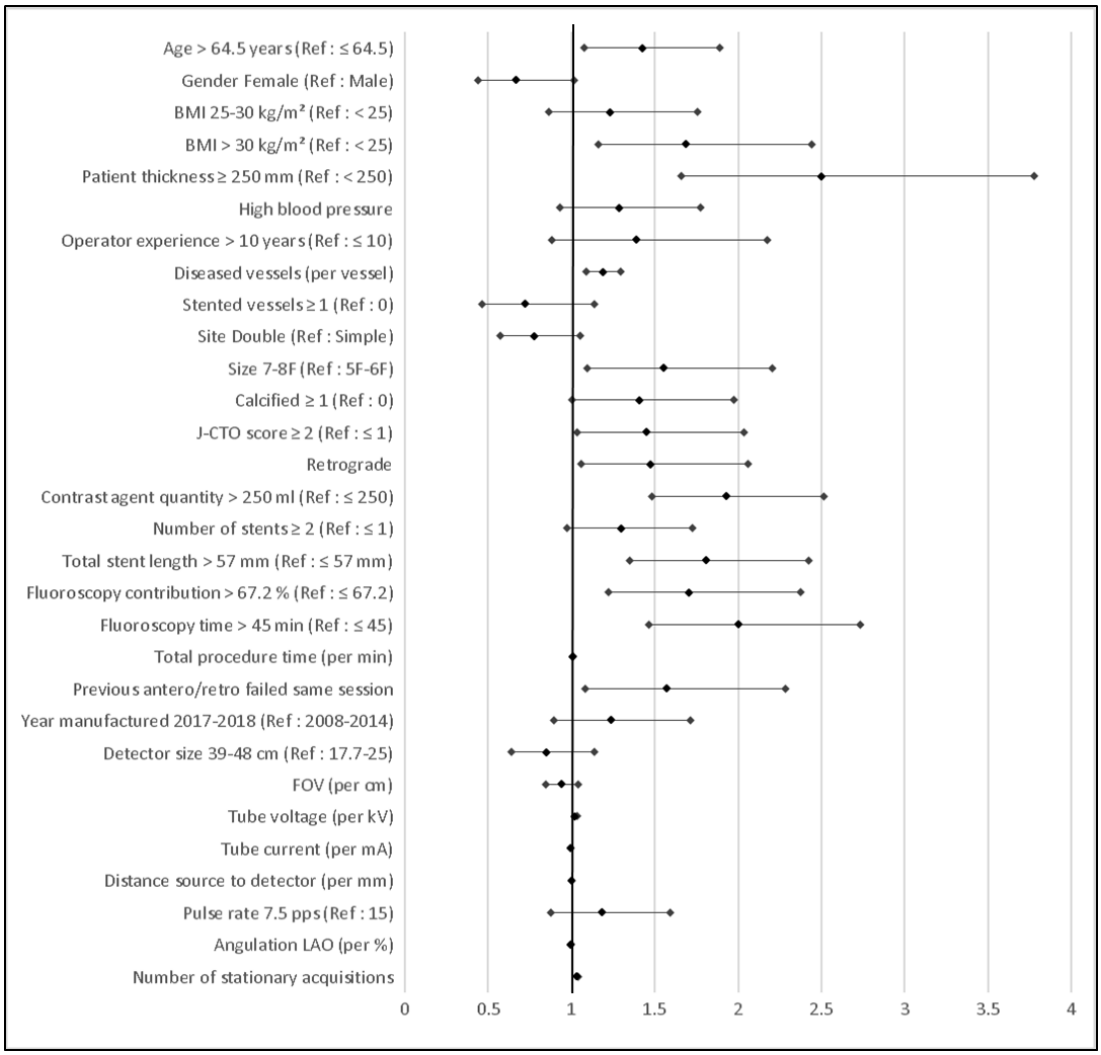


Figure 36: Forest plots univariate results for CTO procedures and PSD *Diamonds represent exponentiated coefficients and error bars represent 95% confidence interval*

2.5.3 Univariate Analysis of clinical and technical factors for TAVI procedures

Total DAP univariate results are shown in the forest plots figures 37-38. Clinical and technical factors found in the questionnaire are shown in the first forest plot figure 37. ***Increasing BMI*** (25-30 kg/m²: 1.53; 95%CI: 1.18-1.98; > 30 kg/m²: 2.58; 95%CI: 1.94-3.45), ***previous CABG*** (2.08; 95%CI: 1.43-3.03), **Double *femoral site implant*** (2.98; 95%CI: 1.53-2.82), ***contrast agent quantity*** (> 200 ml: 1.37; 95%CI: 1.08-1.75), **fluoroscopy time** (1.04; 95%CI: 1.03-1.05), were found to significantly increase total DAP. ***Female sex*** (0.52; 95%CI: 0.41-0.65) was found to decrease total DAP. Technical factors extracted from available RDSR are shown in the second forest plot. ***Patient thickness*** (≥ 250 mm: 1.90; 95%CI: 1.47-2.47), ***tube voltage*** (1.07; 95%CI: 1.05-1.08), ***tube current*** (1.003; 95%CI: 1.001-1.005), ***distance source to detector*** (> 965 mm: 1.38; 95%CI: 1.04-1.83), ***number of stationary acquisitions*** (> 9: 1.52; 95%CI: 1.15-2.00) were found to increase significantly total DAP. In the paper by Sharma et al., a reduction of pulse rate in fluoroscopy from 15 to 3.75-7.5 pps was shown to significantly reduce total DAP for TAVI procedures which could not be demonstrated statistically due most probably to reduced sample size.

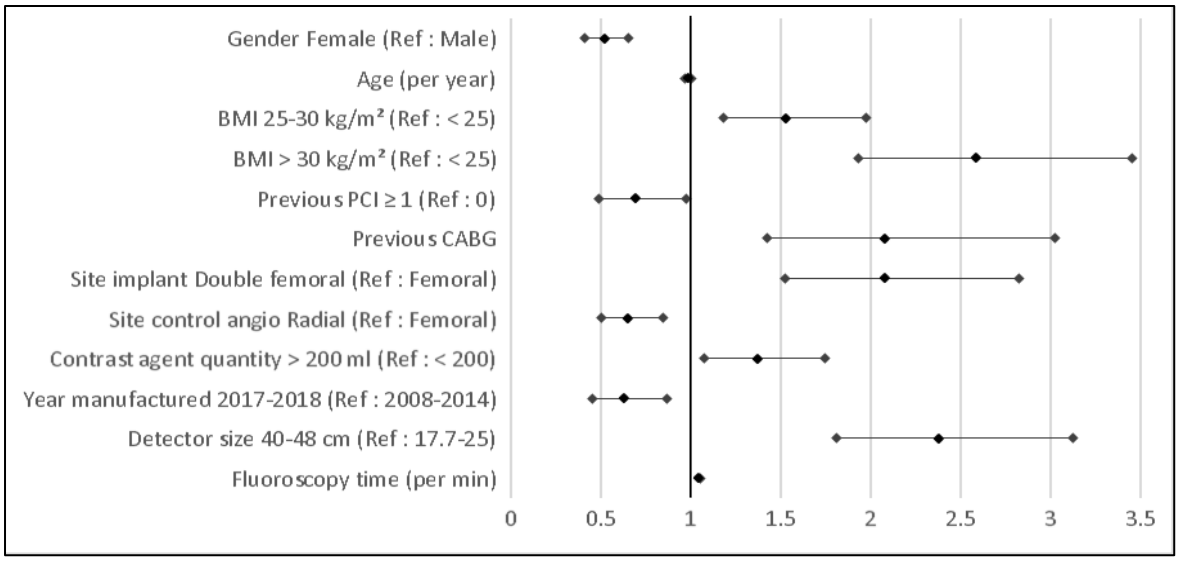


Figure 37: Forest plots univariate results for clinical and technical factors found in the Excel questionnaire for TAVI procedures and total DAP *Diamonds represent exponentiated coefficients and error bars represent 95% confidence interval*

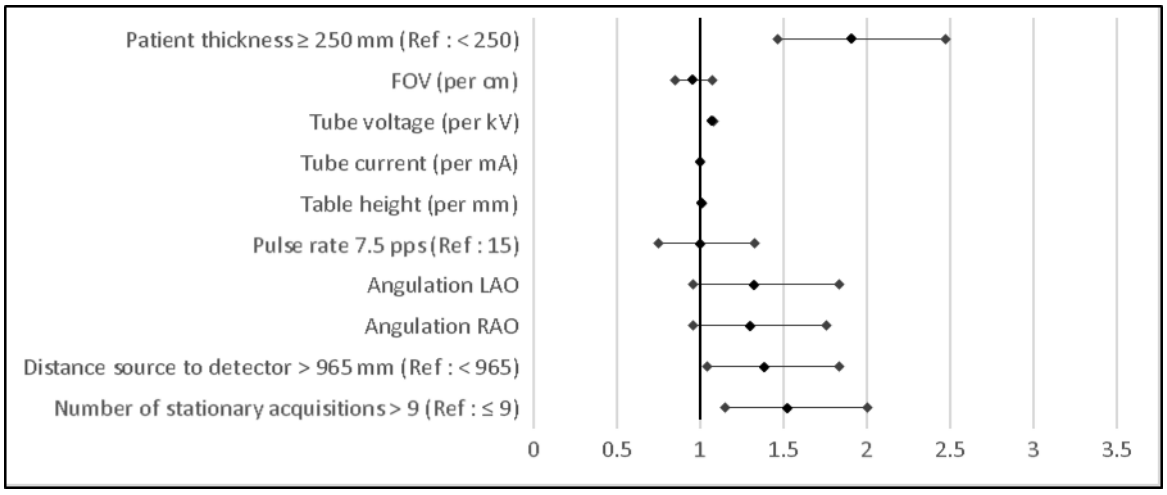


Figure 38: Forest plots univariate results for technical factors extracted from available RDSR for TAVI procedures and total DAP *Diamonds represent exponentiated coefficients and error bars represent 95% confidence interval*

Total AK univariate results are shown in the forest plots figures 39-40. Clinical and technical factors found in the questionnaire are shown in the first forest plot figure 39. ***Increasing BMI*** (25-30 kg/m²: 1.55; 95%CI: 1.23-1.98; > 30 kg/m²: 2.56; 95%CI: 1.95-3.35), ***previous CABG*** (1.87; 95%CI: 1.33-2.61), ***Double femoral site implant*** (1.99; 95%CI: 1.52-2.62), ***contrast agent quantity*** (> 200 ml: 1.41; 95%CI: 1.13-1.77), ***fluoroscopy time*** (1.04; 95%CI: 1.03-1.05), ***large detector size*** (2.09; 95%CI: 1.58-2.76) were found to significantly increase total AK . ***Female sex*** (0.56; 95%CI: 0.45-0.69) was found to significantly decrease total AK. Technical factors extracted from available RDSR are shown in the second forest plot figure 38***.*** ***Patient thickness*** (≥ 250 mm: 1.89; 95%CI: 1.43-2.48), ***tube voltage*** (1.07; 95%CI: 1.05-1.08), ***tube current*** (1.003; 95%CI: 1.001-1.005), ***table height*** (1.006; 95%CI: 1.001-1.012), ***distance source to detector*** (> 965 mm: 1.49; 95%CI: 1.11-2.00), ***number of stationary acquisitions*** (> 9: 1.55; 95%CI: 1.16-2.08) and R***AO angulation*** (1.42; 95%CI: 1.04-1.95) were found to increase significantly total AK .

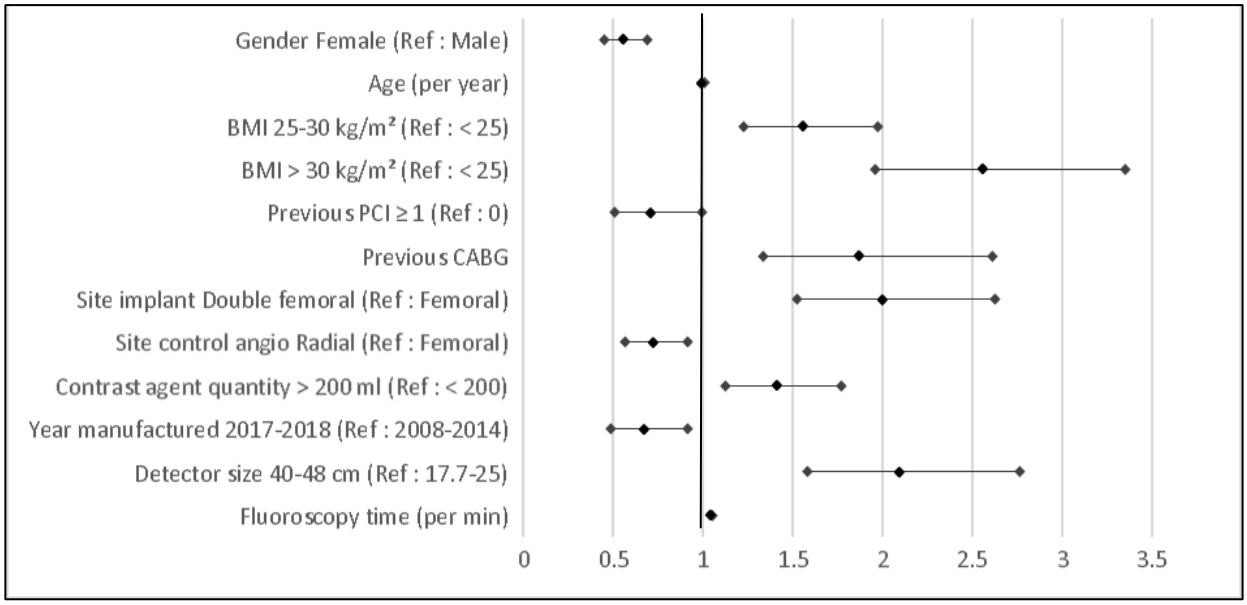


Figure 39: Forest plots univariate results for clinical and technical factors found in the Excel questionnaire for TAVI procedures and total AK *Diamonds represent exponentiated coefficients and error bars represent 95% confidence interval*

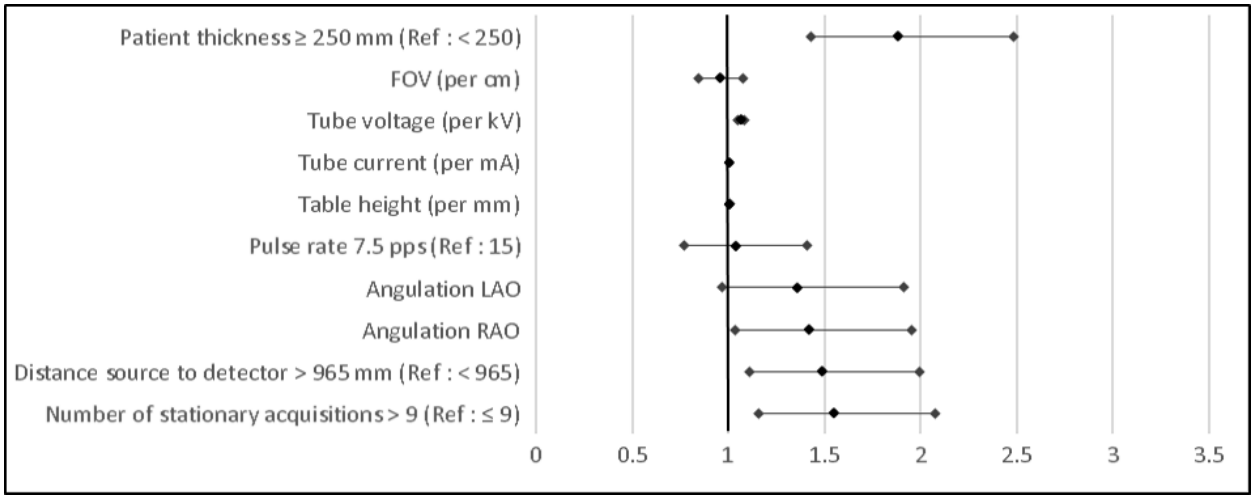


Figure 40: Forest plots univariate results for technical factors extracted from available RDSR for TAVI procedures and total AK *Diamonds represent exponentiated coefficients and error bars represent 95% confidence interval*

PSD univariate results are shown in the forest plot figure 41.

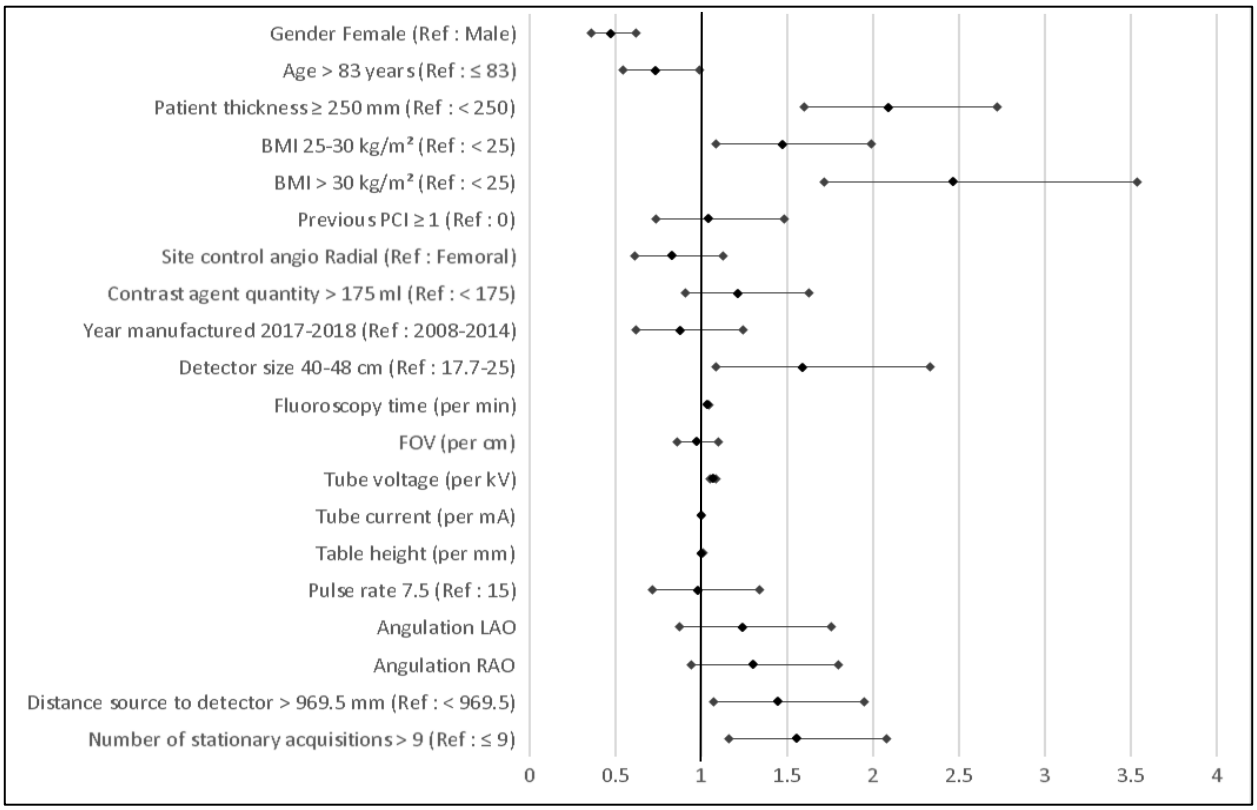


Figure 41: Forest plots univariate results for TAVI procedures and PSD *Diamonds represent exponentiated coefficients and error bars represent 95% confidence interval*

A significant increase of PSD was observed with an increase of BMI. The absolute influence of BMI was found to be 1.09 (95% CI: 1.06-1.12). Age>83 years compared to < 83 years was predictive of decreased dose (0.74; 95% CI: 0.55-0.99) as well as female sex (0.47; 95% 0.36-0.62). More than 9 stationary acquisitions induced an increase in dose (1.56; 95%CI: 1.16-2.08).

A summary of the univariate analysis for each type of procedure is provided in Table 24 and only common influential factors for all dosimetry parameters (total DAP, total AK and PSD) are shown.

Table 24: Univariate analysis summary for PCI, CTO and TAVI

	PCI	CTO	TAVI
Increasing factors common to total DAP,Total AK and PSD	Increasing BMI Previous MI Number of diseased vessels Number of treated vessels Number of stented vessels Cx lesion Number of stents Total stent length Contrast agent quantity Fluoroscopy contribution Fluoroscopy time Total procedure time Patient thickness Tube voltage Tube current Number of stationary acquisitions	Increasing BMI Increasing age Number of diseased vessels Retrograde approach Contrast agent quantity Total stent length Previous antero/retro failed in the same session Fluoroscopy contribution Fluoroscopy time Total procedure time Patient thickness Tube voltage Number of stationary acquisitions	Increasing BMI Fluoroscopy time Patient thickness Tube voltage Tube current Distance source to detector Number of stationary acquisitions
Decreasing factors common to total DAP total AK and PSD	Female sex Increasing FOV	Increasing LAO angulation contribution*	Female sex

*This factor is not in agreement with guidelines and could be due to a bias explained p. 54

The common clinical factor for PCI, CTO and TAVI procedures increasing dosimetry parameters were increasing BMI/patient thickness. Technical factors that are in common for the three types of procedures were tube voltage, tube current and number of stationary acquisitions (cine mode). PCI and CTO increasing common clinical factors were increasing BMI, number of diseased vessels, total stent length and contrast agent quantity. Female sex was associated with decreased dosimetry parameters (DAP, AK and PSD) for both PCI and TAVI.

2.6 DRL for PCI Procedures

Based on the univariate analysis results for PCI, DRL were presented in Table 25-26 in function of the clinical and technical factors that were significant both for total DAP and total AK. A multiplicative factor was provided when compared to classical procedure DRL as defined in section 2.3. For instance, Obese BMI will result in 1.04 times higher DAP DRL compared to classical DAP DRL or a patient thickness higher than 25 cm will result in 2.5 higher DAP DRL/3.2 higher total AK DRL.

Table 25: Total DAP and Total AK DRL for PCI procedures in function of clinical and technical factors significant in univariate analysis

Clinical Factor PCI		DRL Total DAP	Multiplicative Factor DAP DRL 125 Gy cm^2	DRL Total AK	Multiplicative Factor AK DRL 1580 mGy
Age	22-60	158	1.26	1615	1.02
	61-69	170	1.36	2321	1.47
	70-76	143	1.14	2173	1.38
	77-96	84		1588	
Sex	M	131	1.04	1821	1.15
	F	92		1247	
BMI	Underweight or Normal weight	100		1242	
	Overweight	132	1.06	1846	1.17
	Obese	130	1.04	2249	1.42
Diabetes	N	93		1541	
	Y	114	0.91	1553	0.98
High blood pressure	N	97		1000	
	Y	139	1.11	1589	1.01
Previous MI	N	109		1568	
	Y	133	1.07	1931	1.22
Diseased vessels	0	65		1047	
	1	119		1366	
	2	120		1999	1.27
	≥ 3	192	1.54	2124	1.34
Treated vessels	1	126		1437	
	≥ 2	155	1.24	2660	1.68
Stented vessels	≤ 1	123		1448	
	≥ 2	148	1.19	2560	1.62
Site	Radial	110		1667	
	Femoral	138	1.10	1943	1.23
	Femoral + radial	146	1.17	2589	1.64
Size	4F-5F	82		1531	
	6F-7F	149	1.19	1670	1.06

Cx	N	109		1527	
	Y	169	1.35	2533	1.60
Contrast agent quantity	≤ 150	45		1175	
	> 150	171	1.37	2333	1.48
POBA	N	86		1305	
	Y	143	1.14	2493	1.58
Wire complication	N	122		1542	
	Y	242	1.93	2979	1.89
Number of stents	≤ 1	114		1355	
	2	173	1.38	1921	1.22
	3	164	1.31	2369	1.50
	≥ 4	269	2.15	4170	2.64
Total stent length	≤ 33	120		1273	
	> 33	174	1.39	2006	1.27
Fluoroscopy contribution	≤ 55	84		1496	
	> 55	145	1.16	2205	1.40
Fluoroscopy time	≤ 16	81		1186	
	> 16	173	1.38	2923	1.85
Total procedure time	≤ 66	87		1334	
	> 66	170	1.36	2941	1.86
Year manufactured	2005-2010	110	0.88	1555	
	2011-2014	97	0.78	1682	1.06
	2016-2018	60		945	
Detector size	18-25	99	0.79	1617	1.02
	30-48	42		856	

Table 26: Total DAP and Total AK DRL for PCI procedures in function of patient thickness

		DRL Total DAP	Multiplicative Factor DAP	DRL Total AK	Multiplicative Factor AK
Patient thickness*	< 250 mm	32		396	
	≥ 250 mm	79	2.50	1272	3.21

*Available only for site A, E-site 1 and E-site 3

DRLs were also computed for the PSD database in Table 27 and a multiplicative factor is provided when compared to the classical DRL for each type of procedure. In fact, the International Commission on Radiation Protection (ICRP) and the International Atomic Energy Agency (IAEA) have suggested the use of an index of procedure complexity to normalise radiation doses, this factor could be seen as a way of providing such an index (20,21) .

Moreover, knowing the influence of each factor could allow cardiologist to provide a better justification in the DACS when the procedure has exceeded the local DRLs.

The highest increase expected when compared to the classical DRL for PCI was due to increasing order of importance BMI>30, ≥3 diseased vessels and Lesion type Cx.

Georges et al. (17) provided Reference Levels (RL) for PCI procedures in terms of males and females. A factor of 1.3 was observed when dividing male and female reference levels provided in this publication in terms of total AK (RL Total AK Males =1350 mGy; RL Total AK Females=1050 mGy) and total DAP (RL Total DAP Males = 82 Gy cm^2; RL Total DAP Females = 63 Gy cm^2) for PCI procedures. This is comparable to the factor of 1.3 observed for PSD reference levels in Table 27.

Table 27: PSD DRL for PCI procedures in function of clinical and technical factors significant in univariate analysis

PCI	PSD DRL (mGy)	Compared to Classical PSD DRL 663 mGy
Sex		
M	**844**	**1.27**
F	442	
BMI		
≤24.9	416	
25-29.9	**830**	**1.25**
>30	**1166**	**1.76**
Patient thickness* (mm)		
< 250	323	
≥ 250	**724**	**1.09**
Diabetes		
Y	**808**	**1.22**
N	637	
Smoking		
Y	**883**	**1.33**
N	520	
Previous MI		
Y	**852**	**1.29**
N	640	
Diseased vessels		
0	547	
1-2	600	
≥ 3	**1058**	**1.60**
Treated vessels		
1	633	
≥ 2	**881**	**1.33**
Stented vessels		
≤ 1	713	
≥ 2	**903**	**1.36**
Bifurcation		
Y	**840**	**1.27**
N	615	

Lesion type Cx		
Y	1023	**1.54**
N	677	
Contrast Agent Quantity (mL)		
≤ 142	409	
> 142	**955**	**1.44**
Number of stents		
≤ 1	526	
≥ 2	**892**	**1.34**
Total Stent Length (mm)		
≤ 28	531	
> 28	**876**	**1.32**

*Available only for site A and E-site 3

2.7 DRL for CTO Procedures

Based on these univariate analysis results for CTO, DRL were presented in Tables 28-29 in function of the clinical and technical factors that were significant both for total DAP and total AK. For instance, a calcified lesion will result in 1.4 times higher DAP DRL compared to classical DAP DRL or a patient thickness higher than 25 cm will result in 2.8 higher DAP DRL/3.4 higher total AK DRL.

Table 28: Total DAP and Total AK DRL for PCI procedures in function of clinical and technical factors significant in univariate analysis

Clinical Factor CTO		DRL Total DAP (Gy cm2)	Multiplicative Factor DAP DRL 239 Gy cm2	DRL Total AK (mGy)	Multiplicative Factor AK DRL 4251 mGy
Age	≤ 64	221		3888	
	> 64	218	0.91	4497	1.06
Sex	M	243	1.02	4762	1.12
	F	169		2971	
BMI	Underweight or Normal weight	143		2711	
	Overweight	244	1.02	4481	1.05
	Obesity	291	1.22	5416	1.27
High blood pressure	N	181		4383	
	Y	242	1.01	4635	1.09
Operator experience	≤ 10 years	183		2979	
	> 10 years	223	0.94	4093	0.96
Diseased vessels	0	115		1913	
	1	187		3011	
	2	229		3884	
	≥ 3	263	1.10	4680	1.10

Stented vessels	0	295	1.23	4972	1.17
	≥ 1	237		4818	
Site	Simple	244	1.02	4391	
	Double	182		4800	1.13
Size	4F-5F-6F	230		4525	
	7F-8F	270	1.13	4524	1.06
Retrograde	N	185		3692	
	Y	271	1.14	4159	0.98
Tortuosity	0	239		4942	1.16
	≥ 1	272	1.14	4201	
Calcified	0	260		5200	
	1	337	1.41	5343	1.26
	≥ 2	289	1.21	4039	
Contrast agent quantity	≤ 305	152		3002	
	> 305	292	1.23	6028	1.42
Wire complications	N	236		4003	
	Y	311	1.30	6721	1.58
N of stent	0	288		4972	
	1	142		2607	
	2	253	1.06	5185	1.22
	≥ 3	289	1.21	5377	1.26
Total stent length	≤ 61	190		3890	
	> 61	264	1.11	4613	1.09
Fluoroscopy contribution	≤ 66	205		4609	1.08
	> 66	238	1.00	3655	
Fluoroscopy time (min)	≤ 39	154		2566	
	> 39	356	1.49	5625	1.32
Total procedure time	≤ 109	203		4178	
	> 109	300	1.26	5297	1.25
Previous failed same session (antero or retro)	N	213		4013	
	Y	274	1.15	4064	0.96
Septal	N	178		3091	
	Y	274	1.15	5558	1.31

Table 29: Total DAP and Total AK DRL for CTO procedures in function of patient thickness

		DRL Total DAP (Gy cm2)	Multiplicative Factor DAP	DRL Total AK (mGy)	Multiplicative Factor AK
Patient thickness*	< 250 mm	70		1018	
	≥ 250 mm	198	2.85	3434	3.37

*Available only for site A, and E-site 3

As shown in Table 30 with PSD DRL for CTO procedures, the highest increase expected when compared to the classical DRL for CTO was due to increasing order of importance: 7-8 F size, > 57 mm total stent length, 1 or 2 diseased vessels and retrograde approach.

Table 30: PSD DRL for CTO procedures in function of clinical and technical factors significant in univariate analysis

CTO	PSD DRL (mGy)	Compared to Classical PSD DRL 2339 mGy
Age		
≤ 64	2232	
> 64	**2405**	**1.03**
BMI		
≤ 24.9	1613	
25-29.9	**2731**	**1.17**
> 30	**3086**	**1.32**
Patient thickness (mm)*		
< 250	917	
≥ 250	**2640**	**1.13**
Calcified		
0	2031	
≥ 1	3063	1.31
J-CTO score		
≤ 1	1905	
≥ 2	**2882**	**1.23**
Retrograde		
Y	**3323**	**1.42**
N	2341	
Diseased vessels		
0	1536	
1-2	**3346**	**1.43**
Size		
5-6 F	2087	
7-8 F	**3602**	**1.54**

Previous failed same session (antero/retro)		
Y	**3144**	**1.28**
N	2074	
Contrast Agent Quantity (mL)		
≤ 250	1907	
> 250	**3063**	**1.31**
Total Stent Length (mm)		
≤ 57	1595	
> 57	**3547**	**1.52**

*Available only for site A and E-site 3

2.8 DRL for TAVI Procedures

Based on these univariate analysis results for TAVI, DRL were presented in Tables 31-32 in function of the clinical and technical factors that were significant both for total DAP and total AK. For instance, Obesity will result in 1.47 times higher DAP DRL compared to classical DAP DRL or a patient thickness higher than 25 cm will result in 2.8 higher DAP DRL/2.6 higher total AK DRL.

Table 31: Total DAP and Total AK DRL for TAVI procedures in function of clinical and technical factors significant in univariate analysis

Clinical Factor TAVI		DRL Total DAP (Gy cm^2)	Multiplicative Factor DAP DRL 174 Gy cm^2	DRL Total AK (mGy)	Multiplicative Factor AK DRL 1216 mGy
Sex	M F	201 146	1.15	1304 1029	1.07
BMI	Underweight or Normal weight Overweight Obesity	135 172 257	 1.47	836 1296 1720	 1.41
Previous PCI	0 ≥ 1	185 86	0.49	1217 833	0.68
Previous CABG	N Y	180 190	1.09	1174 1582	1.30
Site implant	Femoral Double femoral	142 122	0.82	1213 893	1.00
Site control angio	Femoral Radial	179 113	1.03	1216 890	1.00
Contrast agent quantity (mL)	≤ 200 > 200	142 147	0.85	956 1213	1.00
Year manufactured	2017-2018 2011-2014 2008	89 168 46	0.97 0.26	717 1214 374	1.00 0.31
Detector size	18-25 40-48	111 211	1.21	915 1128	0.93

Table 32: Total DAP and Total AK _DRL for TAVI procedures in function of patient thickness

		DRL Total DAP (Gy cm²)	Multiplicative Factor DAP	DRL Total AK (mGy)	Multiplicative Factor AK
Patient thickness*	< 250 mm ≥ 250 mm	36 101	2.79	319 826	2.59

*Available only for site A, and E-site 3

As shown in Table 33 with PSD DRL for TAVI procedures The highest increase expected when compared to the classical DRL for TAVI was due to in increasing order of importance: BMI>30, Age ≤ 83 years old and male sex.

For TAVI procedures, older patients (≥83 years old) pathology is more adapted for this type of treatment than younger patients who have higher incidence of bicuspid aortic valves for instance (19). This could explain the higher DRL for younger patients.

Table 33: PSD DRL for TAVI procedures in function of clinical and technical factors significant in univariate analysis

TAVI	PSD DRL (mGy)	Compared to Classical PSD DRL 561 mGy
Sex		
M	**789**	**1.41**
F	348	
Age		
≤ 83	**832**	**1.48**
> 83	356	
BMI		
≤ 24,9	330	
25-29,9	**592**	**1.06**
>30	**1050**	**1.87**
Patient thickness (mm)*		
< 250	286	
≥ 250	**798**	**1.42**

*Available only for site A and E-site 3

2.9 Multivariate Analysis of clinical factors for all procedures

To examine independent associations between the natural log of Total AK, Total DAP or PSD and studied parameters, multiple linear regressions models were performed, from the significantly associated variables in univariate analysis and in order to limit multicollinearity and heteroscedasticity. During multivariate analysis, a missing data class was added for variables with more than 10% missing data. Results of multivariate regressions were presented as exponentiated coefficients which can be interpreted as relative dose multiplier and their 95% confidence intervals.

Multivariate analysis of clinical factors was performed for all three types of procedures separately for total AK as well as PSD. A variation in percentage for each of those factors is computed as well as the associated p-value.

2.10 Multivariate analysis for PCI procedures

Significant clinical factors for PCI and their associated variation in percentage for total AK as well as the associated p-value are summarized in the table 34.

Table 34: Multivariate results for PCI and total AK

Clinical Factors	Variation in % for total AK	p-value
BMI Overweight vs Normal Obesity vs Normal	 31.3 73.4	$<10^{-3}$
Contrast Agent Quantity > 150 mL vs ≤ 150 mL	33.5	0.002
Bifurcation	22.0	0.014
POBA	22.6	0.027
Size 6-7F vs 4-5F	28.0	0.028
Stent Length >33mm	26.3	0.003
Fluoroscopy time per additional minute	2.5	$<10^{-3}$
Sex Female vs Male	-31.5	$<10^{-3}$

*Only significant clinical factors are shown

The forest plot figure 42 summarizes all factors that were taken into account in the multivariate model for total AK and PCI procedures.

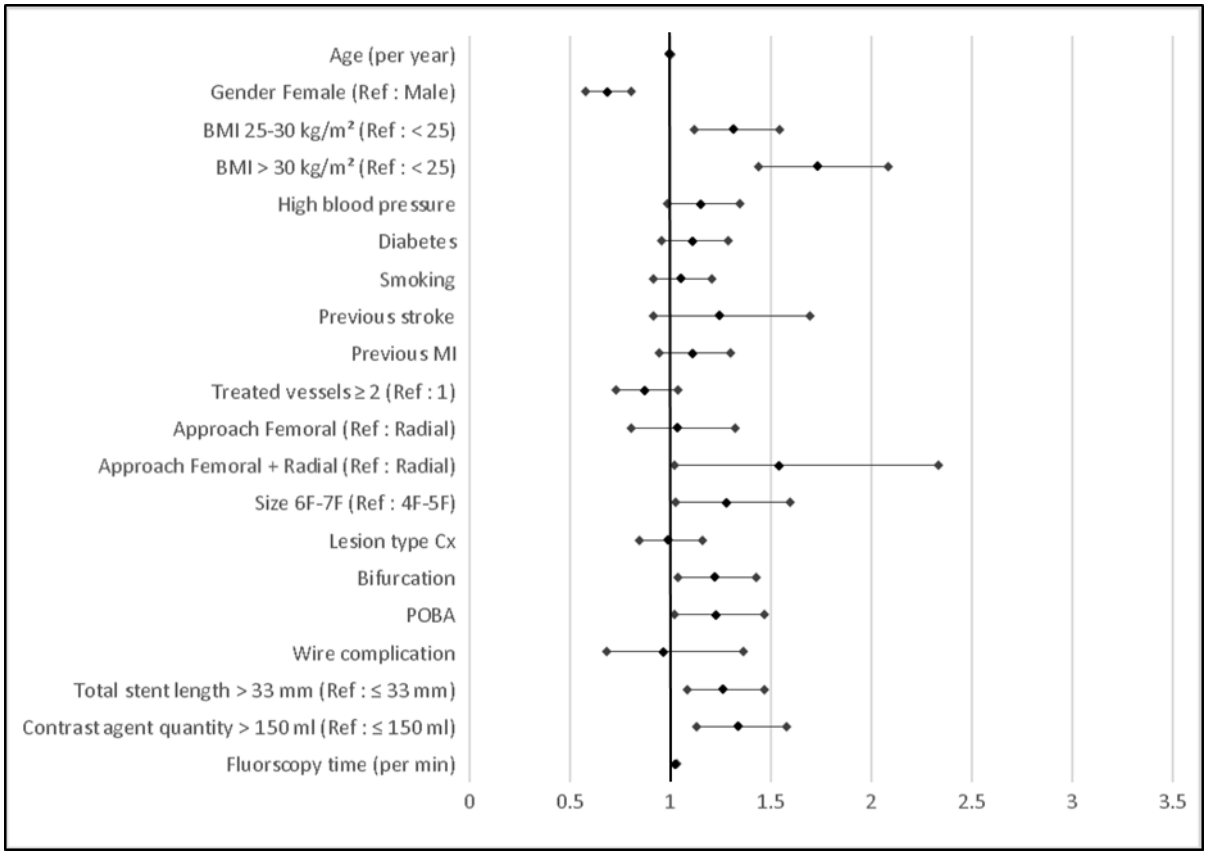


Figure 42: Forest plots multivariate results for clinical and technical factors found in the Excel questionnaire for PCI procedures and total AK *Diamonds represent exponentiated coefficients and error bars represent 95% confidence interval*

A multivariate model is also included for total AK for the database containing RDSR and therefore with technical factors that could be extracted, the forest plot is in figure 43.

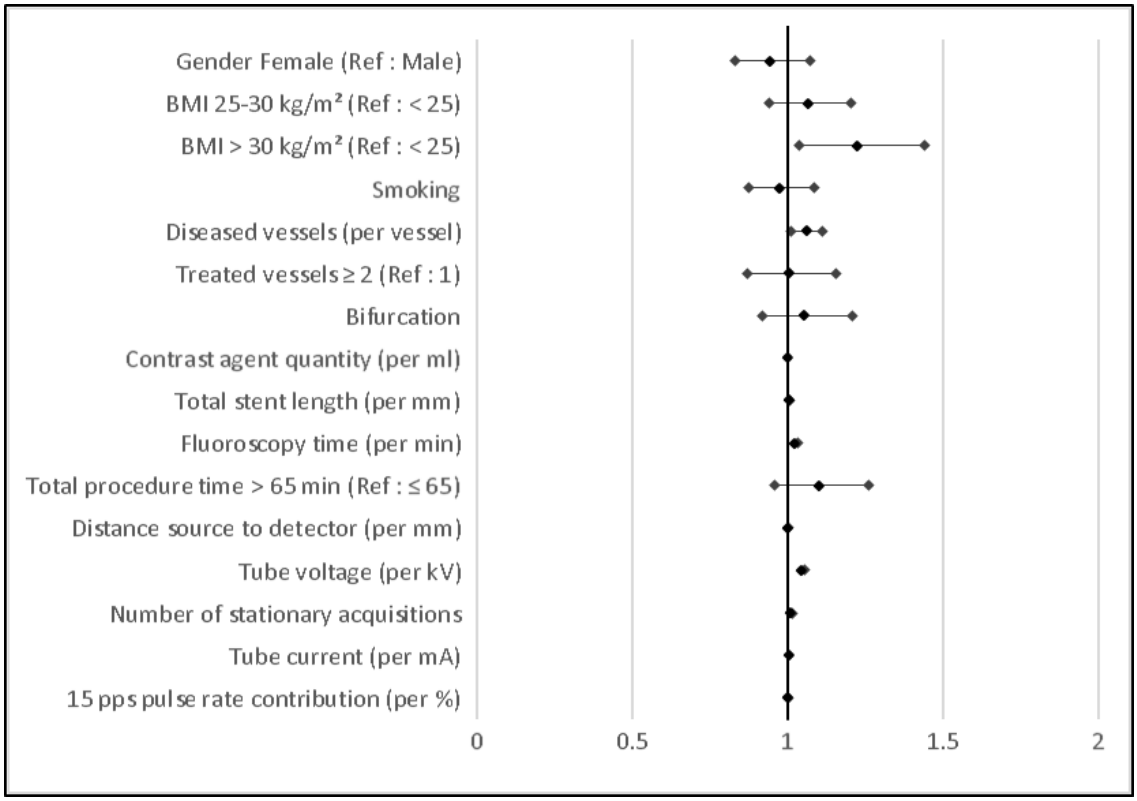


Figure 43: Forest plots univariate results for technical factors extracted from available RDSR for PCI procedures and total AK *Diamonds represent exponentiated coefficients and error bars represent 95% confidence interval*

For PSD, two multivariate models are suggested one with clinical factors only (table 35 and forest plot figure 44) and one including both clinical and technical factors (figure 45).

Table 35: Multivariate results for PCI and PSD

Clinical Factors*	Variation in % for PSD	p-value
BMI		$< 10^{-3}$
Overweight vs Normal	24.9	
Obesity vs Normal	80.3	
Contrast Agent Quantity per mL	0.3	$< 10^{-3}$
Bifurcation	27.2	0.023
Number of stents≥2 vs ≤1	31.4	0.011
Sex Female vs Male	-23.0	0.021

*Only significant clinical factors are shown.

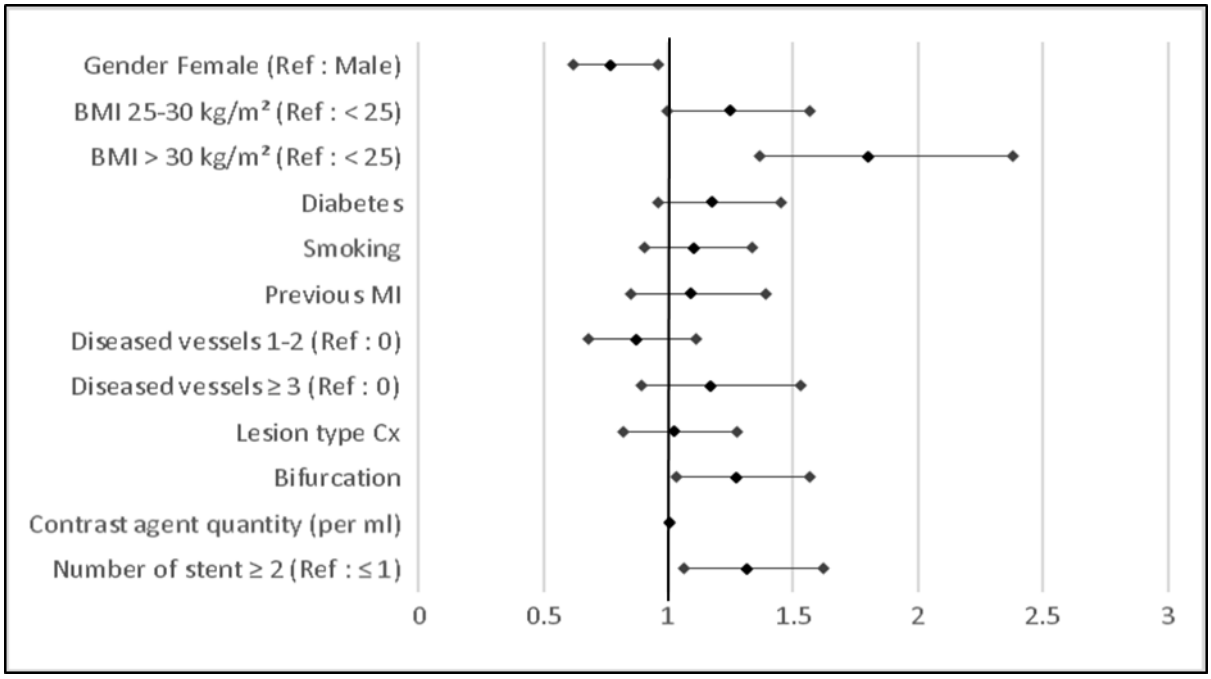


Figure 44: Forest plots multivariate results for clinical factors for PCI procedures and PSD
Diamonds represent exponentiated coefficients and error bars represent 95% confidence interval

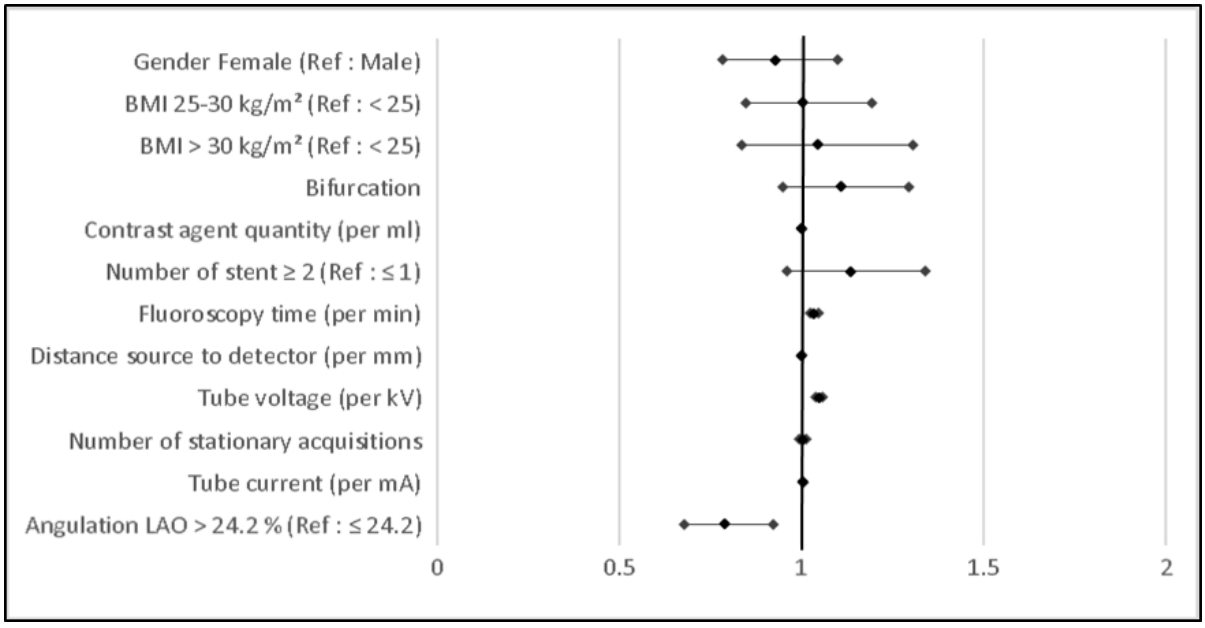


Figure 45: Forest plots multivariate results for clinical and technical factors for PCI procedures and PSD
Diamonds represent exponentiated coefficients and error bars represent 95% confidence interval

Most influential factors are common to both total AK and PSD: BMI, Contrast agent quantity, Bifurcation and Sex. It is clear from the multivariate analysis that BMI and sex are separate factors to be taken into account as each one of them has a significant influence in the multivariate analysis.

2.10.1 Multivariate analysis for CTO procedures

Significant clinical factors for CTO and their associated variation in percentage for total AK as well as the associated p-value are summarized in the table 36.

Table 36: Multivariate results for CTO and total AK

Clinical Factors*	Variation in % for total AK	p-value
BMI Overweight vs Normal Obesity vs Normal	 57.5 83.7	$<10^{-3}$
Site Double vs Simple	-22.6	0.009
Contrast Agent Quantity > 305 mL vs ≤ 305 mL	74.5	$<10^{-3}$
Age > 64	32.1	0.002
Sex Female vs Male	-31.7	0.005
Fluoroscopy time per additional minute	0.8	$<10^{-3}$
Total stent length > 61 mm vs ≤ 61 mm	31.6	$<10^{-3}$

*Only significant clinical factors are shown

The forest plot figure 46 below summarizes the factors that are taken into account in the multivariate model for total AK .

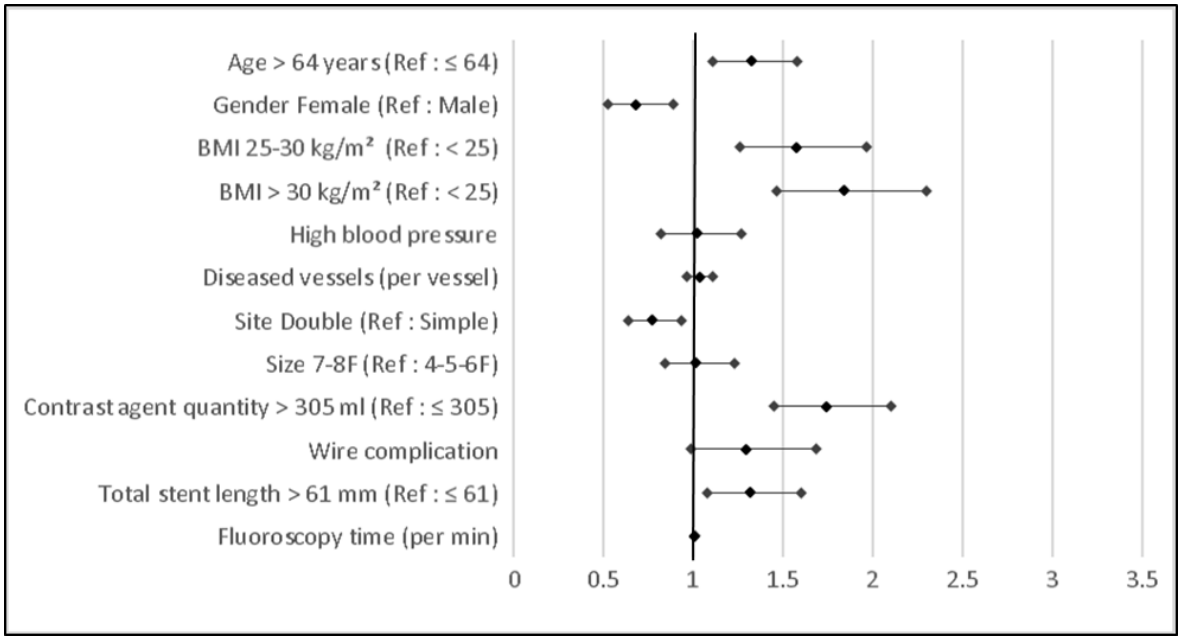


Figure 46: Forest plots multivariate results for clinical factors for CTO procedures and total AK
Diamonds represent exponentiated coefficients and error bars represent 95% confidence interval

A multivariate model is also included for total AK for the database containing RDSR and therefore with technical factors that could be extracted (figure 47).

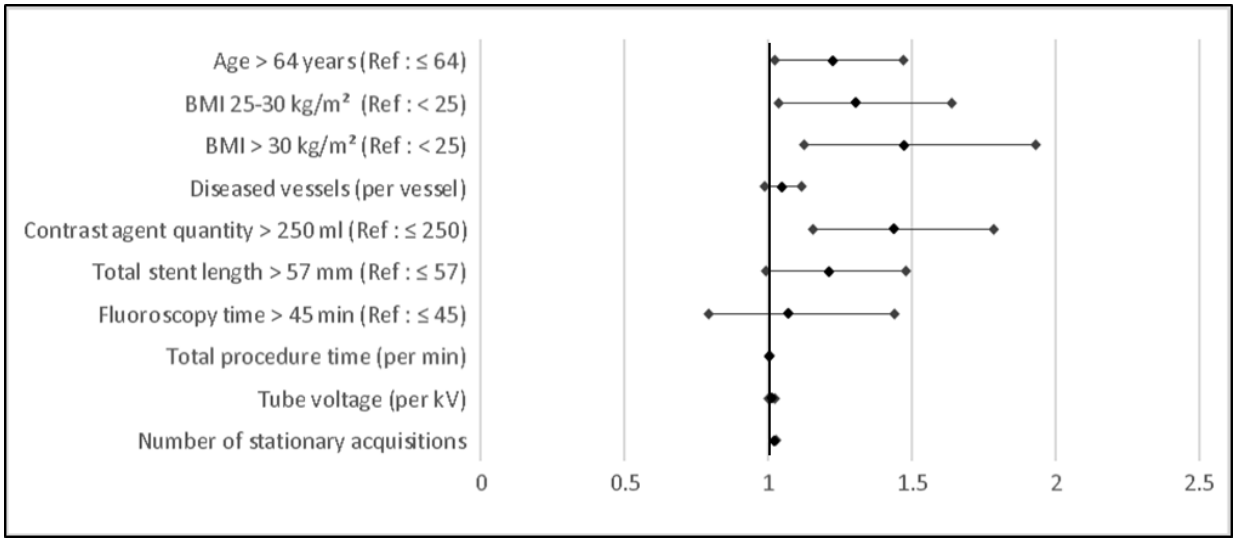


Figure 47: Forest plots multivariate results for clinical and technical factors for PCI procedures and total AK *Diamonds represent exponentiated coefficients and error bars represent 95% confidence interval*

For PSD, two multivariate models are suggested one with clinical factors only (table 37 and forest plot figure 48) and one including both clinical and technical factors (forest plot figure 49).

Table 37: Multivariate results for CTO and PSD

Clinical Factors*	Variation in % for PSD	p-value
BMI Overweight vs Normal Obesity vs Normal	 41.8 63.5	0.008
Contrast Agent Quantity > 250 mL	57.2	0.001
Stent Length > 57mm	53.1	0.006
Age > 64	41.3	0.004
Number of diseased vessels Per additional vessel	9.9	0.019

*Only significant clinical factors are shown

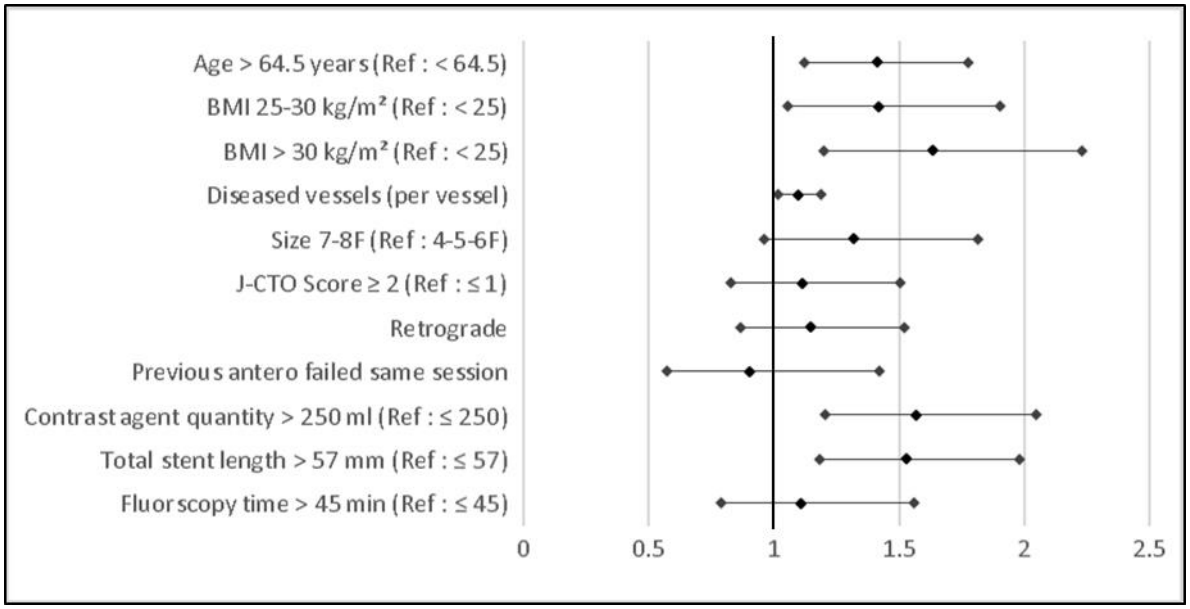


Figure 48: Forest plots multivariate results for clinical factors for CTO procedures and PSD
Diamonds represent exponentiated coefficients and error bars represent 95% confidence interval

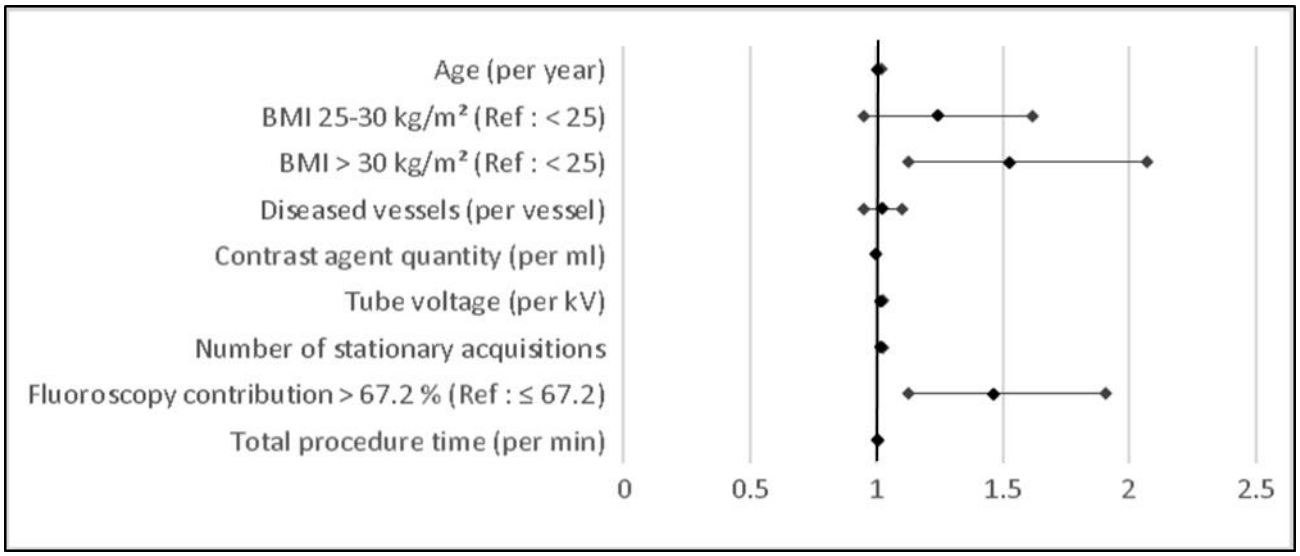


Figure 49: Forest plots multivariate results for clinical and technical factors for CTO procedures and PSD
Diamonds represent exponentiated coefficients and error bars represent 95% confidence interval

Most factors are common to both total AK and PSD: BMI, Contrast agent quantity, Age and Sex.

2.10.2 Multivariate analysis for TAVI procedures

Significant clinical factors for TAVI and their associated variation in percentage for total AK as well as the associated p-value are summarized in the table 38.

Table 38: Multivariate results for TAVI and total AK

Clinical Factors*	Variation in % for total AK	p-value
BMI Overweight vs Normal Obesity vs Normal	 24.8 112.6	$<10^{-3}$
Site Implant : Double Femoral vs Femoral	68.8	$<10^{-3}$
Fluoroscopy time per additional minute	4.3	$<10^{-3}$
Site control angio Radial vs Femoral	-19.7	0.021
Sex Female vs Male	-33.9	$<10^{-3}$

*Only significant clinical factors are shown.

The forest plot figure 50 summarizes the factors that are tAK en into account in the multivariate model for total AK .

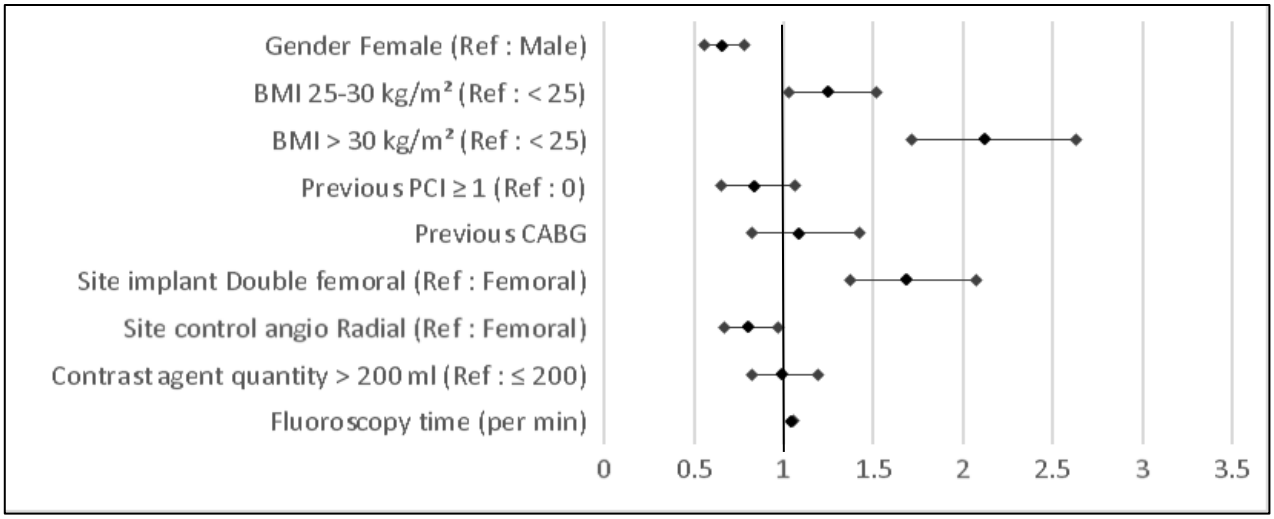


Figure 50: Forest plots multivariate results for TAVI procedures and total AK
Diamonds represent exponentiated coefficients and error bars represent 95% confidence interval

A multivariate model is also included for total AK for the database containing RDSR and therefore with technical factors that were extracted in figure 51.

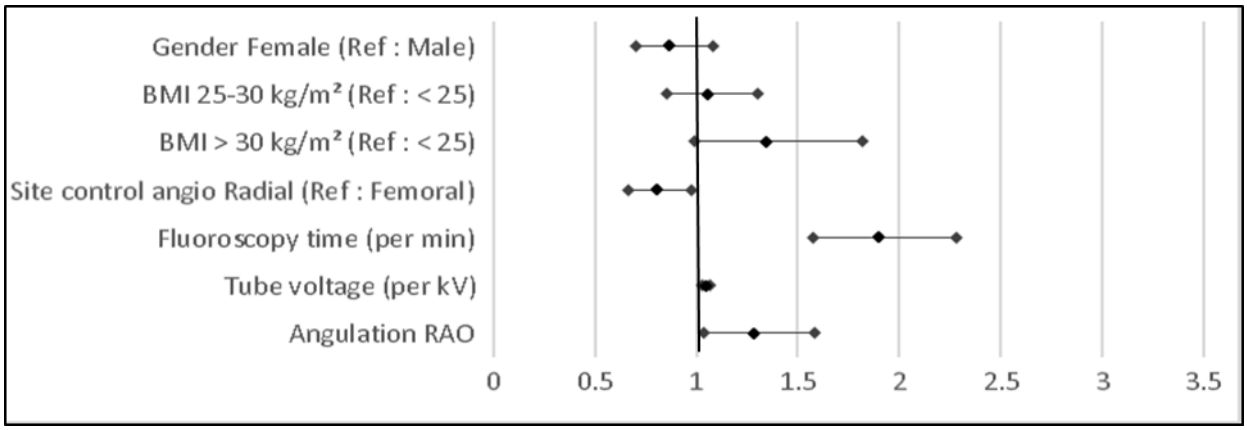


Figure 51: Forest plots multivariate results for clinical and technical factors for TAVI procedures and total AK

Diamonds represent exponentiated coefficients and error bars represent 95% confidence interval

For PSD, two multivariate models are suggested one with clinical factors only (table 39 and forest plot figure 51) and one including both clinical and technical factors (forest plot figure 51).

Table 39: Multivariate results for TAVI and PSD

Clinical Factors*	Variation in % for PSD	p-value
BMI Overweight vs Normal Obesity vs Normal	 13.0 94.2	$<10^{-3}$
Fluoroscopy time per additional minute	3.0	$<10^{-3}$
Sex Female vs Male	-45.9	$<10^{-3}$

*Only significant clinical factors are shown.

The forest plot below summarizes the factors that are taken into account in the multivariate models for total PSD without technical factors extracted from RDSR (figure 52) and with technical extracted factors (figure 53).

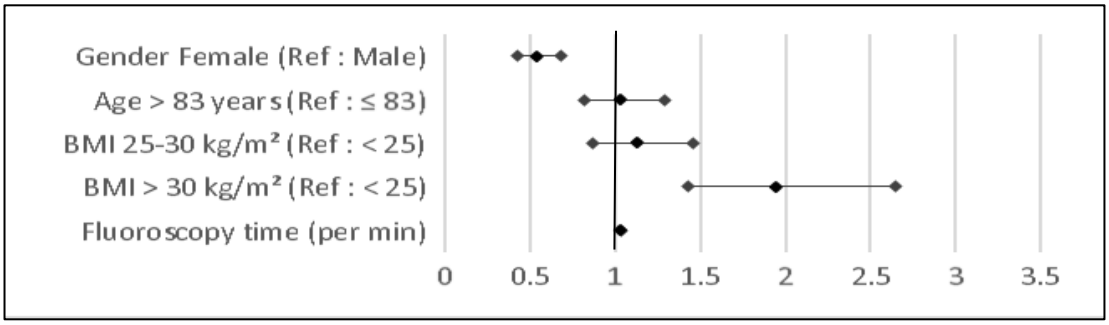


Figure 52: Forest plots multivariate results without technical factors for TAVI procedures and PSD

Diamonds represent exponentiated coefficients and error bars represent 95% confidence interval

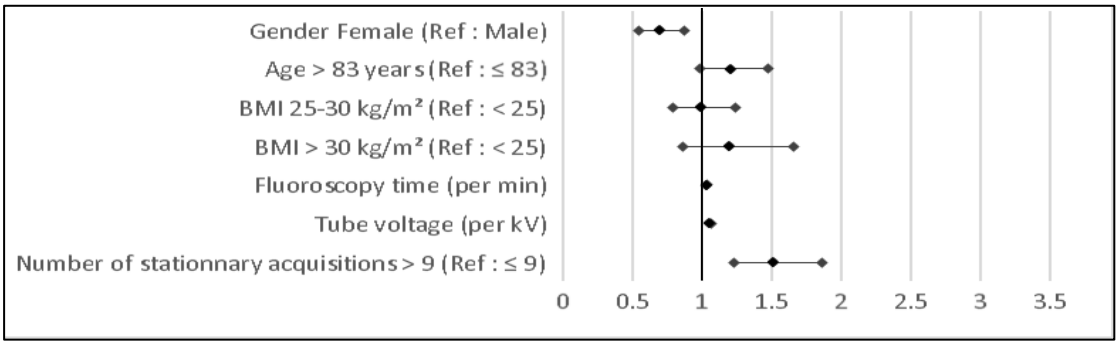


Figure 53: Forest plots multivariate results with technical factors for TAVI procedures and PSD

Diamonds represent exponentiated coefficients and error bars represent 95% confidence interval

Most factors are common to both total AK and PSD: BMI, Fluoroscopy Time, and Sex. It is clear from the multivariate analysis that BMI and sex are separate factors to be taken into account as both are significant

3 Investigation of skin dose determinants and optimisation of medical practice

3.1 A priori and a posteriori models for PCI, CTO and TAVI procedures

Based on the presented multivariate analysis, two models within Veridic project are suggested for PSD: 1. an a priori model allowing the interventional cardiologist to have an idea of PSD with clinical factors at the start of the procedure as well as 2. an a posteriori model based on clinical and technical factors used during the procedure.

In order to predict PSD, predictive models were built using stepwise multiple linear regressions. In fact, logistic regression could not be used as there was not enough procedures exceeding a meaningful PSD treshhold such as 2 Gy. For each procedure, two types of predictive models were built: an a priori model was applied using the patient characteristics available before the procedure, and an a posteriori model that also included technical factors. A 4-fold cross validation was performed, with 75% of the data used to generate and train the model.estimation of peak skin dose was performed in the 25% remaining. Predictive model performance was evaluated for each fold, using the Root Mean Square Error (RMSE), the coefficient of determination (R^2) and the linear correlation coefficient between the observed and the predicted values. The results were summarized with the mean of these indicators. The 'caret' package of R was used to divide the training and testing data, to train models in training samples and to predict values in testing samples.

A priori model for PCI

An a priori model was developed for PCI procedures including clinical factors only based on the multivariate models that were suggested. Sex, BMI, Smoking, Diseased vessels and bifurcation were found to be factors in the a priori predictive model for PSD. The model is formulated as:

PSD = EXP (-2,6775 -0,2675 SEX +0,07 BMI+0,245 SMOKING+0,095 DISEASED VESSELS + 0,315 BIFURCATION)

with Sex (0= Male;1= Female), Smoking/Bifurcation: (1= Y; 0= N) and a root mean square error of 0.70±0.06 and determination coefficient R2=0.26 ±0.09

The predictive model results were compared to the observed PSD for the particular procedures, as presented in Figure 54. The overall correlation coefficient between predicted and observed PSD was 0.45 as presented in Figure 55.

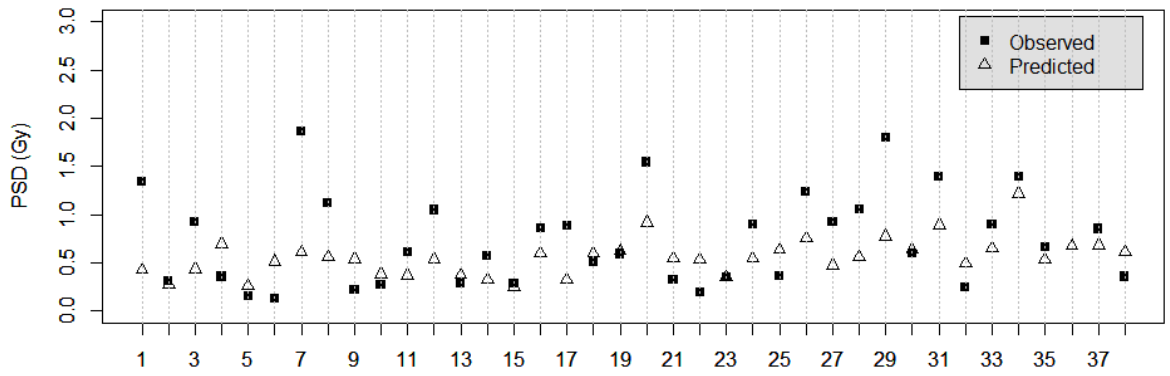


Figure 54: Observed and Predicted PSD values according to the a priori model for PCI procedures

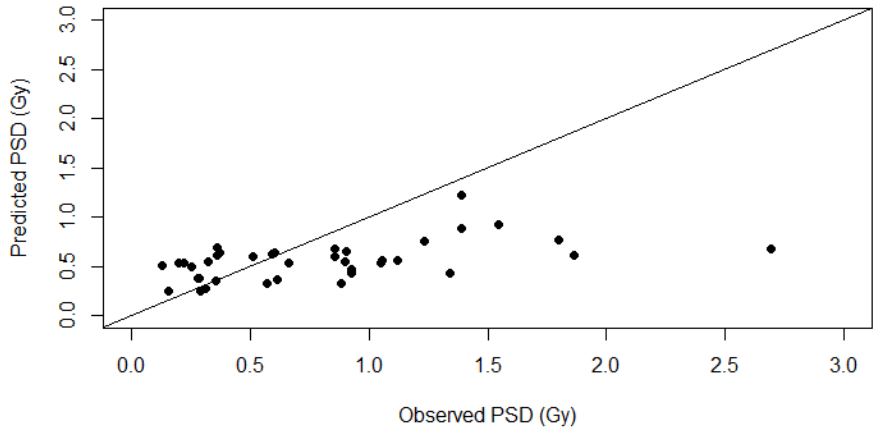


Figure 55: Correlation between predicted and observed PSD for PCI procedures

A posteriori model for PCI

An a posteriori model was developed for PCI procedures including clinical and technical factors based on the multivariate models that were suggested. However, for this procedure, technical factors were more influential than clinical factors as the clinical ones were no more significant in the a posteriori model and the model developed includes only technical factors.

The model equation is as follow:

PSD = EXP (-4.375+ 0.0405 FLUOROSCOPY TIME + 0.0525 TUBE VOLTAGE +0.0025 TUBE CURRENT -0.002 DISTANCE TO DETECTOR – 0.24725 IF LAO CONTRIBUTION>24.2%) with a root mean square error of 0.43±0.06 and determination coefficient R2= 0.77±0.06

The predictive model results were compared to the observed PSD for the particular procedures, as presented in Figure 56. The overall correlation coefficient between predicted and observed PSD was 0.89 as presented in Figure 57 which shows clearly that technical factors improve the model, and largely explains PSD values. The a posteriori model predicts better in the range 0-1.5 Gy than above mainly to due small high dose sample size.

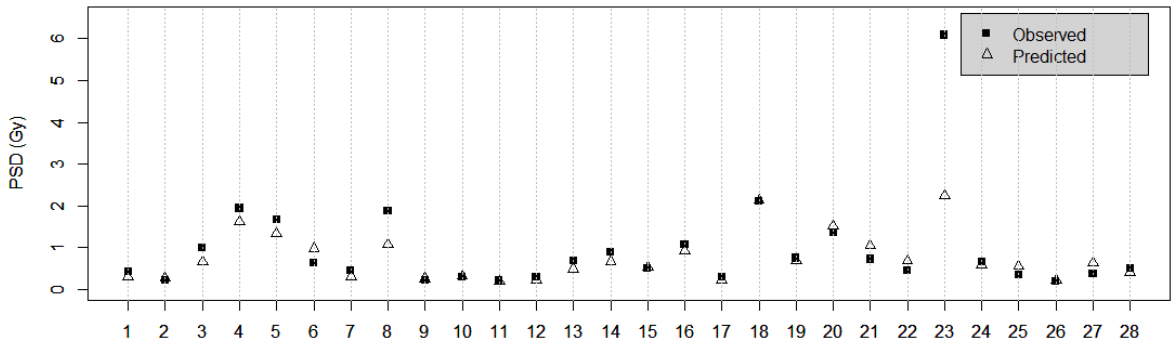


Figure 56: Observed and Predicted PSD values according to the a posteriori model for PCI procedures

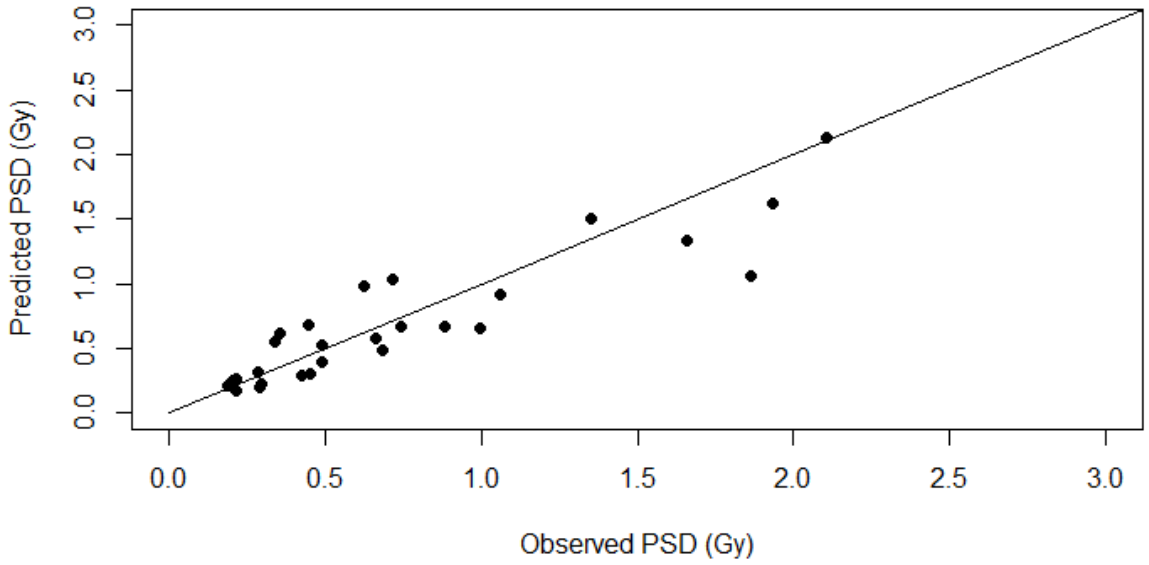


Figure 57: Correlation between predicted and observed PSD for a posteriori model in PCI procedures

A priori model for CTO

An a priori model was developed within Veridic for CTO procedures including clinical factors only based on the multivariate models that were suggested.

The model equation is as follow:

PSD = EXP (-1.0295 + 0.0175 AGE + 0.169 IF_BMI_OVERWEIGHT+ 0.451_BMI_IF OBESITY+0.155 NUMBER OF DISEASED VESSELS) with a root mean square error of 0.69 ±0.075 and determination coefficient R^2= 0.205±0.1.

The predictive model results were compared to the observed PSD for the particular procedures, as presented in Figure 58. The overall correlation coefficient between predicted and observed PSD was 0.44 as presented in Figure 59, which indicates clearly that clinical factors alone cannot explain PSD.

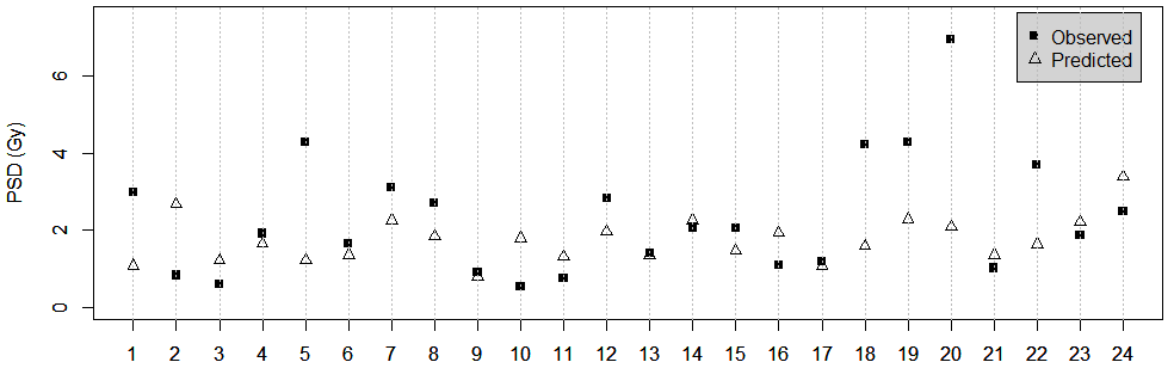


Figure 58: Observed and Predicted PSD values according to the a priori model for CTO procedures

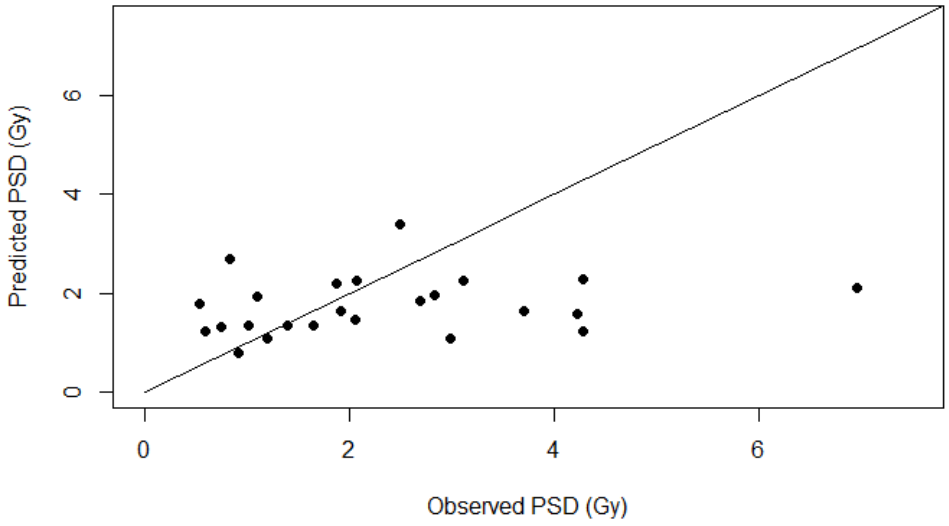


Figure 59: Correlation between predicted and observed PSD for a priori model in CTO procedures

A posteriori model for CTO

An a posteriori model was developed for CTO procedures including both clinical and technical factors based on the multivariate models that were suggested.

The equation of the model was as follow:

PSD= EXP(-0.82625 + 0.24225 AGE IF >64.5 yrs +0.1705_IF_BMI_OVERWEIGHT + 0.607_IF BMI_OBESITY -0.4505 SEX +0.3765 IF SIZE 7-8 F +0.003 NUMBER OF FLUORO ACQUISITIONS +0.017 NUMBER OF STATIONARY ACQUISITIONS) with a root mean square error of 0.57 ±0.067 and determination coefficient R^2= 0.47±0.11.

The predictive model results were compared to the observed PSD for the particular procedures, as presented in Figure 60. The overall correlation coefficient between predicted and observed PSD was 0.67 as presented in Figure 61, which indicates a real benefit from adding technical factors as a way of improving the model.

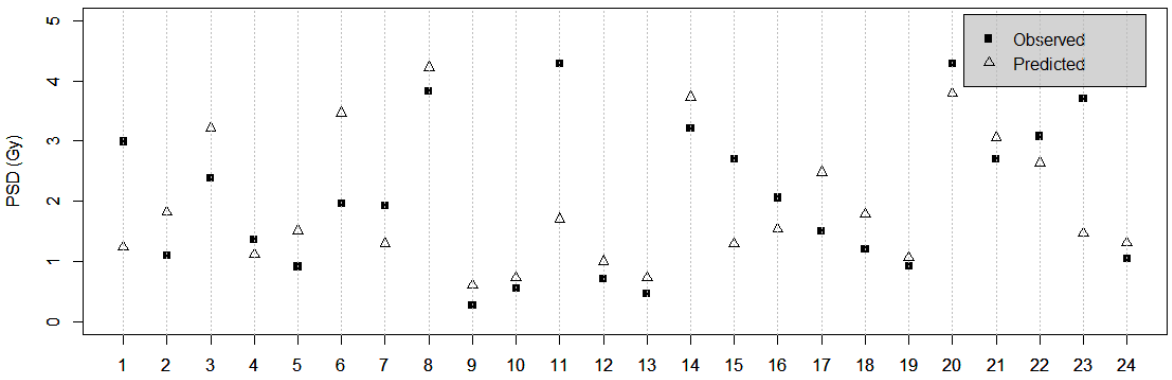


Figure 60: Observed and Predicted PSD values according to the a posteriori model for CTO procedures

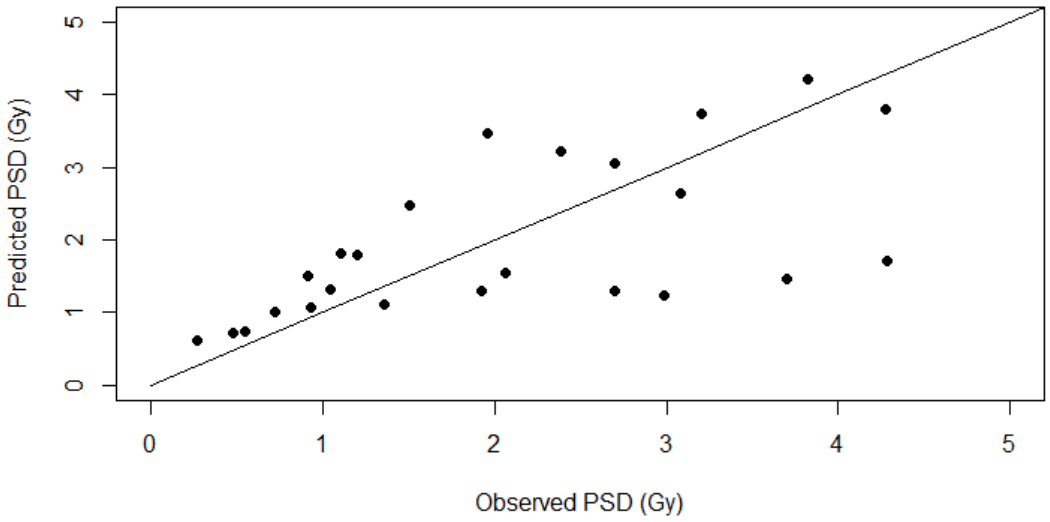


Figure 61: Correlation between predicted and observed PSD for a posteriori model in CTO procedures

A priori model for TAVI

An a priori model was developed for TAVI procedures including clinical factors only based on the multivariate models that were suggested.

The equation of the model was as follow:

PSD = EXP (-2,3765-0,57975*SEX+0,0685*BMI) with Sex (0= Male;1= Female) with a root mean square error of 0.66 ±0.083 and determination coefficient R^2= 0.36±0.12.

The predictive model results were compared to the observed PSD for the particular procedures, as presented in Figure 62. The overall correlation coefficient between predicted and observed PSD was 0.58 as presented in Figure 63.

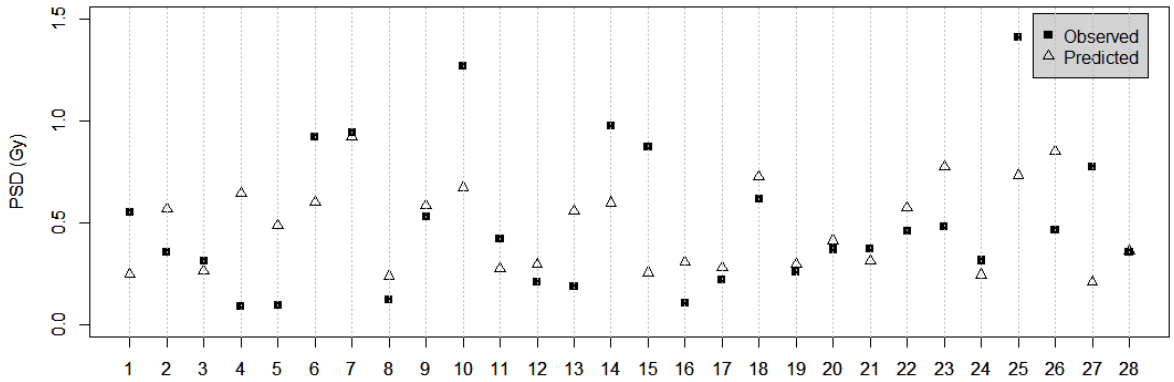


Figure 62: Observed and Predicted PSD values according to the a priori model for TAVI procedures

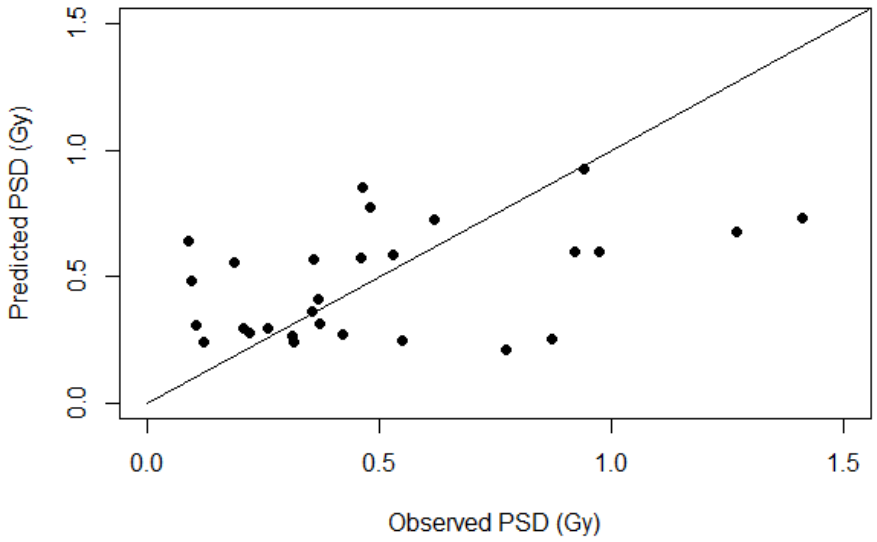


Figure 63: Correlation between predicted and observed PSD for a priori model in TAVI procedures

A posteriori model for TAVI

An a posteriori model was developed for TAVI procedures including both clinical and technical factors based on the multivariate models that were suggested.

The equation of the model was as follow:

PSD = exp(-6,13475 – 0,33925*Sex + 0,22875 * Age>83 + 0,033 * Fluoroscopy time + 0,05575*KVP + 0,40475 * Stationary>9) with a root mean square error of 0.54 ±0.09 and determination coefficient R^2= 0.54±0.12.

Observed and predicted PSD were close in the 0-1 Gy range however for PSD values greater than 1 Gy the model found it harder to predict mainly because of very few procedures exceeding this threshold (figure 64). The correlation coefficient between predicted and observed PSD was 0.65 as illustrated in figure 65. The improvement of the model by adding technical factors was not as straightforward as illustrated for PCI or CTO procedures.

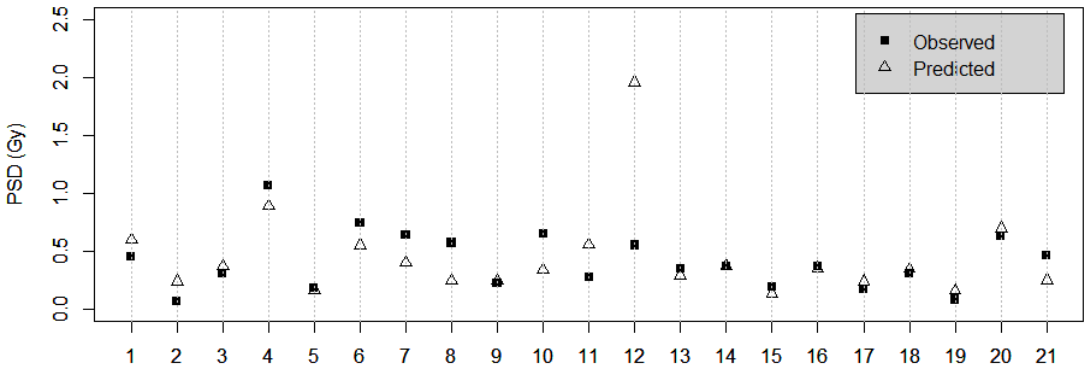


Figure 64: Observed and Predicted PSD values according to the a posteriori model for TAVI procedures

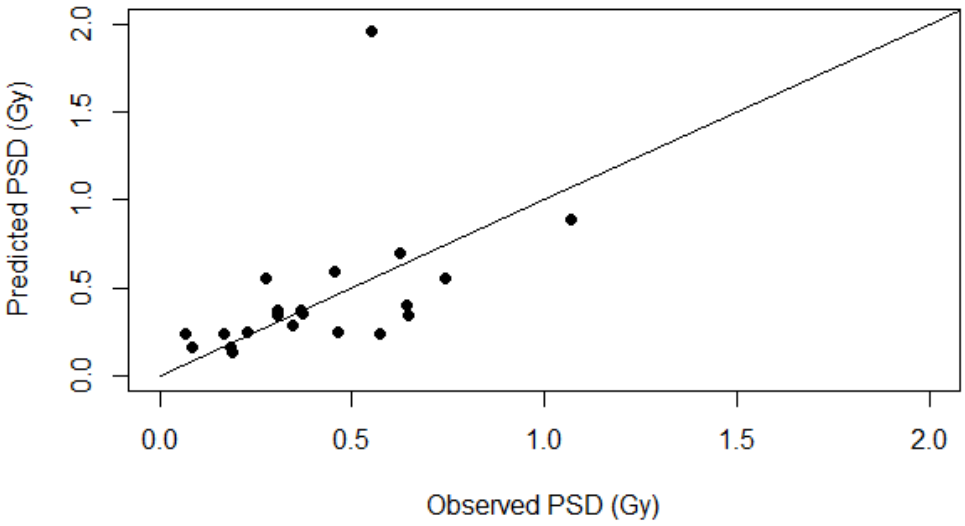


Figure 65: Correlation between predicted and observed PSD for a posteriori model in TAVI procedures

3.2 Frequency of high dose procedures

A total of 11 712 procedures with DAP, 11 218 procedures with total AK from 8 countries and 3 076 procedures with PSD from two sites were analysed and divided into the three different threshold levels for total DAP, total AK and PSD as illustrated in Table 40.

Very few procedures over the 3-6 months analysed turned out to be level 3 dose levels (0.2% in level 3 DAP, 0.8% in level 3 $K_{a,r}$ and 0.3% in level 3 PSD).

When looking by country, the highest DAP level 1-3 frequency was in country D with 7.9% in level 1, 3.5% in level 2 and 0.7% in level 3.

The highest AK level 1-3 frequency was in country G with 19.5% in Level 1, 7.3% in Level 2 and 2.4% in Level 3.

This result is indicative of the possibility of improvement of practices in both those sites.

In the 3-6 months data collection, Total AK was overestimating PSD in 88.2% of the procedures collected.

Table 40: Frequency of high dose procedures according to three treshhold levels for total DAP, total AK and PSD

Total DAP (Gy.cm2)	Percentage	Total AK (Gy)	Percentage	PSD(Gy)	Percentage
200<DAP≤300 Level 1	1.7%	2<AK ≤3 Level 1	4.6%	2<PSD ≤3 Level 1	1.1%
300<DAP≤500 Level 2	0.7%	3<AK ≤5 Level 2	2.7%	3<PSD≤5 Level 2	0.8%
P>500 Level 3	0.2%	AK > 5 Level 3	0.8%	PSD > 5 Level 3	0.3%

3.3 Optimization of practice

Clinical factors such as overweight/obese BMI, male patient, an important number of diseased vessels are predictors of high PSD. BMI has been shown by several studies in the past as a relevant parameter leading to an increase in PSD or total AK (Osei et al. , Fetterly et al.). In Veridic project, patient thickness was found to be a better correlating factor to Peak Skin Dose than BMI as median patient thickness in PA angulation correlated better to PSD.

The multivariate models have also shown that technical parameters are much more related to PSD than clinical factors when associated jointly. Therefore, optimization of practices is of outmost importance in all clinical complex cases.

Although many publications illustrate that fluoroscopy time is a poor predictor of patient dose (Siiskonen, most of the models found in this deliverable included fluoroscopy time as a predictor of PSD as well as an influencing technical factor. For instance the model by Balter et al. found a simple linear relationship between fluoroscopy time and complexity index (22) .

The number of stationary acquisitions had an influence both on CTO and TAVI procedures. Limiting these stationary acquisitions will have a positive impact in reducing PSD. For TAVI, one option to reduce these stationary acquisitions would be to perform valve deployment under fluoroscopy and store the sequence (23).

The use of lateral angulation in PCI procedures has shown an increase of 34.9% of PSD in the univariate results (the sample size was not sufficient for it to be significant in multivariate results) which indicates clearly that the use of such angulation is not encouraged. Lateral patient thickness is more important than posterior-anterior thickness which explains higher PSD and it is unlikely that the clinical information from this angulation is worth the excess of dose.

A surprising result in CTO procedures was found as LAO angulation decreased the dose although many publications and guidelines have shown that this angulation is associated with higher radiation dose to the patient as with high angulation x ray encounters increased tissue volume. This may be due to the fact that one specific procedure with very low LAO angulation contribution had a very high total AK (for other reasons) and completely biased our statistical analysis.

The use of the zoom should be limited to minimal as a higher Field of View (FOV) was associated in a decrease in PSD.

Many publications (17, 23) have illustrated that the use in fluoroscopy of reduced dose rate 7.5 pps instead of 15 pps is a good way of decreasing total AK as it does not usually affect total fluroscopy time or contrast agent quantity.In data collected in Veridic project for CTO procedures, using reduced fluoroscopy dose rate increased total fluoroscopy time.

As it has been shown in PCI and CTO procedures where operators with different levels of experience performed these procedures, operator experience plays a major role in reducing the dose as experienced operators are better trained in ways of optimizing their practices and are confident enough in the procedure itself to be able to use strategies for reducing patient radiation dose.

In Veridic project, DRL specific for clinical parameters that have an influence on dosimetrical parametrs were defined for each type of procedures as a way of allowing the operator to justify with a specific item any deviation from standard DRL.

Two types of models were developed within Veridic project for each type of procedure to estimate PSD. A priori models that include only clinical parameters would serve operators to have a rough idea of the patients at risk of having high PSD at the start of the procedure. A posteriori models would serve the

operators in knowing the influence of clinical/technical parameters and provide a rough figure in case PSD calculation software is not available.

The main limitation of the developed models was the lack of high peak skin dose procedures in the collected database as well as the uncertainty in the peak skin dose calculation as different softwares were used.

4 Conclusions

This report summarizes the findings following the data collection in 8 countries, 22 IC rooms and 12 hospitals for three types of therapeutic cardiology procedures (PCI, CTO and TAVI).

Cardiologists could use clinical determinants illustrated in this report as a justification in the DACS of exceeding the local DRLs as multiplicative factors are provided to select the determinants that are the most influential. A posteriori models were found to be in general more adapted in predicting correctly PSD, which highlights the importance of technical factors and thus the need of optimizing practices.

The a priori and a posteriori models enabling PSD calculation were developed within Veridic project for each type of procedure and need to be refined with a database including higher values of PSD to improve its performance. These models could be therefore included in the DACS software for future use.

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6 Annex I

All our acknowledgments goes to participating hospitals and more specifically:

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