Risk of deterministic effects during endovascular aortic stent graft implantation

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ABSTRACT. Since the 1990s, stent graft implantation for aortic pathology has become an alternative to extensive surgical procedures in some patients. Indeed, many patients with such pathology are now treated endovascularly. Only limited data concerning the risk of a deterministic effect during aortic stent graft implantation are available. Accordingly, 179 consecutive patients treated in our institute between October 2002 and July 2008 with endovascular aortic stent grafts were included in this study. Dosimetric data (kerma area product (KAP) and cumulative dose at the interventional reference point (CD_{irp})) from radiograph reports were analysed for 172 patients. On a group of 19 patients, GAFCHROMIC XR type dosimetric films were also used to verify the automatic measurements. Readings from the integrated KAP meter were found to be too high and were therefore corrected — KAP to dose area product (DAP) and CD_{irp} to entrance skin dose (ESD). Median DAP was 153 Gy cm² (35–700 Gy cm²) and median ESD was 0.44 Gy (0.12–2.73 Gy). Recorded dosimetric quantities were found to be good predictors of the skin dose and highlighted 4 patients (2.3%) who received skin doses that might cause possible deterministic effects. Endovascular stent graft implantation is less invasive than a surgical procedure and is widely used; mid-term results are encouraging. In a small number of patients, deterministic effects can occur even in departments with well-trained staff. Operators should inform the patients of possible skin injury after receiving high doses of ionising radiation and proper support must be available should that occur.

Received 25 May 2009
Revised 12 November 2009
Accepted 8 December 2009

DOI: 10.1259/bjr/64623458

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Radiology

Endovascular procedures are increasingly indicated with new developments in medicine. Although minimally invasive and less traumatic than classic treatment procedures, especially surgery, such procedures are mostly planned and performed under radiographic guidance. In most procedures, exposure of the patient and staff to ionising radiation is low, although in some procedures the dose can reach deterministic levels [1–8]. The highest doses are encountered in cardiac interventional procedures and in some general interventional procedures (e.g. transjugular intrahepatic portosystemic shunt (TIPS), endovascular therapy in cerebral vessels and some abdominal endovascular procedures). In some cases, deterministic effects such as skin erythema, epilation or even skin necrosis occur [1–6, 9,10]. Some pre-existing health factors may be associated with an increased risk of radiation-induced complications; these include ataxia telangiectasia, connective tissue disease, diabetes mellitus and treatment with chemotherapeutic agents [5, 6].

The first successful attempts to exclude aortic aneurysm endovascularly were recorded in the 1980s. Stent

grafts for the treatment of pathology in the infrarenal abdominal aorta began in 1991, and subsequently similar treatments for the descending thoracic aorta became widely used [11]. Such stent grafts are planned mostly by CT and guided by fluoroscopy and digital subtraction angiography (DSA). After stent graft implantation, follow-up with ultrasound, CT and/or MRI is necessary for the long-term evaluation of treatment success.

Many patients, especially elderly patients, are poor candidates for surgery because of frequent co-morbidities and are therefore candidates for endovascular treatment. Constant technical improvements in the devices and techniques used in endovascular stent grafting make this method ideal for such patients. The initial results have been encouraging, and so many patients (even surgical candidates) prefer angiographic intervention to surgery and more and more patients are being treated endovascularly. Endovascular treatment offers a less extensive procedure and fewer complications, resulting in shorter recovery times [12–14].

The increasing number of endovascular procedures that are being carried out means that more patients with unfavourable anatomical conditions are also being treated. Additional procedures such as percutaneous transluminal angioplasty (PTA), stenting of the pelvic, subclavian or renal arteries, and/or embolisation of

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arteries originating in the aneurysm are sometimes necessary. Such complications prolong the procedure. Good image quality is mandatory for precise deployment of stent grafts, and hence fluoroscopy time can be lengthy, sometimes exceeding an hour or more. The irradiated area is relatively constant and the abdominal and/or pelvic area is included in the radiation field; high-dose fluoroscopy is necessary for good image contrast in these areas. For these reasons, deterministic effects can appear in some patients.

The aim of this study was to establish the patient exposure to ionising radiation during endovascular aortic stent graft implantation. The possibility of deterministic effects was estimated, and we suggest how it might be possible to reduce the potential for skin injuries during these procedures.

Methods and materials

Between October 2002 and July 2008, 179 patients (29 women and 150 men, aged 30–89 years, mean age 71 years) had an endovascular implantation of a stent graft for treatment of aortic pathology in our department. The majority of patients (152 patients, 85%) had a stent graft implanted to treat an abdominal aortic pathology. In 20 patients (11.1%), the thoracic aorta was involved. In 4 patients (2.2%), procedures were combined and in 3 (1.7%), aneurysms in the iliac area were excluded with bifurcated stent grafts. Five procedures were performed because of aortic rupture: the others were elective.

All procedures were performed by experienced interventional radiologists; patients were under the supervision of an anaesthetist. Pulsed fluoroscopy was used on all patients, the pulse frequency varying depending on the complexity of the procedure. The most common settings were 7.5 images s^{-1} in fluoroscopy mode and 3 frames s^{-1} in cine mode. Collimation of the X-ray beam was adjusted to the size of the region of interest for each patient, and magnification was set as low as possible to allow good visibility in each step of the procedure. During attachment of the contralateral leg to the trunk of the stent graft in particular, the first or second level of magnification was used.

Patient dosimetry

All procedures were performed using a Siemens Multistar (Siemens; Erlangen, Germany) X-ray angiographic system, which has an integrated ionisation chamber for the measurement of the kerma area product (KAP) and cumulative dose at the interventional reference point (CD_{irp}) [15]. The X-ray system automatically records both of these dosimetric parameters and the fluoroscopy time. As our study began at the beginning of 2007, the data from 113 patients (63%) were collected retrospectively (for treatments carried out from 2002 until the end of 2006), whereas data were collected prospectively from the beginning of 2007 (66 patients; 37%). In 7 patients (3.7%), the retrospective data were incomplete and excluded from the study.

At the beginning (January 2007) and at the end of the project, dosimetric calibration of the X-ray unit was

performed using a calibrated electrometer (Unidos E, PTW; Freiburg, Germany) within the ionisation chamber (TW 77337, PTW; Freiburg, Germany) and with an external KAP meter (DIAMENTOR KDK, PTW; Freiburg, Germany).

The readings from the integrated KAP meter were found to be too high and were therefore corrected by a calibration factor of 0.71. This calibration factor was determined with the bed and mattress in the beam, as had been the case during the procedures in this study. The calibration factor determined at the beginning of the study was consistent with the value found at the end of the project, indicating that the X-ray system was stable.

The other recorded dosimetric quantity was the CD_{irp} . Procedures are almost exclusively performed in postero-anterior projection (X-ray tube under the table with a useful beam directed vertically), with only a few procedures requiring other projections. Procedures were performed by eight different radiologists, who used slightly different table heights. Radiation dose at the skin level differs with table height, although the CD_{irp} recorded does not change. To account for this, the usual table height was recorded. The patient table was usually about 1 m from the floor and the focal spot of the X-ray machine (in posteroanterior projection) 26 cm above the floor. The procedures were simulated using a 20 cm water phantom and $15 \times 15 \text{ cm}^2$ field size (which is close to the usual field size on the patient surface) in order to measure skin dose at this table position, and these data were compared with the recorded CD_{irp} . Recorded CD_{irp} was found to be almost twice (1.87 times) the real entrance skin dose (ESD). The overestimations of both recorded quantities (KAP and CD_{irp}) were taken into account in the results.

In addition, 19 direct skin dose measurements were made using GAFCHROMIC XR type films (International Speciality Products Technologies Inc.; Wayne, NJ) were performed at the conclusion of the study. Films were laid on the patient table so that, in the posteroanterior projection, they were practically in contact with patient's skin. The films were calibrated on the same X-ray unit in radiographic mode using 73 kVp and doses from 1 Gy to 4.5 Gy. There was no backscatter because the films were laid on the exit window of the X-ray tube.

All patients who received doses above the threshold of deterministic effects ($>2 \text{ Gy}$) during the procedures were contacted in January 2009, 12–40 months (mean 32 months) after treatment, to enquire about skin changes.

Results

Stent grafts were successfully implanted at the first attempt in 175 patients (primary success rate 97.8%). A further three patients had a stent graft successfully implanted at the second attempt after changing the model of the stent graft (secondary success rate 99.4%). One periprocedural death occurred after a combined radiological-surgical procedure.

In 62 patients (34.6%), additional procedures were performed during stent graft implantation; these were considered to be complex cases. Dilatation of the pelvic

arteries was the most common procedure, performed in 18 patients (10%). Embolisation of the pelvic arteries was performed in 16 patients (8.9%); in 5 of these (2.8% of all patients) embolisation was followed by stent graft extension in the pelvic arteries. There was a need for distal extension in 10 patients (5.6%), whereas proximal leakage was excluded in 3 patients (1.7%) by proximal extension. In one such patient, proximal extension covered the ostium of the right renal artery; a renal stent was deployed and the patency of the renal artery was successfully restored. In another 8 patients (4.5%), percutaneous transluminal renal artery angioplasty (PTRA) was necessary because of atherosclerotic stenosis in the area. Retrograde leakage into an aneurysm was prevented by embolisation of aortic branches (inferior mesenteric artery, accessory renal arteries, lumbar arteries or internal iliac arteries) in 9 patients (5%). In two patients, stents were implanted into the left subclavian artery to restore patency after covering the ostium with a thoracic stent graft. During these procedures, two limbs of the stent graft were thrombosed and manual aspiration was necessary to restore patency. 11 patients (6.1%) needed more than one additional procedure (PTRA and PTA of iliac arteries, PTA of iliac arteries and proximal stent graft extension, etc.).

Data recorded by the X-ray machine (KAP and CD_{irp}) were converted to patient exposure data (dose area product (DAP) and ESD) using correction factors estimated from the dosimetric measurements. DAP was calculated from machine-reported KAP with a correction factor of 0.71. ESD was calculated from reported CD_{irp} with a correction factor of 0.53.

The median DAP was 153 Gy cm^2 (35–700 Gy cm^2 , third quartile 219 Gy cm^2) and the median ESD was 0.44 Gy (0.12–2.73 Gy, third quartile 0.66 Gy). Only a small difference in the median values of DAP was found when thoracic (132 Gy cm^2) and abdominal (154 Gy cm^2) procedures were compared, although the maximum value for thoracic procedures (416 Gy cm^2) was much lower than that for abdominal procedures (700 Gy cm^2).

DAP and ESD are reasonably well correlated ($r^2=0.83$) because field size throughout the whole procedure is fairly constant. The correlation between DAP and ESD is shown in Figure 1.

ESD values greater than 2 Gy (2.5–2.7 Gy) estimated from CD_{irp} were noted in 4 patients (2.3%), all of whom underwent complex procedures. In the first patient, PTA

of iliac arteries was performed and an artificial patch was necessary to close the puncture site. In another patient, the accessory renal artery was embolised and distal extension was necessary. Proximal stent graft extension covered the ostium of the renal artery and a renal stent was deployed to restore patency in the third patient. The fourth patient to receive a high radiation dose had been refused surgery owing to obesity. During bifurcated infrarenal stent graft implantation for exclusion of aneurysms of iliac arteries, the stump of the contralateral limb (the part of the stent graft necessary for contralateral limb attachment) deployed into the ipsilateral iliac artery. Prolonged fluoroscopy was necessary for repositioning, resulting in the high registered dose. The scanned GAFCHROMIC XR type film from this patient is shown in Figure 2.

All four patients with estimated skin doses above 2 Gy were contacted in January 2009. One patient had died 14 months after stent graft implantation of an unrelated cause. The remaining three responded to a questionnaire, in which none of them reported any skin, or other, changes after the procedure.

Median recorded fluoroscopy time was 17 min (2.9–97.8 min, mean 21 min, third quartile 27 min) and was typically somewhat shorter for tubular stent graft implantation (thoracic aorta) than for abdominal procedures. The longest duration for the procedure was recorded for a patient who required reopening of the right renal artery with a stent after covering it with a proximal stent graft extension. The dependence of DAP on fluoroscopy time is illustrated in Figure 3; there is some correlation between the two ($r^2=0.37$) but the spread is very large.

Analysis of the GAFCHROMIC XR type films showed that the peak skin doses were below 1 Gy in 17 of the 19 films. Skin doses were close to or above 2 Gy (1.7–2.7 Gy) in just 2 cases. When the peak skin doses estimated from GAFCHROMIC XR type films were compared with recorded CD_{irp} , the recorded CD_{irp} were found to be overestimated by a factor of 1.4 to 2.

Discussion

To our knowledge, only limited data about the radiation dose burden of patients during aortic stent graft implantation have been published to date [16–18].

Figure 1. Correlation between dose area product (DAP) and entrance skin dose (ESD). Outliers were analysed and found to represent cases in which the procedure differed from the norm (e.g. heavy patients, unforeseen complications, etc.).

Figure 2. GAFCHROMIC XL type film of a patient with an estimated peak skin dose of 2.7 Gy.

There are considerable differences in the threshold levels of deterministic effects between studies published by oncologists and radiologists, the levels reported in the oncology literature being higher [1, 9, 19]. In evaluating the results of the present series, we make reference to other radiological series in which the case mix was similar. In the present series, all procedures were performed by interventional radiologists in co-operation with nurses and radiographers, all of whom had an extensive experience in interventional procedures. Threshold levels (2 Gy) that could result in possible deterministic effects were reached in just 2.3% of our patients. Similar doses for interventional procedures have been described in the literature [1–9]. Skin doses above the threshold level could cause transient erythema within a few hours after the procedure, matching the shape of the entrance X-ray beam. This reaction subsides after approximately 48 h. There is also a second hyperaemic phase, beginning 10 days after a dose of about 6 Gy [9] and reaching a peak at 14 days. Temporary epilation can be noted 3 weeks after procedures, in which a single dose exceeds 3–6 Gy. Permanent epilation is a feature in patients receiving doses above 7 Gy [9].

The irradiated part of the body in our series was relatively constant. It included mostly the central part of the thorax during the implantation of a thoracic stent graft and the lower abdomen during the implantation of abdominal aortic stent grafts. For abdominal aortic stent graft implantation in particular, considerable doses of radiation may be necessary for acceptable visibility. Threshold levels were recorded in a small number of patients with aneurysms in the abdominal area but not in those treated for pathology in the thorax. When the bifurcated stent graft (abdominal aorta) is implanted in addition to the trunk of the stent graft (thoracic aorta), the contralateral limb of the stent graft has to be implanted, resulting in longer fluoroscopy times.

Upon contacting patients who may have received possible deterministic effects, none reported any effects consistent with changes induced by radiation. The number of patients was small (three out of the four patients who experienced threshold levels) and the questionnaires were sent a long time after the procedures. The changes that might have been expected at the dose levels experienced would have been mild and localised on the lower back of the abdomen, and thus might have gone unnoticed by the patients. The dose levels for the induction of skin injuries reported in the radiological literature are probably too low: in two recent studies, no skin injuries were found after exposure of patients to similar doses [20, 21].

The endovascular procedure was of considerable duration in certain patients — up to 97.8 min. The median value (17 min) for time of procedure is, however, comparable to that in other studies [16–18]. As in some other studies [17, 22–24], we found a weak correlation ($r^2=0.37$) between DAP and fluoroscopy time. In some older angiographic units, fluoroscopy time remains the only parameter available for estimating X-ray exposure.

Implantation of stent grafts is increasingly indicated. A new consensus about endovascular therapy is emerging with a trend towards endovascular treatment. It is used not only for pathology of descending thoracic and infrarenal aorta, but also in complicated dissection of the thoracic aorta [25–27], penetrating aortic ulcers and intramural haematomas [28], and iliac artery aneurysms [29]. With the introduction of branched stent grafts [30], it is possible to treat even more patients endovascularly.

As the procedure becomes more complex, however, the X-ray exposure during the treatment is likely to rise. The number of procedures performed in younger

Figure 3. Correlation between dose area product (DAP) and fluoroscopy time (FT).

patients may increase in future, and so the possible induction of stochastic effects should not be forgotten in addition to concerns over possible skin injuries.

There is a strong trend towards the use of endovascular procedures by physicians in medical specialties other than radiology, mostly cardiologists and vascular surgeons, often without proper training in radiation protection. Hence, as reported by Weerakkody et al [18], doses in other centres may exceed those recorded in our study.

The DAP values for our patients were on average much larger than those reported by Geijer et al [16], but very similar to those reported by Weiss et al [17] and by Weerakkody et al [18]. The dosimetric parameters from our study and from three studies reported in the literature are compared in Table 1. Fluoroscopy time is also comparable for all four studies, whereas somewhat larger differences are observed in estimated skin doses. In the study by Geiger et al [16], the procedures were performed using a mobile C-arm X-ray machine, but, interestingly, these authors also reported that simulated DAP values would be calculated for case procedures using a dedicated angiographic X-ray machine. Our DAP values were much lower than these simulated DAP values. It is our belief that good image quality is mandatory for precise stent graft implantation, and so a dedicated angiographic unit should be used in most cases. Optimisation of the procedure results in acceptable DAP values that are lower than those simulated by Geijer et al [16].

Two warning levels for approaching the threshold for skin injury were derived from our study. The DAP warning level was set at 500 Gy cm² (see Figure 1). As we have no ability to calibrate the integrated KAP meter on our X-ray unit, the practical trigger level for this X-ray unit was set to a KAP of 700 Gy cm², taking into account the calibration factor of 0.71. Similarly, the practical trigger level for CD_{irp} was set at 4 Gy because on our unit this parameter overestimates the ESD by factor of roughly 2. This overestimation is because the skin entry point in this procedure is further away from the X-ray focal spot than the interventional reference point. Overestimation in the range 1.4–2 was confirmed using GAFCHROMIC XR type dosimetric films. Such a wide range can be assigned partly to the variation in table heights used by different radiologists and partly to uncertainties in the dose measurement using films.

It should be noted that the set trigger levels are only applicable locally. Different types of procedures with different techniques undertaken on other X-ray units would probably result in different values for trigger levels.

In order to find, and properly treat, potential radiation damage we informed all patients, whose treatment had

exceeded the trigger levels, about the possible skin changes in the few months after treatment. Anyone suffering any skin changes (including epilation) in the irradiated area should be advised to contact their operator. The patient should then be referred with the description of the procedure to his or her GP or to a dermatologist for the clinical follow-up. To reduce eventual additional damage, follow-up and further therapy in these patients should be performed with minimal use of X-ray equipment; MRI and ultrasound should be used as much as possible. After additional procedures, those patients should be monitored closely for eventual post-irradiation skin changes.

Conclusion

There is emerging concern about the irradiation burden during aortic stent graft implantation because this procedure can require prolonged manipulation under fluoroscopic control. The procedure is performed by a number of physicians, often non-radiologists, some reporting high skin doses.

In our study, which included 172 patients, we found only a small risk (in less than 3% of patients) that patient skin dose received during the procedure is large enough to produce skin injury. As the irradiated part of the body is fairly constant throughout the procedure, dosimetric quantities recorded by the X-ray system were used to set a warning level above which skin injury is possible.

It is our belief that procedures that are associated with higher possible patient doses should be identified. Detailed analysis of local practises for each type of procedure should be performed, including physical measurements on phantoms, so that the correlation between the doses reported by the X-ray systems and skin doses can be estimated. Warning levels of the reported quantities can then be established. If these levels are exceeded, the patient should be informed about potential skin injuries so that proper action can be taken if they appear.

Follow-up of patients with high dose levels should be introduced and special attention paid to radiation protection in any further procedures so that deterministic and stochastic effects can be minimised.

Special attention to radiation protection should be included in the training of all physicians who perform these types of procedure.

Acknowledgments

The project was partially supported by technical cooperation project RER/9093 of the International Atomic Energy Agency.

Table 1. Comparison of dosimetric quantities reported by other authors [16–18] with our results

Reference	Dose area product median (range) (Gy/cm ²)	Entrance skin dose median (range) (Gy)	Fluoroscopy time median (range) (min)
Geijer et al [16]	60.1 (16.6–195)	0.33 (0.09–1.1)	21.4 (7.4–78.9)
Weiss et al [17] ^a	151.7 (52.1–245)	0.75 (0.27–1.25)	20.6 (12.6–34.2)
Weerakkody et al [18] ^b	150 (90–659)	0.85 (0.51–3.74)	21 (16–31)
Our study	153 (35–700)	0.44 (0.12–2.73)	17 (2.9–97.8)

^a Mean values.

^b Interquartile range.

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