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Clinical factors increasing radiation doses to patients undergoing long-lasting procedures: Abdominal stent-graft implantation

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- A Study Design
- B Data Collection
- C Statistical Analysis
- D Data Interpretation
- E Manuscript Preparation
- F Literature Search
- G Funds Collection

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Summary

Background: An important negative factor of EVAR is the radiation acquired during long-lasting procedures. The aim of the study was to document the radiation doses of EVAR and to discuss potential reasons for prolongation of radiological procedures.

Material/Methods: Dose-area product (DAP) (Gy cm^2) and air kerma (AK) (Gy) obtained during EVAR from 92 patients were analyzed retrospectively in regards to body mass index (BMI), angulations of aneurysm neck, length of aneurysm neck and occurrence of tortuosity of iliac arteries.

Results: Total AK for fluoroscopy differed significantly between normal BMI (373 mGy) and BMI 25-29.9 (1125 mGy) or BMI >30 (1085 mGy). Iliac artery tortuosities >45° and short aneurysm necks caused higher doses of total AK (1097 mGy and 1228 mGy, respectively) than iliac artery tortuosities <45° and long aneurysm necks (605 mGy and 720 mGy, respectively).

Conclusions: The main factors contributing to a high radiation dose being acquired by patients during EVAR are: BMI >25, tortuosity of iliac arteries >45° and short aneurysm necks.

key words: **stent-graft • dose-area product • dosage • X-ray • radiation**

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BACKGROUND

Interventional radiology is an essential part of modern operative treatment; fluoroscopically-guided interventional procedures have been increasingly practiced during the past 15 years. Because of the increasing complexity of endovascular interventions that need exposure to ionizing radiation, concern has grown regarding X-ray exposure to both patients and operators.

In recent years, the numbers of abdominal stent-graft placements have significantly increased [1,2]. Endovascular repair of infrarenal abdominal aortic aneurysms (EVAR) has become a generally accepted alternative to open surgery for selected patients; in randomized trials it has been shown to be effective in reducing both morbidity and mortality [1,3,4].

Stent-graft implantation is a less invasive procedure, especially in lower-risk patients with pre-existing severe neurological, cardiovascular, pulmonary or renal dysfunction [5]. For that reason it allows shorter hospitalization and faster convalescence. An important negative factor as compared with conventional surgery is the radiation that patients are exposed to during the procedure. Radiation exposure is known to cause cancer and can also lead to acute skin injury [6,7]. The patients subjected to aortic stent-grafting are, in general, in the higher age range, which means that risk of cancer is not the greatest concern, considering the usual latency time of 10–20 years after exposure [2]. Instead, the major radiation risk is acute skin injury, which is dealt with in the ICRP (International Commission on Radiological Protection) report 85 [8]. This type of skin injury is usually apparent a few weeks after a procedure when the dose exceeds approximately 2 Gy [2,9]. For this reason it is important to estimate radiation doses that patients receive during certain procedures and to ensure that the dose is within the range deemed to be safe.

In interventional radiology, the dose-area product (DAP) and air kerma (AK) are the main factors related to potential risk of radiation. DAP (in milligray per square centimeter [Gy cm^2]) is defined as the absorbed dose to air averaged over the area of the X-ray beam in a plane perpendicular to the beam axis, multiplied by the area of the beam in the same plane. The DAP is measured by placing an ionization chamber just beyond the X-ray collimators, and is an overall measurement of the total radiation energy delivered to the patient. The DAP measurements have been proven to correlate reasonably well with the effective radiation dose, and therefore reflect the probability of stochastic effects [10]. Air kerma is the same as the absorbed dose delivered to the volume of air in the absence of scatter (Gy). Absorbed dose can be defined by the ratio E/m, where E is the energy absorbed by the medium due to a beam of ionizing radiation being directed at a small mass, m. With X-ray examinations, the absorbed dose is the same as the equivalent dose (Gy).

Only a few publications have reflected this aspect of X-ray radiation to patients undergoing abdominal stent-graft implantation [2,11]. To our knowledge, no reports on stent-graft implantation have explored the relationship between radiation doses and clinical factors such as angulations of aneurysm neck, length of aneurysm neck and occurrence of tortuosity of iliac arteries. Only 1 study (besides our study) considered the influence of body mass index (BMI) [12].

Table 1. Risk factors and concomitant medical conditions of 92 patients treated with EVAR.

	Yes		No	
Smoking of the cigarette	66	(72%)	26	(28%)
Cerebral stroke	5	(5%)	87	(95%)
Chronic obstructive lung disease	6	(6%)	86	(94%)
Chronic renal disease	10	(11%)	82	(89%)
MI	5	(5%)	87	(95%)
CHD	53	(58%)	39	(42%)
DM	7	(8%)	85	(92%)
Arterial hypertension	52	(57%)	40	(43%)

Therefore, the main purpose of the present study was to document the radiation doses during abdominal aortic stent-graft implantation and to discuss potential reasons for prolongation of the radiological parts of this procedure.

MATERIAL AND METHODS

Doses of digital subtraction angiography (DSA) and fluoroscopy during EVAR were controlled and analyzed retrospectively from 92 patients (11 females and 81 males) aged from 40 to 91 years (mean 72±9), treated between January 2004 and December 2008. Risk factors and concomitant medical conditions of the 92 patients treated with EVAR are listed in Table 1.

All procedures were jointly performed by 1 vascular surgeon and 1 interventional operator. None of the patients died during the procedure. Patients who exceeded the dose of 1Gy were observed for 6 months with monthly visits and patients who exceeded the dose of 3 Gy were observed with monthly visits for 1 year including consultations by the dermatologist.

Abdominal aortic aneurysms (AAA) were excluded by stent-grafts (Cook Inc. USA; Terumo Corp., Tokyo, Japan). The implantation of each abdominal stent-graft was performed via a bifemoral approach with suprarenal fixation in the standard way. The implantations were performed under general or epidural anaesthesia.

In this study, necks measuring 8–15 mm were considered short, and those measuring more than 15 mm were categorized as long. Neck angle, defined by the angle formed between the flow axes of the neck and body of the aneurysm, should not measure more than 60°. Three groups of neck angles according to the difficulty in proper positioning of the proximal part of stent-grafts (<30°, 30–44° and 45–60°) have been established and these were used in the present study [13,14]. Moreover, according to the level of difficulty in deployment of distal parts of stent-grafts, patients were divided into 2 groups: 1 having iliac arteries bent less than 45° and the other with curvatures of 45° or more (Figure 1). Patients were also divided into 3 groups with regards to BMI. The body mass index (BMI) (weight [kg]/height squared [cm]) was obtained for each patient to analyze radiation dose variations relative to body size. The BMIs are characterized

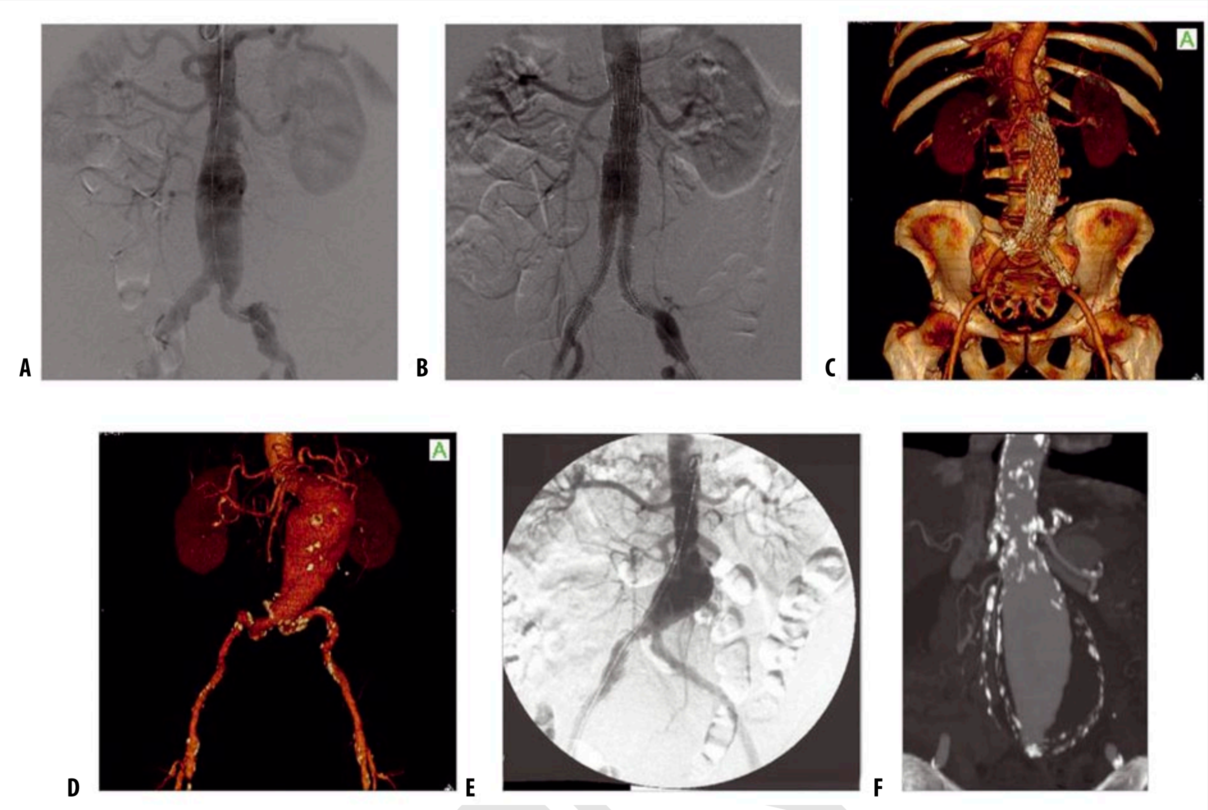

Figure 1. Digital subtraction angiography (**A**) before and (**B**) after abdominal stent-graft implantation, (**C**) 3D computer tomography images of implanted stent-graft, (**D**) tortuosity of iliac arteries over 45°, (**E**) tortuosity of iliac arteries less than 45° and (**F**) long and short aneurysm necks.

with values in the range of <18.5 to >30 and can be divided into 4 categories: underweight (<18.5), normal weight (18.5–24.9), overweight (25–29.9), and obese (≥30). None of the analyzed patients were underweight.

All clinical procedures were performed in an operating C-arm unit (Allura, Philips Medical Systems, Best, The Netherlands). Available image intensifier field sizes were 17 cm, 23 cm and 31 cm. The patients were placed on an operating table with a floating table-top. In the C-arm unit, dose data were calculated from exposure values and expressed as dose-area product DAP (Gy cm^2) and air kerma AK (Gy) together with the total time of fluoroscopy (real-time images: coater introduction procedure, min) and radiography (X-ray images taken during the injection of contrast medium, ms). The DAP received by the patient was recorded for each procedure using a PTW Diamentor Kerma Xplus1020-132 DAP meter (PTW, Belhofer, Shwarcenberg, Germany). This DAP meter was calibrated to diagnostic X-ray qualities using a Keithley 3504 X-ray monitor with a 10×5.6 ionization chamber IC 300, which had a calibration traceable to the PTB primary standard.

Patients receiving a dose more than 1 Gy were assessed for blood morphology and skin changes at days 3 and 7 and at months 1, 3 and 6 after procedures for exclusion of eventual stochastic and deterministic effects of the radiation.

Statistics

Patient doses were divided and analyzed with the Kruskal-Wallis test (H-test) according to subgroups based on BMI and aneurysm neck angulations, and with the Mann-Whitney U-test for iliac artery tortuosity and aneurysm neck length. A p-value of ≤0.05 was considered significant.

RESULTS

Specific radiation data for EVAR – exact sample size, dose-area product (DAP) values, air kerma and radiation times in general and in the division of patient's body mass index, aneurysm neck angulation, aneurysm neck length and occurrence of tortuosity of iliac arteries – are presented in Table 2. The mean total air kerma value and DAP for the analyzed group of patients were 797 mGy and 626 Gy cm^2, respectively, which are higher than those found by previous studies [2,14]. The possible reasons for the variation of radiation doses, besides the experience of radiologists, are presented in detail in the discussion.

In 39 of the analyzed patients (42.4%) AK was between 1 and 2 Gy, and for 7 patients (7.6%) it exceeded 2 Gy. For the remaining 46 patients (50%) radiation dose was lower than 0.5 Gy. The maximum radiation dose obtained by a patient was 4363 mGy. The mean AK (fluoroscopy) of patients with BMI within the range 25–29.9 and with BMI >30 was significantly increased compared to that of patients with BMI 18-24.9 (H=40.2, df=2; p=0.0000001 and p=0.000003, respectively). This same dependence was found in the case of total AK (H=24.1, df=2; p=0.00005 and p=0.0005). Neck angulations within the range 46-60° produced a slightly raised AK during the coater introduction procedure compared to neck angulations within the range 30–45° and <30° (H=6.8, df=2; p=0.05 and p=0.05,

Table 2. Sample size, dose-area product (DAP) values, air kerma and radiation times in general and in the division of patient body mass index, aneurysm neck angulation, aneurysm neck length and occurrence of iliac artery tortuosity.

		Air kerma (fluoroscopy) [mGy]		Air kerma (radiography) [mGy]		Total air kerma [mGy]		DAP (fluoroscopy) [Gy cm^2]		DAP (radiography) [Gy cm^2]		total DAP [Gy cm^2]		Fluoroscopy time [s]		Radiography time [ms]	
	N° of cases	Mean (median)	Max	Mean (median)	Max	Mean (median)	Max	Mean (median)	Max	Mean (median)	Max	Mean (median)	Max	Mean (median)	Max	Mean (median)	Max
General	92	526 (399)	3214	596 (568)	1910	797 (634)	4363	137 (116)	687	237 (204)	1174	626 (456)	3102	975 (777)	4980	480 (427)	1440
BMI 18–24.9	39	266 (222)	790	512 (472)	1017	372 (172)	1523	80 (68)	279	177 (153)	419	715 (527)	3102	463 (321)	1218	380 (281)	1210
BMI 25–29.9	35	718 (576)	3214	707 (673)	1910	1125 (1063)	4363	186 (144)	687	309 (247)	1174	574 (448)	1760	1320 (1254)	4980	513 (501)	1440
BMI >30	18	712 (688)	1537	564 (498)	1151	1085 (634)	2473	161 (150)	323	230 (212)	486	536 (401)	1740	1414 (1263)	3084	538 (393)	1210
Angulation of aneurysm neck <30°	58	498 (397)	3214	534 (482)	1148	711 (579)	4363	128 (116)	687	211 (162)	1073	574 (435)	3102	931 (765)	4068	445 (376)	1440
Angulation of aneurysm neck 30–45°	22	430 (340)	946	645 (609)	1910	830 (768)	2780	108 (97)	234	245 (193)	1174	671 (386)	2952	871 (819)	1962	476 (483)	880
Angulation of aneurysm neck 46–60°	12	836 (750)	2078	806 (769)	160	1158 (1030)	2564	232 (227)	558	351 (293)	924	796 (638)	1696	1381 (993)	4980	648 (588)	1210
Short aneurysm neck	14	769 (650)	2078	646 (756)	1910	1228 (1227)	2564	174 (146)	366	283 (294)	486	647 (489)	2952	1388 (1173)	4980	639 (529)	1210
Long aneurysm neck	78	482 (366)	3214	587 (556)	1017	720 (580)	4362	130 (100)	687	229 (186)	1174	622 (435)	3102	901 (764)	4068	440 (400)	1440
Tortuosity of iliac arteries over 45%	36	664 (516)	3214	639 (623)	1910	1097 (1080)	4363	170 (132)	687	306 (244)	1174	577 (386)	1760	1271 (1032)	4980	531 (475)	1440
Tortuosity of iliac arteries less than 45%	56	436 (352)	1377	569 (539)	1151	605 (325)	2054	115 (97)	287	194 (176)	479	658 (469)	3102	785 (647)	2976	431 (376)	1022

respectively). A similar relationship was found for DAP (H=9.02, df=2; p=0.016 and p=0.015, respectively). In case of X-ray images taken during the injection of contrast medium (radiography), significant differences for AK and DAP were only found between neck angulations within the range 46-60° and <30° (H= 6.6, df=2; p=0.04 and H= 8.6, df=2, p=0.01, respectively).

Significant differences in total AK and exposure time were observed regarding aneurysm length (U=312, p=0.01; U= 296, p=0.007, respectively). In addition, the presence of iliac artery tortuosities over 45° lead to higher doses regarding total AK (U= 620, p=0.002), which was related to extended time of fluoroscopy (U=687, p=0.01) and radiography (U=735, p=0.03). Patient age and sex were not significant factors for DAP and AK in either fluoroscopy or radiography acquisition (p>0.05).

Correlation analyses were performed to describe relationships between radiation time and dose. For fluoroscopy, the correlation between air kerma (DAP) and radiation time was 0.81 (0.76). The linear regression equations obtained for air kerma and fluoroscopy time showed that a 10 min prolongation of the coater introduction procedure caused an increase in AK by approximately 104 mGy and an increase in DAP – by approximately 29.5 Gy cm^2.

Percentages of the total number of runs with various values of tube voltage and rotation in the division of patient's body mass index, of aneurysm neck angulation, aneurysm neck length and occurrence of tortuosity of iliac arteries are presented in Table 3.

In most cases 0° rotation (81–92.6% of total) and 80/90 kV tube voltage (91.4–97.4% of total) were used.

No cases of deterministic and stochastic effects of acquired radiation were observed in short- (3–7 days) or middle-term (6 months) observations including skin changes and blood morphology changes. The trend toward drop of neutrophiles was noted at day 3 after the procedure, but it was not statistically significant and the problem was spontaneously resolved by the time of the month 1 visit (Figure 2).

Table 3. Percentages of the total number of runs with various values of tube voltage and rotation in the division of patient body mass index, aneurysm neck angulation and aneurysm neck length.

	70 kV	80 kV	85 kV	90 kV	Rotation 0°	Rotation 15°	Rotation 25°	Rotation 40°	Rotation 45°	Rotation 60 °	Rotation 90 °
BMI 18–24.9	2.1	46.8	0.5	50.8	90.9	2.7	1.6	0.0	3.2	0.5	1.1
BMI 25–29.9	0.0	65.6	4.5	29.9	88.1	4.4	4.4	0.0	2.7	0.0	0.4
BMI >30	0.0	60.0	8.8	31.2	92.0	1.6	3.2	0.8	2.4	0.0	0.0
Angulation of aneurysm neck <30°	1.2	55.3	3.0	40.5	88.4	4.1	3.3	0.3	3.0	0.3	0.6
Angulation of aneurysm neck 30–45°	0.0	68.2	3.8	28.0	92.6	0.8	5.0	0.0	0.8	0.0	0.8
Angulation of aneurysm neck 46–60°	0.0	49.4	8.6	42.0	92.6	2.5	0.0	0.0	4.9	0.0	0.0
Short aneurysm neck	0.0	62.1	8.4	29.5	81.0	2	7.0	1.0	8.0	0.0	1.0
Long aneurysm neck	0.9	56.5	3.1	39.5	92.0	3.4	2.3	0.0	1.6	0.2	0.5
Tortuosity of iliac arteries over 45°	0.0	64.1	3.7	32.2	87.2	5.8	2.9	0.4	3.3	0.0	0.4
Tortuosity of iliac arteries less than 45°	1.4	52.0	4.4	42.2	92.2	1.0	3.4	0.0	2.4	0.3	0.7

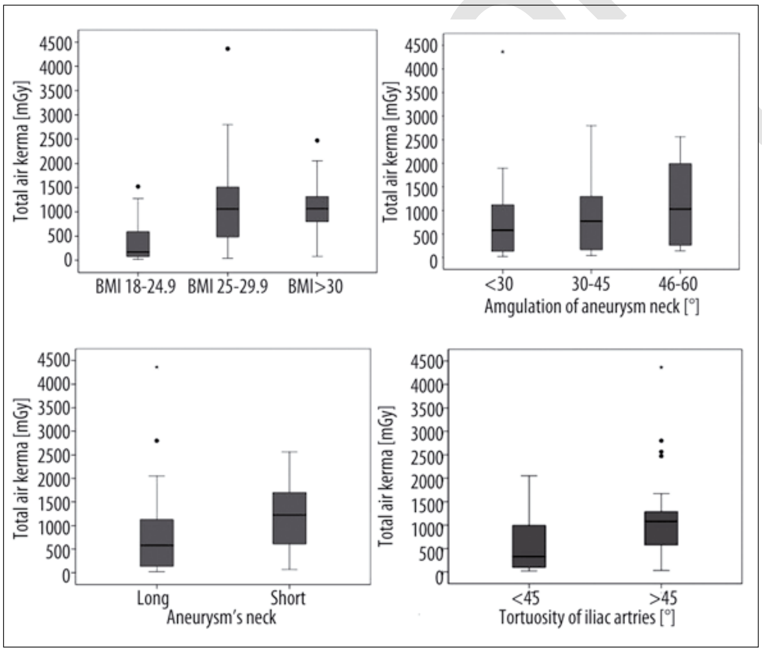

Figure 2. Mean total air kerma values for abdominal aortic aneurysms in the division of patient body mass index, aneurysm neck angulation, aneurysm neck length and occurrence of iliac artery tortuosity (* extreme values, • diverging values).

DISCUSSION

Interventional procedures performed using ionizing radiation have become increasingly prominent tools in the treatment of vascular and cardiac diseases. However, radiologists must take into account the deterministic effects (DE) and stochastic effects (SE) of X-ray radiation for their patients. The threshold for radiation damage to skin (DE) varies from individual to individual, but is generally estimated to be in the range of 2 Gy [15–17]. However, radiation-induced cancer is a stochastic effect of radiation where there is no threshold value. The probability of cancer occurrence increases with dose, but the cancer may occur at any dose [15]. Our data demonstrated that patients undergoing abdominal stent-graft implantation receive a mean radiation dose lower than 1 Gy (759 mGy). It should be noted however that the dose of radiation during stent-graft implantation is not the only dose required. This procedure requires frequent follow-up visits with ionizing imaging, such as computer tomography scans, after endograft placement to be sure that the stent-graft continues to function properly.

Aortic endograft implantation can be disturbed by many factors which, in turn, lead to prolongation of the procedure time and thus an increase in the radiation dose that both the patient and hospital personnel are exposed to. Previous studies have measured patient radiation doses during various endovascular procedures, but measurements of radiation exposure during abdominal stent-graft implantation in regard to aneurysm neck angulation, aneurysm neck length and iliac tortuosity have not previously been documented.

First, angulation of the aneurysm neck determines the difficulty of proper stent-graft placement [15]. Less angulated necks allow a more precise implantation of the main body of the graft. Moreover, different projection angles and repetition of series for DSA are often required in angulations exceeding 45°, contributing to a greater overall dose of radiation.

Secondly, the shorter the aneurysm neck, the more precise positioning of the main body of the graft is required so that the renal artery origins remain uncovered by the endograft [18,19].

Sometimes, when attempting to deploy the contralateral leg of the bifurcated endograft, there are difficulties when entering the main body of the graft via the contralateral stump This problem can be managed by using different catheters and guide wires, at the same time increasing fluoroscopy duration or providing additional access via the brachial artery and using a lasso technique to catch the guide wire.

Moreover, the difficult anatomy of the iliac arteries can severely hamper the procedure. Tortuosity of iliac arteries often prevents the main body of the graft from passing through the iliac system with ease. For this reason, several patients required pressure to be applied to their abdomens, thus straightening the iliac arteries and decreasing the friction between the main body of the graft and the wall of the artery.

If after endograft deployment and during control DSA series an endoleak into the sac of the aneurysm is detected, it is necessary to use a low pressure balloon catheter to expand the stent-graft wall so that it adheres better to the wall of the aorta. The angioplasty may increase the procedure time and usually requires additional control DSA series. However, this condition did not influence the total dose in the present study.

A BMI exceeding 25 is an independent risk factor contributing to higher radiation dose acquisition. Obese patients with a BMI >30 are particularly at risk of a high radiation dose (mean AK >1 Gy). This is consistent with results obtained by Weiss et al. [26]. It has been shown (for a small group of patients) that the mean peak skin radiation dose of obese patients (BMI >30) was significantly increased compared to that of non-obese patients (1.1 *vs.* 0.5 Gy). In obese patients the X-ray beam penetrates through more tissue to reach the image detector. Therefore, high radiation exposure should always be considered when planning endovascular procedures on obese patients. Attempts to reduce the X-ray dose with the use of collimators, pulsed fluoroscopy and minimized fluoroscopy time should always be made [12].

In our study, all of the patients who received a radiation dose exceeding 2 Gy had a BMI above 30. In addition to a higher BMI, greater aneurysm neck angulations were found in patients who received radiation doses exceeding 2 Gy. Such anatomical features should probably be taken into consideration, favoring open repair in young obese patients with AAA to avoid eventual stochastic effects of the radiation. In general, a proper anatomical preoperative classification allows reduction of the risk related to high radiation exposure.

It should also be noted that in the case of breathing movements (not considered as an independent value in this study), repetition of the DSA control series may be a common reason for increasing the patient's exposure to radiation and the dose of administered contrast media. The breathing movement can be suppressed by temporarily disconnecting a patient from the respirator or asking them to hold their breath if they are not under general anaesthesia and able to cooperate.

In many cases, EVAR is performed in patients with an elevated risk of significant comorbidities with open surgical repair (OSR). Even with a difficult anatomy, the risk of symptomatic radiation overdose in such patients is much lower than the risk of denying treatment or OSR.

CONCLUSIONS

This study supports the conclusion that the main factors contributing to a high radiation dose being acquired by patients during EVAR are: BMI >25, tortuosity of iliac arteries >45° and short aneurysm neck. The patient, who must make a conscious decision about the surgery (and sign the informed consent), should be informed about possible complications that can lead to receiving a high dose of radiation.

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