

Comparison of radiation dose exposure in patients undergoing percutaneous coronary intervention vs. peripheral intervention

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Abstract

Introduction: Most endovascular techniques are associated with patient and personal exposure to radiation during the procedure. Ionising radiation can cause deterministic effects, such as skin injury, as well as stochastic effects, which increase the long-term risk of malignancy. Endovascular operators need to be aware of radiation danger and take all necessary steps to minimise the risk to patients and staff. Some procedures, especially percutaneous peripheral artery revascularisation, are associated with increased radiation dose due to time-consuming operations. There is limited data comparing radiation dose during percutaneous coronary intervention (PCI) with percutaneous transluminal angioplasty (PTA) of peripheral arteries.

Aim: To compare the radiation dose in percutaneous coronary vs. peripheral interventions in one centre with a uniform system of protection methods.

Material and methods: A total of 352 patients were included in the study. This included 217 patients undergoing PCI (single and multiple stenting) and 135 patients undergoing PTA (in lower extremities, carotid artery, renal artery, and subclavian artery). Radiation dose, fluoroscopy time, and total procedural time were reviewed. Cumulative radiation dose was measured in gray (Gy) units.

Results: The total procedural time was significantly higher in PTA (PCI vs. PTA: 60 (45–85) min vs. 75 (50–100) min), $p < 0.001$. The radiation dose for PCI procedures was significantly higher in comparison to PTA (PCI vs. PTA: 1.36 (0.83–2.23) Gy vs. 0.27 (0.13–0.46) Gy), $p < 0.001$. There was no significant difference in the fluoroscopy time (PCI vs. PTA: 12.9 (8.2–21.5) min vs. 14.4 (8.0–22.6) min), $p = 0.6$. The analysis of correlation between radiation dose and fluoroscopy time in PCI and PTA interventions separately shows a strong correlation in PCI group ($r = 0.785$). However, a weak correlation was found in PTA group ($r = 0.317$).

Conclusions: The radiation dose was significantly higher during PCI in comparison to PTA procedures despite comparable fluoroscopy time and longer total procedure time in PTA. Fluoroscopy time is a reliable parameter to control the radiation dose exposure in coronary procedures. The increasing complexity of endovascular interventions has resulted in the increase of radiation dose exposure during PCI procedures.

Key words: radiation dose exposure, fluoroscopy time, peripheral intervention, percutaneous transluminal angioplasty, percutaneous coronary intervention.

Introduction

The introduction of percutaneous endovascular techniques to treat patients with peripheral vascular and coronary artery disease has to some extent replaced vascular surgeries. Ionising radiation is an essential part of the diagnosis and treatment of peripheral and coronary artery disease.

As endovascular interventions become more complex, the radiation dose during these procedures tends to

increase. Immediate risk of skin injury will then probably be more prevalent, and the predicted long-term malignancy risk can increase for both patient and staff [1].

The cumulative radiation skin dose received by patients during percutaneous intervention does not only depend on the type and complexity of the procedure, but also on the type and performance of X-ray equipment, the level of training in radiation protection, the patient's condition, and the operator's experience [2].

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The data comparing radiation dose during percutaneous coronary intervention (PCI) and percutaneous transluminal angioplasty (PTA) of peripheral arteries is limited and requires further research and analysis.

Aim

The study goal was to compare the radiation dose between these two types of percutaneous interventions in one centre with a uniform system of protection methods.

Material and methods

Patients

A total of 352 patients were included in the study and divided into two groups. The first group consisted of 217 patients admitted between January 2012 and December 2012 with stable or unstable angina and treated with percutaneous coronary intervention (PCI group). The second group consisted of 135 patients admitted between September 2006 and December 2012 and treated with peripheral interventions (in the legs, carotid artery, renal artery, and subclavian artery) (PTA group). Single-vessel coronary disease was diagnosed when $\geq 70\%$ stenosis in one of the native coronary arteries was present. Multiple-vessel coronary disease was diagnosed when $\geq 70\%$ stenosis were found in at least two native coronary arteries. Peripheral interventions were performed in symptomatic patients with critical stenosis. All patients in both groups had already undergone coronary/peripheral angiogram before current hospitalisation.

Procedures

Coronary angioplasty was performed through femoral or radial access with stenting, in one or more vessel. Angiographic success was defined as restoration of the coronary flow to TIMI grade 3 and residual stenosis of less than 30%.

Peripheral angioplasty was performed through the femoral, radial, or brachial artery with or without stenting, in one or more vessel. In 29% of patients undergoing intervention in the lower limb, angioplasty was performed without stent implantation. Peripheral interventions were performed in the lower extremity (above and below the knee), carotid artery, renal artery, and subclavian artery. Angiographic success was defined as restoration of the blood flow and residual stenosis of less than 30%.

Complex procedures for PCI and for PTA were defined as intervention in more than one vessel and/or more than one stent implantation. All procedures were performed in one institute, by the same operators, and according to the contemporary standards.

Angiographic equipment

All procedures were performed using a Siemens AX-IOM Artis FC angiograph (Siemens, Erlangen, Germa-

ny). The machine provides optimal image quality at the lowest possible dose, by using a radiation protection package: C.A.R.E. (Combined Application to Reduce Exposure). The X-ray tube for the system was a MEGALIX Cat 125/35/80/-121GW. The tube and housing have a total filtration of ≥ 2.5 mm Al equivalent and 0.1–0.9 mm Cu. An image intensifier of a nominal circular field size of 23 cm was used. Cumulative radiation dose was measured in gray (Gy) units.

Statistical analysis

Data were analysed according to the established standards. Categorical data were presented using percentages and counts. Likelihood-ratio test was used for comparison of categorical variables. Due to non-normal distributions of all presented continuous data they were presented as median with lower and upper quartile and compared with Mann-Whitney *U* test.

To adjust baseline characteristics of PCI and PTA subjects a propensity score matching was performed. The propensity scores used for matching were calculated in a logistic regression model incorporating baseline covariates, including age, arterial hypertension, body mass index, chronic kidney failure, cigarette smoking, diabetes mellitus, dyslipidaemia, gender, history of myocardial infarction, and prior stroke/transient ischaemic attack (TIA). Matching was performed without replacement on a 1 : 1 basis using nearest neighbour with calliper method. Standardised differences for all baseline characteristics were less than 10%, which indicates a negligible difference in the mean or prevalence of a covariate between groups. Comparisons of adjusted data were performed using Wilcoxon signed-rank test for continuous variables and McNemar's test for categorical data. All statistical tests were two-sided. A *p*-value < 0.05 was considered statistically significant.

Results

There were significant differences between the two groups in terms of age and body mass index. In the PTA group 84% of the patients had typical past medical history of coronary artery disease (CAD). Demographic data and medical history are presented in Table I as raw and after adjustment. After the adjustment, no statistically significant changes observed for age and body mass index (BMI). Angiographic characteristics of atherosclerotic lesions in peripheral and coronary interventions are shown in Table II. The total procedural time was significantly higher in the PTA group. The radiation dose for PCI was significantly higher compared with the PTA group before and after adjustment. There was no significant difference in the fluoroscopy time (Table III). In peripheral procedures the highest radiation dose was observed in renal stenting and the longest fluoroscopy time in the below-knee procedures (Table IV). For single-vessel PCI in total occlusion, the radiation dose was significantly

Table I. Demographic data and medical history of patients after percutaneous coronary intervention and percutaneous transluminal angioplasty of peripheral arteries (unadjusted and adjusted results)

Variable	Unadjusted results			Adjusted results		
	PCI (n = 217)	PTA (n = 135)	Value of p	PCI (n = 33)	PTA (n = 33)	Value of p
Age [years]	66.0 (59.0; 76.0)	63.0 (57.0; 73.0)	0.039*	65.0 (59.0; 76.0)	64.0 (59.0; 73.5)	0.992
Male gender	71.89%	74.07%	0.653	75.76%	72.73%	0.796
BMI [kg/m ²]	28.1 (24.9; 31.2)	26.3 (24.1; 27.5)	0.005*	26.9 (24.6; 29.1)	27.1 (26.1; 28.8)	0.713
History of MI	55.13%	51.32%	0.635	60.61%	57.58%	0.763
Arterial hypertension	83.33%	84.21%	0.882	78.79%	81.82%	0.738
Diabetes mellitus	24.68%	28.95%	0.550	18.18%	18.18%	1.000
Dyslipidaemia	80.77%	80.26%	0.936	75.76%	75.76%	1.000
Current smokers	20.78%	27.63%	0.321	27.27%	30.30%	0.781
Chronic kidney failure	12.99%	5.26%	0.092	12.12%	12.12%	1.000
Prior stroke/TIA	10.39%	19.74%	0.103	9.09%	12.12%	0.654

PCI – percutaneous coronary intervention, PTA – percutaneous transluminal angioplasty, BMI – body mass index, MI – myocardial infarction, TIA – transient ischaemic attack

Table II. Angiographic characteristics of atherosclerotic lesions in peripheral and coronary interventions

Peripheral interventions	(n = 135)
Carotid	37.04% (50)
Subclavian	6.67% (9)
Renal	2.96% (4)
Lower extremity (above – knee)	48.15% (65)
Lower extremity (below – knee)	5.19% (7)
Coronary interventions	(n = 217)
Single-vessel	68.66% (149)
Two-vessel	20.74% (45)
Multiple-vessel	10.60% (23)

higher than in critical stenosis (2.14 (0.99–3.22) Gy vs. 1.1 (0.73–2.05) Gy, *p* = 0.001, respectively). However, no significant differences were reported for fluoroscopy

time. The radiation dose in complex PCI was significantly higher than in non-complex PCI. Fluoroscopy time in complex PTA was significantly higher than in non-complex PTA (Table V).

The analysis of correlation between radiation dose and fluoroscopy time in PCI and PTA interventions separately shows a strong correlation in the PCI group (*r* = 0.785, *p* < 0.001) (Figure 1). However, a weak correlation was found between radiation dose and fluoroscopy time in the PTA group (*r* = 0.317, *p* = 0.009) (Figure 1). The analysis of the correlation between radiation dose and BMI shows a weak but significant correlation in the PCI group (*r* = 0.43, *p* = 0.036). However, no correlation was found in the PTA group (*r* = 0.024, *p* = 0.835).

Discussion

Comparison of radiation dose and fluoroscopy time in patients undergoing PCI to peripheral interventions indicate that an experienced team of operators can conduct complex peripheral vascular procedures using a dig-

Table III. Comparison of radiation dose, fluoroscopy time, and total procedural time in coronary and peripheral interventions (unadjusted and adjusted results)

Parameter	Unadjusted results			Adjusted results		
	PCI (n = 217)	PTA (n = 135)	Value of p	PCI (n = 33)	PTA (n = 33)	Value of p
Radiation dose [Gy]	1.36 (0.83; 2.23)	0.27 (0.13; 0.46)	< 0.001	1.33 (0.74; 2.04)	0.33 (0.18; 0.54)	< 0.001
Fluoroscopy time [min]	12.90 (8.25; 21.50)	14.48 (8.00; 22.68)	0.601	11.74 (7.15; 17.98)	14.50 (8.53; 25.30)	0.170
Total procedural time [min]	60.0 (45.0; 85.0)	75.0 (50.0; 100.0)	< 0.001	55.0 (40.0; 80.0)	75.0 (50.0; 115.0)	0.018

PCI – percutaneous coronary intervention, PTA – percutaneous transluminal angioplasty

Table IV. Cumulative radiation dose and fluoroscopy time for coronary and peripheral interventions depending on procedure

Variable	Radiation dose [Gy]	Fluoroscopy time [min]
Coronary interventions:		
Single-vessel	1.24 (0.77; 2.20)	12.40 (7.95; 24.70)
Two-vessel	1.56 (0.95; 2.31)	13.20 (9.00; 19.57)
Multiple-vessel	1.75 (1.33; 2.38)	14.10 (11.90; 20.36)
Peripheral interventions:		
Carotid	0.21 (0.12; 0.42)	15.45 (9.29; 20.30)
Subclavian	0.25 (0.08; 0.83)	11.79 (6.50; 36.14)
Renal	0.44 (0.34; 0.53)	7.50 (5.85; 10.95)
Lower extremity (above – knee)	0.32 (0.16; 0.48)	14.30 (7.48; 25.48)
Lower extremity (below – knee)	0.10 (0.09; 0.21)	25.94 (15.73; 32.27)

ital angiographic system without exposing patients and staff to increased radiation.

The exposure of tissues to X-rays causes ionisation within cells, which may provoke chromosomal damage and induce malignancy [3]. The deleterious effects of radiation on tissue are divided into two types: deterministic and stochastic. Deterministic effects occur only once a threshold of exposure has been exceeded. Skin erythema, radiation-induced cataract formation, and sterility are examples of deterministic effects [4]. Stochastic effects occur due to the ionising radiation effect of symmetrical translocations taking place during cell division. There is no threshold level, and the risk of an effect occurring increases as the dose increases [5]. Stochastic risk depends somehow on the age of the patient undergoing fluoroscopic imaging, because the time to manifest malignancy is longer than the patient’s survival.

Exposure to ionising radiation during endovascular procedures depends on numerous factors such as BMI, field of view, fluoroscopy pulse rate, acquisition frame rate, variable beam filtration, total fluoroscopy time, and total acquisition time. The radiation dose is also dependent

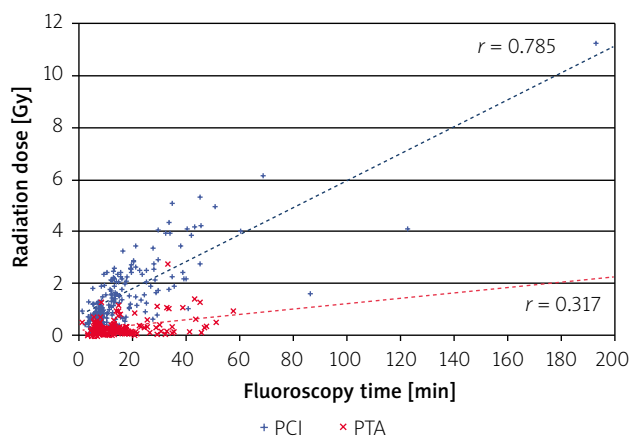


Figure 1. Correlation between radiation dose and fluoroscopy time in coronary and peripheral interventions

of the equipment-related factors, including beam collimation, servicing, filter usage, field of view size, movement capabilities of the X-ray source, fluoroscopic, software image filtering, and X-ray photon energy spectra [4, 6–11].

There are a several studies which present the radiation dose that the patient receives during invasive endovascular procedures, with the effective dose ranging from 5 to 21 mSv, depending on the complexity of the procedure [12–14]. However, less is known about the radiation doses received by patients and staff during peripheral endovascular procedures. A number of studies have reported the radiation doses during PTA, some of them for the lower limb stenting reports mean dose-area product (DAP) 64 Gy × cm² [13] and other studies with the mean DAP for renal or iliac interventions ranging between 127–176 Gy × cm², depending on the procedure and the centre [15].

Radiation doses during implantation of aortic stent-graft area round 2 Gy, but in rare cases they may exceed 6 Gy [16]. In this study there were no abdominal procedures or stenting of descending aortic aneurysms. The only peripheral thoracic procedures were within the subclavian artery.

Irradiation of the abdomen and pelvic regions is associated with higher radiation exposure compared to

Table V. Cumulative radiation dose and fluoroscopy time in complex and non-complex coronary and peripheral interventions

		Complex procedures	Non-complex procedures	Value of p
Radiation dose [Gy]	PCI	1.60 (1.15; 2.33)	1.24 (0.77; 2.20)	0.031
	PTA	0.36 (0.11; 1.07)	0.27 (0.13; 0.46)	0.465
Fluoroscopy time [min]	PCI	13.95 (9.21; 19.72)	12.40 (7.95; 19.72)	0.555
	PTA	32.7 (17.60; 38.40)	14.08 (9.20; 21.18)	0.004

PCI – percutaneous coronary intervention, PTA – percutaneous transluminal angioplasty

thoracic and neck regions. Many studies have examined the radiation exposure to the spine. Radiographic examinations of the cervical spine give radiation doses similar to the chest, but lumbar spine exposure generates higher doses [17–19].

In this study the radiation dose that the patient receives during PTA is statistically lower than during PCI procedures, despite comparable fluoroscopy time and longer total procedural time in PTA. In peripheral procedures the highest radiation dose was observed in renal stenting and the lowest dose in below-knee interventions. However, the opposite has been observed in fluoroscopy time, where the longest time was in below-knee interventions and the shortest in renal stenting.

This presumably results from the fact that in coronary procedures, the X-ray tube usually remains static, so the skin reference point rarely moves. However, during peripheral procedures the X-ray tube often moves along and around the patient, so no one point on the patient receives the total dose [11].

The radiation dose in complex PCI was significantly higher than in non-complex PCI. There were no differences in radiation dose for complex and non-complex PTA procedures, despite a significantly longer fluoroscopy time in complex PTA.

Usually, peripheral arterial revascularisations are more complex because of the long occlusion, and they often require implantation of more than one stent [20], but this did not lead to the increase in the radiation dose compared to non-complex PTA.

Previous studies have documented that radiation dose during chronic total occlusion (CTO) interventions can reach significant levels [21, 22]. Likewise, in this study the radiation dose during single-vessel PCI in total occlusion was significantly greater than in critical stenosis.

This study also shows that fluoroscopy time correlates with radiation dose in coronary procedures. However, in peripheral procedures only a weak correlation was found. This could indicate that fluoroscopy time is a good parameter to control the radiation dose exposure mostly in PCI, but not during PTA procedures. No clear correlation was found between radiation dose and BMI.

It is remarkable that interventional operators are exposed to long-term, low-dose occupational radiation. A recent study reports higher radiation doses for eyes and hands in peripheral procedures (pelvic, upper limb, and below-the-knee) than in coronary procedures [23].

Currently, physicians use a number of methods of radiation protection, such as the casing attached to the treatment table, covers, body parts, or glasses, that allows a reduction in the radiation dose to patients and staff [11].

Finally, the complexity of endovascular interventions with the development of new techniques is increasing. These procedures are likely to increase radiation dose exposure, so it is important to estimate the radiation dose

exposure for both patients and staff, and attempt to reduce it.

The study has a number of limitations. First, it has all the limitations inherent to single-centre registries. Second, the groups were not parallel in the time included in the study. Third, this study had no abdominal procedures or stenting of descending aortic aneurysms. Finally, the study included a small number of renal, below-knee, and subclavian procedures.

Conclusions

The radiation dose was significantly higher during PCI in comparison to PTA procedures, despite comparable fluoroscopy time and longer total procedural time in PTA. Fluoroscopy time is a reliable parameter to control the radiation dose exposure in coronary procedures, but not necessarily in peripheral interventions. The increasing complexity of endovascular interventions resulted in the increase of radiation dose exposure during PCI procedures, as opposed to PTA procedures, where complexity has no impact on radiation dose.

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