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Patients' Radiation Doses During the Implantation of Stents in Carotid, Renal, Iliac, Femoral and Popliteal Arteries CME

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Abstract *Objectives and Design:* The aim of the study was to document the radiation doses to patients during the implantation of stents in various arteries and to discuss potential reasons for prolongation of radiological procedures.

Materials and Methods: Measurements of air kerma (Gy) and dose–area product (Gy cm^2) (DAP) were carried out simultaneously on a sample of 345 patients, who underwent different interventional radiological procedures involving angioplasty with stenting of 73 carotid (21.5%), 22 renal (6.5%), 160 iliac (45%), 63 femoral (18.6%) and 27 popliteal (7.9%) arteries.

Results: The highest mean air kerma values for fluoroscopy and exposure were found for renal angioplasty (340 and 420 mGy, respectively). With regard to total DAP values, the highest were obtained for renal (148 Gy cm^2) and iliac/The Inter-Society Consensus for Management of Peripheral Arterial Disease (TASC) II C (199 Gy cm^2) stent implantation. The lowest values were for carotid (53 Gy cm^2), iliac/TASC II A (6.3 Gy cm^2) and femoral/TASC II A (53 Gy cm^2) arteries. For 3.5% of the patients, the air kerma was between 1 and 1.5 Gy and for 1.5%, it was between 1.5 and 2 Gy.

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Conclusions: In procedures performed on the arteries of the lower limbs, a significantly higher dose was received by patients with TASC II C lesions. With regard to the number of stents implanted, the total DAP value was 50% higher for simultaneous three-stent implantation than for one or two stents.

Introduction

Ionising radiation exposure is an inherent component of endovascular surgery. As procedures become more complex, greater radiation exposure is incurred by both staff and patients. Ionising radiation carries an oncogenic risk that is linearly related to the dose.[1] Stochastic effects, such as mutations, can result in cancer and hereditary effects. Deterministic effects, such as cell killing, can be more immediate and have a threshold above which severity increases with radiation dose. Air kerma (AK), measured in Gy, indexes the amount of radiation at a point in space and assesses the hazard at that specific location. AK multiplied by the cross-sectional area of the X-ray beam at the point of measurement yields the dose–area product (DAP), expressed as Gy cm^2. The DAP has the advantage of being constant at any distance from the tube focus; hence, wherever the DAP is measured, it reflects the AK radiation field size product at the patient's skin. The DAP might also be useful for estimating the effective dose by calculating the total energy imparted to the patient, which can then be used to calculate the stochastic risk as a potential quality indicator.[1]

There has been a considerable body of work on the radiation dose administered to patients during invasive cardiology procedures; however, less is known about the radiation doses incurred by patients during peripheral vascular endovascular procedures. The main purpose of this study was to detect the doses patients received during the implantation of stents in carotid, renal, iliac, femoral and popliteal arteries that are used as a non-surgical alternative for patients with prohibitively high surgical risk. The angioplasty of various peripheral arteries is an essential part of the practice of interventional radiology. The number and complexity of endovascular procedures have increased in recent years.[2–22]

Materials and Methods

In this study, measurements of AK and DAP were simultaneously carried out from May 2006 to September 2008 on a sample of 345 adult patients (246 males and 99 females; mean age: 64 ± SD 11), who underwent five different interventional procedures with stent implantation (one stent: 266 patients, two stents: 57 and three stents: 22). Radiation doses were controlled and analysed retrospectively. All clinical procedures were performed in an operating C-arm unit (Allura, Philips Medical Systems, Best, The Netherlands) using pulsating X-ray radiation. Available image-intensifier field sizes were 17 cm, 23 cm and 31 cm. The patients were placed on an operating table with a floating tabletop. In the C-arm unit, dose data were calculated from exposure values and expressed as DAP (Gy cm^2) and AK (Gy), together with the total time of fluoroscopy (real-time images: stent placement, min) and exposure (X-ray images taken during the injection of contrast medium, ms). Contrast medium was administered during image acquisition to make vessel morphology assessment possible. During exposure time, the patient received a higher radiation dose than during fluoroscopy because higher Peak kilovoltage (kVp) was required in this procedure to get better, higher-contrast imaging. Usually, the difference between the doses received in the two procedures averages from 20 kVp in abdominal examination to 40 kVp in limb examination. Accordingly, in some cases, patients exposed for a prolonged time during fluoroscopy with a short exposure time could receive a smaller dose of radiation than patients exposed to a short fluoroscopy time and a longer exposure time.

During the fluoroscopic examinations, the positioning of the patient was observed and average values for tube potential were noted for each projection by observing the acquisition display.

Carotid artery stents were implanted in 73 patients, including 24 (33%) asymptomatic patients. Patients had more than 70% internal carotid stenosis. One to three stents, 7–12 mm in diameter and 20–60 mm in length (Precise Control Stent Cordis Corp. NJ, USA; carotid wall stent, Boston Scientific, MA, USA; and carotid wallstent, Acculinc Stent, Abbott Laboratories, IL, USA) were implanted.

Renal artery stenting was indicated in 22 patients who failed medical treatment and had stenosis of the artery of more than 70%. Seventeen stenosed lesions of the renal artery were located in the proximal segment, four were in the middle segment and one in the distal segment. After performing the angioplasty, stents were assembled on balloons, 5–7 mm in diameter and 12–25 mm in length (Genesis, Cordis Corp, NJ, USA), and implanted.

The 160 patients with stenosis or occlusion of the iliac artery, who underwent angioplasty with stenting, were grouped according to the Inter-Society Consensus for Management of Peripheral Arterial Disease (TASC II)[23] into three morphological groups: type A, $n = 42$ (27%) type B, $n = 52$ (33%) and type C, $n = 66$ (40%) patients. There were no indications for stenting in the type D classification among our patients.[23]

Sixty-three patients with stenosis or occlusion of the superficial femoral artery underwent angioplasty or subintimal angioplasty with stenting. These patients were also divided into three TASC II classification groups: type A, $n = 16$ (25%), type B, $n = 20$ (31%) and type C and $n = 27$ (43%) patients.

Angioplasty with stenting of the popliteal artery was performed in 27 patients (24 with stenosis and three with occlusion). Nitinol self-expanding stents, 6–8 mm in diameter and 20–40 mm in length (Smart, Cordis Corp, NJ, USA) were used.

The objective of the study was to analyse radiation doses in patients undergoing stenting procedures in various arteries, and to discuss potential reasons for prolongation of radiological procedures.

Table 1 Types of angiographic procedures and sample size, dose—area product (DAP) values [Gy cm^2] and air kerma [mGy].

			Total air kerma [mGy]		Total DAP [Gy cm^2]		Fluoroscopy time [s]		Exposure time [ms]	
Endovascular procedure	Tasc II	Sample size	Mean (median)	Standard deviation (interquartile range)	Mean (median)	Standard deviation (interquartile range)	Mean (median)	Standard deviation (interquartile range)	Mean (median)	Standard deviation (interquartile range)
Illiac artery stenting (IAS)	A	42	156 (126)	87 (103—194)	53 (43)	28 (29—76)	329 (279)	305 (174—357)	114 (98)	77 (59—139)
	B	52	417 (345)	289 (258—508)	132 (99)	114 (67—137)	463 (393)	304 (234—592)	276 (230)	204 (162—304)
	C	66	662 (591)	369 (385—844)	199 (162)	114 (127—261)	728 (540)	699 (366—792)	418 (362)	233 (249—553)
Femoral artery stenting (FAS)	A	16	33 (31)	12 (22—40)	6.3 (6)	2.7 (4—8)	445 (414)	169 (333—553)	12 (8)	8 (6—19)
	B	20	61 (64)	13 (48—70)	15.5 (11.7)	10.8 (8—18)	636 (574)	301 (405—810)	24 (22)	14 (14—36)
	C	27	250 (168)	234 (104—330)	70 (46)	54 (28—103)	873 (789)	434 (600—1023)	131 (58)	203 (37—138)
Carotid artery stenting (CAS)	—	73	317 (273)	190 (196—429)	53 (42)	42 (25—67)	907 (792)	447 (618—1038)	437 (209)	443 (68—731)
Renal artery stenting (RAS)	—	22	687 (658)	278 (454—820)	148 (145)	66 (96—207)	885 (693)	547 (576—1206)	767 (588)	670 (387—841)
Popliteal artery stenting (PAS)	—	27	296 (203)	224 (72—131)	63 (46)	54 (14—48)	847 (762)	388 (576—1374)	474 (145)	642 (26—81)

Statistics

Statistical analysis was carried out using the statistical package in Python (open source software). Patient doses and exposures were separately analysed with the Kruskal—Wallis test (H-test), according to subgroups regarding TASC II classification and the number of stents implanted. A p-value ≤ 0.05 was considered significant.

Results

The longest duration of fluoroscopy was for carotid, renal, femoral-TASC II C and popliteal angioplasty (Table 1). However, the mean (median) exposure time (X-ray images taken during the injection of contrast medium) for renal stent implantation was the highest at 767 ms (588 ms). Significant differences for fluoroscopy and exposure times were found between TASC II in angioplasty of both the femoral ($H = 15.6$, 2 df, $p < 0.0004$ and $H = 32.5$, 2 df, $p < 0.0001$, respectively) and iliac arteries ($H = 32.6$, 2 df, $p < 0.0001$ and $H = 67.5$, 2 df, $p < 0.0001$, respectively). It should be noted that significant differences have been found for TASC II A versus B, TASC II A versus C and TASC II B versus C for both the angioplasty procedures. TASC II C lesions required double the duration of fluoroscopy compared with TASC II A in both angioplasty of the femoral artery and angioplasty of the iliac artery (Fig. 1). The exposure time in the iliac artery of TASC II C lesions was four times longer than for TASC II A lesions; in the case of the femoral artery, the TASC II C/TASC II A ratio was 10. The highest mean AK values were found for renal, carotid and iliac TASC II B and C angioplasties. The lowest value was found for femoral-TASC II A. With regard to total mean (median) DAP values, the highest values were obtained for stent implantation of the renal artery at 148 Gy cm^2 (145 Gy cm^2) and the iliac artery/TASC II C at 199 Gy cm^2 (162 Gy cm^2). The lowest values were for stent implantation of the carotid artery at 53 Gy cm^2 (42 Gy cm^2), the iliac artery/TASC II A at 53 Gy cm^2 (43 Gy cm^2), the femoral artery/TASC II A at 6 Gy cm^2 (6 Gy cm^2) and the femoral artery/TASC II B 15.5 Gy cm^2 (11.7 Gy cm^2).

In terms of the number of stents implanted in a single patient, the mean (median) DAP was about 50% higher for the implantation of three stents at 153 Gy cm^2 (145 Gy cm^2) compared with one stent at 92 Gy cm^2 (101 Gy cm^2) or two stents at 101 Gy cm^2 (110 Gy cm^2). The p-value was on the border of significance ($H = 5.6$, 2 df, $p = 0.06$). In particular, a significant difference was obtained in the case of implantation of one versus three stents ($p = 0.02$). Despite the fact that the mean (median) AK for the implantation of three stents at 512 Gy cm^2 (459 Gy cm^2) was higher than for one at 353 Gy cm^2 (343 Gy cm^2) or two at 355 Gy cm^2 (368 Gy cm^2), the analysis indicated no significant differences between these parameters ($H = 2.1$, 2 df, $p = 0.34$). All individual differences: one versus two stents, one versus three stents and two versus three stents were statistically non-significant ($p > 0.05$).

In all procedures, imaging was performed with a rotation angle of 0°, and only renal and carotid stenting required imaging at different angles (rotation 90°: 34.9% and 48.7% of the total number of runs, respectively). Most of the series (79%) was acquired using 70 kVp voltage.

Discussion

The potential for high patient radiation doses during interventional radiological procedures is well known.[24] A simple chest X-ray exposes a patient to a radiation dose

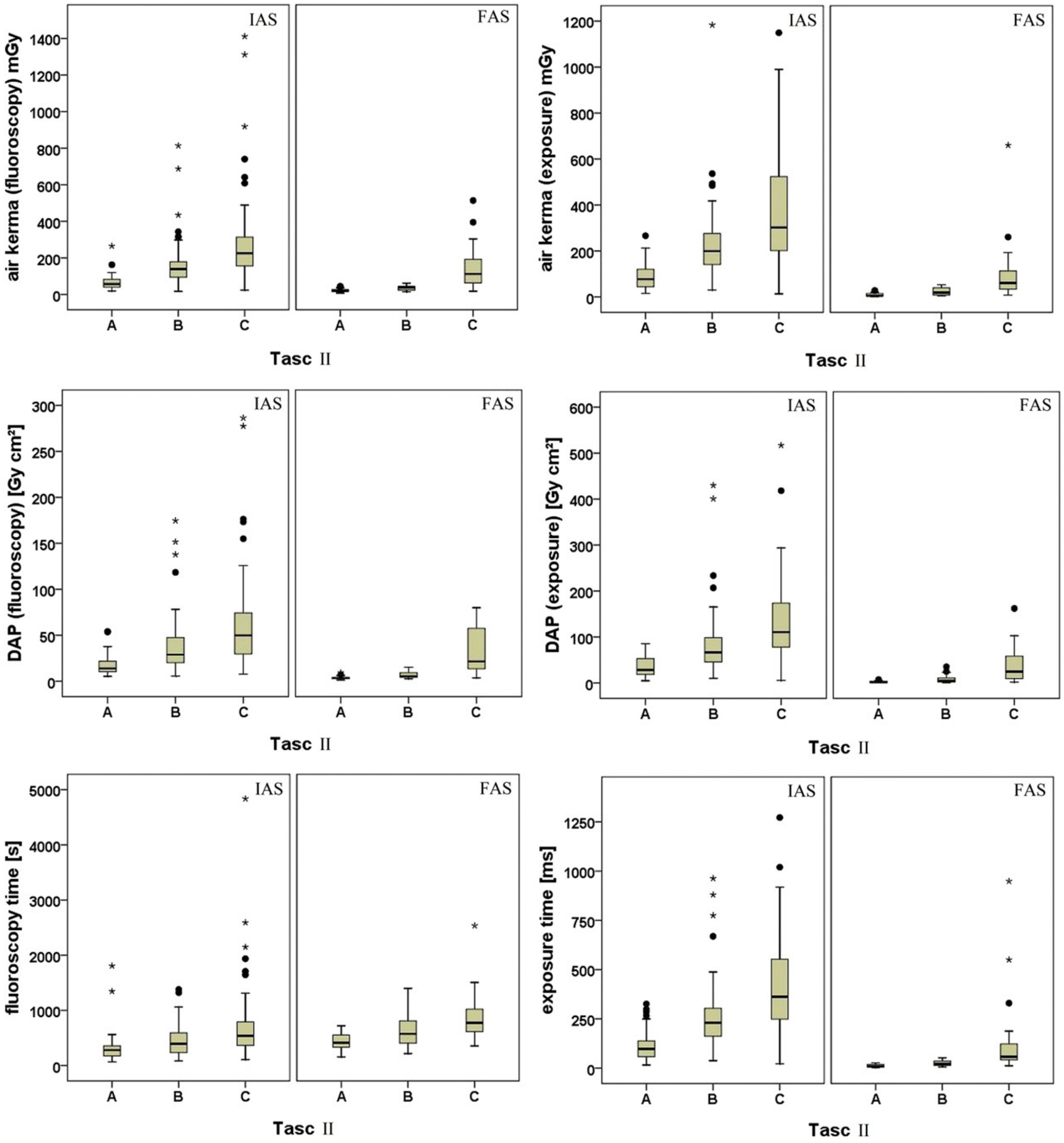

Figure 1 Mean radiation time, air kerma and Dose Area Product (DAP) values for fluoroscopy and exposure in iliac artery stenting (IAS) and femoral artery stenting (FAS) by TASC II type A, B and C groups (95% confidence intervals, ∗ - extreme outliers, • - mild outliers).

of about 0.1 mGy, compared with 0.01 mGy for a dental X-ray. The highest permitted dose for a radiation worker amounts to 100 mGy over 5 years. By contrast, therapeutic exposures involve much higher doses precisely delivered to the volume of a tumour (prescribed doses are typically in the range of 20—60 Gy). Radiation sickness results when humans are exposed to more than a 1 Gy dose of ionising radiation. Doses greater than 6 Gy are generally not treated successfully and usually result in death within 2 days to 2—3 weeks, depending on the duration of the exposure.[24—26]

Angioplasty of the carotid, renal, iliac, femoral and popliteal arteries are common endovascular procedures performed routinely in most interventional radiology institutes. The available data suggest that the radiation exposure during endovascular aneurysm repair involves some of the highest radiation doses.[27] In our study, for 3.5% of the patients, the AK was between 1 and 1.5 Gy (six patients with an iliac stent, four with a renal stent and one for carotid and popliteal stent implantation) and, for 1.5%, it was between 1.5 and 2 Gy (only during angioplasty of the iliac artery). Each of these patients was monitored for 3 months post-procedurally to look for the appearance of radiation sickness. No individual presented any suspected signs or symptoms, probably because the highest level of irradiation was observed among long-lasting multi-stenting procedures. Despite this, we assume that endovascular procedures exposing patients to doses greater than 1 Gy can be risky and should be applied only if necessary from a life- or limb-saving point of view. The aforementioned patients are still under observation to assess possible late post-irradiatory complications. In contrast to these cases, more than 50% of all patients, who received a radiation dose between 100 and 500 mGy, revealed no side effects. Because the patient's dose has a linear relationship with radiation time, the most important issue is the reason for using a procedure involving prolonged radiation exposure, as discussed below.

Carotid artery stenting

Internal carotid arteries are highly sensitive to manipulations with a guide wire or cerebral protection systems. Rough manoeuvres can lead to vasospasm and require treatment with vasodilators accompanied by control angiographies every few minutes until the problem is resolved.

The main reason for the implantation of more than one stent was the imprecise assessment of the required stent length or dissection after the deployment of the first stent. Endovascular interventionists should abide by the basic tenet of radiation protection: as low as reasonably practicable (ALARP) to achieve the necessary result.

Renal artery stenting

Difficult lesions in renal arteries, located just before the bifurcation of the artery, required placing two guide wires in such a way as to secure the branches in case the plaque is moved during angioplasty into one of them.

Iliac, femoral and popliteal arteries stenting

One of the reasons for prolonging the stenting procedure of the common iliac artery, especially in its proximal segment, was the detachment of the atherosclerotic plaque in the bifurcation of the aorta. As a consequence, the plaque occluded or narrowed the contralateral common or external iliac artery, which required placing another stent to secure the plaque and restore the flow.

During angioplasty of the superficial femoral artery, we often experienced flow-limiting intimal dissection that had to be remedied with stent implantation, and this contributed to an increase in radiation dose.

Heavily calcified lesions occluding the popliteal artery sometimes required the use of different guide wires and catheters. Even the use of these time-consuming manoeuvres can prove unsuccessful; hence, an interventionist has to make a reasonable decision as to when to stop the procedure.

The largest exposures in our study were generated by the renal revascularisation procedures. Given that the Angioplasty and Stenting for Renal Artery Lesions (ASTRAL) trial showed little or no benefit of endovascular procedures plus medical therapy over medical therapy alone in patients with atheroslerotic renovascular disease, it seems reasonable that renal angioplasty should be limited to only certain groups of patients with severe renal artery stenosis (e.g., those presenting with 'flash' pulmonary oedema[28] or acute kidney injury[29]).

Iliac and femoral artery stenting procedures in patients with mild-to-moderate lesions (TASC A and B) required relatively low radiation doses. This fact, together with the results obtained in the mild-to-moderate intermittent claudication (MIMIC) study,[30] where adjuvant benefit of PTA (percutaneous transluminal angioplasty) over supervised exercise and best medical therapy in the treatment of intermittent claudication were assessed, undoubtedly justifies exposing patients to certain amounts of radiation: initial claudication distance (ICD) and absolute walking distance (AWD) were significantly improved in the group treated with PTA.

Although the DAP and radiation times are useful parameters for comparing patient exposures, this comparison is complicated by the dependency of the DAP on a number of equipment-related factors, including beam collimation, servicing, filter usage, movement capabilities of the X-ray source, fluoroscopic specifications (pulse rate, acquisition frame rate and acquisition input dose rates), X-ray photon energy spectra, the position of the projection and potential variations in the skill of the radiologist.[31] Several recommendations have been made to minimise the radiation dose incurred during coronary angiography, including keeping fluoroscopy use to a minimum and using low doses (pulsed modes where possible), using the smallest possible number of runs with the lowest possible number of frames and placing the patient as far as possible from the X-ray source.[1,31] As stent implantation seems to involve similar radiation exposure, these recommendations could equally be applied to the endovascular suite. However, further studies concerning radiation doses in different medical centres (using different apparatus) and during treatment executed by various radiologists should be conducted.

Conclusion

This study has presented radiation doses during the implantation of stents in the carotid, renal, iliac, femoral and popliteal arteries studied with regard to the number of stents implanted. This study supports the following conclusions:

- Most patients (55%) received a relatively low radiation dose (100—500 mGy); in 3.5% of patients the AK was between 1 and 1.5 Gy and, for 1.5%, it was between 1.5 and 2 Gy;
- The highest total mean AK values were found for renal and iliac TASC II C angioplasties (687 and 662 mGy, respectively). The lowest mean AK value was found for femoral stent implantation (33 mGy);
- With regard to the number of stents implanted in a single patient, the mean DAP value was 50% higher for a simultaneous three-stent implantation than for one or two stents; in such cases, the mean radiation dose was higher than 0.5 Gy and the maximum reached 1.7 Gy; the use of one long stent instead of three stents to reduce radiation exposure should be investigated.

Conflict of Interest/Funding

None.

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