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Operator-controlled Imaging Significantly Reduces Radiation Exposure during EVAR

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WHAT THIS PAPER ADDS

- This study presents data from a contemporary series of patients undergoing EVAR and demonstrates that changing to operator-controlled imaging is a useful and achievable method of improving safety and efficiency during EVAR.

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ABSTRACT

Introduction: Adoption of endovascular aneurysm repair (EVAR) has led to significant reductions in the short-term morbidity and mortality associated with abdominal aortic aneurysm (AAA) repair. However, EVAR may expose both patient and interventionalist to potentially harmful levels of radiation, particularly as more complex procedures are undertaken. The aim of this study was to assess whether changing from radiographer-controlled imaging to a system of operator-controlled imaging (OCI) would influence radiation exposure, screening time or contrast dose during EVAR.

Method: Retrospective analysis identified patients that had undergone elective EVAR for infra-renal AAA before or after the change to operator-controlled imaging. Data were collected for radiation dose (measured as dose area product; DAP), screening time, total delivered contrast volume and operative duration. Data were also collected for maximum aneurysm diameter, patient age, gender and body mass index.

Results: 122 patients underwent EVAR for infra-renal AAA at a single centre between January 2011 and December 2011. 57 of these were prior to installation of OCI and 65 after installation. Median DAP was significantly lower after installation of OCI (4.9 mGy m^2; range 1.25–13.3) than it had been before installation (6.9 mGy m^2; range 1.91–95.0) ($p = 0.005$). Median screening times before and after installation of OCI were 20.0 min and 16.2 min respectively ($p = 0.027$) and median contrast volumes before and after the change to OCI were 100 ml and 90 ml respectively ($p = 0.21$).

Conclusion: Introduction of operator-controlled imaging can significantly reduce radiation exposure during EVAR, with particular reduction in the number of 'higher-dose' cases.

Introduction

Over the past two decades, endovascular repair (EVAR) has become widely accepted as a safe and effective alternative to open repair (OR) for the treatment of abdominal aortic aneurysms (AAA). Whilst this technique has brought with it significant reductions in short-term morbidity and mortality, it has also led to concerns about the degree to which both patient and interventionalist (i.e. surgeon or interventional radiologist) are exposed to radiation during treatment and follow-up. Efforts to reduce the postoperative radiation burden have seen a progressive shift towards duplex ultrasound for graft surveillance rather than repeated computed tomography (CT).[1] As a result, concerns about the amount of radiation delivered to patients are increasingly focused on intra-operative exposure. This is particularly relevant as operators become more skilled and are undertaking increasingly complex procedures that necessitate prolonged fluoroscopic imaging.

The potential significance of radiation exposure is well recognized in other radiographic procedures[2] and effects can be classified as either deterministic (causing direct tissue damage) or

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stochastic (inducing gene mutation). It has previously been suggested that radiation exposure may reach a level that is theoretically sufficient to cause deterministic effects in up to 30% of EVAR cases.[3,4] However, whilst deterministic effects have often been reported during coronary angiography,[5] reports of direct radiation damage during EVAR are scarce.[6,7] This may be due to a paucity of radiation data relating to EVAR, the result of the frequent change in focal point during this procedure, or more likely, the non-reporting of patient radiation injuries.

While a number of authors have assessed the level of radiation exposure during EVAR,[3,8,9] few have explicitly examined ways in which this exposure might be reduced. This study used a planned change in theatre configuration to assess whether changing to a system of operator-controlled imaging (OCI) would influence radiation exposure, operative duration, screening time, or contrast dose during EVAR.

Methods

Data were collected retrospectively for consecutive patients that underwent elective EVAR for infra-renal AAA at a single centre between January 2011 and December 2011. This time period was chosen to provide data from patients both before and after conversion to OCI, which occurred on 29th June 2011. Patients who underwent more complex forms of endografting, such as thoracic, fenestrated, or iliac-branch grafts were excluded, as were patients who underwent insertion of aortouniiliac endografts (AUI), in order to minimize morphological heterogeneity. Patients who underwent EVAR solely for the treatment of iliac artery aneurysm were also excluded, whilst those with both AAA *and* iliac aneurysm were included, since variations in iliac size are common and were not considered likely to significantly confound the data.

The variables of primary interest were: Intraoperative radiation dose expressed as dose area product (DAP in mGy m^2); delivered contrast medium volume (ml); overall screening time and operative duration. Data were also collected for the individual operators, maximum aneurysm diameter and patient age, gender and body mass index (BMI). All data were gathered from theatre logbooks, Picture Archiving and Communication System (PACS), patient case-notes and Electronic Patient Records (EPR).

All procedures were performed in a single operating theatre by a consultant vascular interventionalist experienced in EVAR or a final-year trainee under consultant supervision. Prior to June 29th 2011, procedural imaging was performed using an OEC 9800 Mobile C-arm (GE Medical Systems, Utah, USA), with a standard, static, radiolucent theatre table. For procedures after 29th June 2011, imaging was carried out using an OEC 9900 MD Elite (Vascular) Mobile C-arm (GE Medical Systems, Utah, USA), with a Stille ImagiQ cardiovascular table (Stille-Sonesta Inc., Texas, USA) and multiple video output screens on a NuBoom articulating support (GE Medical Systems, Utah, USA). The new imaging system is operated via a sterile, tableside control panel that gives the interventionalist precise, fully motorized control of the C-arm, patient position and imaging mode. Though image acquisition is the same resolution on old and new systems, high definition video output screens also offer improved anatomical visualization.

Low-dose fluoroscopy and high-dose 'digital acquisition' were performed using pulse-beam fluoroscopy at 12 frames per second. The method of delivering contrast media was unchanged throughout the study period and was via a Medrad Mark V Plus angiographic injector (Medrad UK Ltd., Ely, UK).

DAP was recorded by transmission ionization chambers integral to both old and new C-arms. These were calibrated according to manufacturers instructions. Screening time was also recorded automatically by the software in both old and new C-arms. The time recorded was a combined total for low-dose fluoroscopy and high-dose digital-acquisition. Contrast medium volume was documented as the total volume delivered throughout the procedure.

All patients underwent preoperative CT-scanning to assess aneurysm morphology and cases were planned using 3mensio Vascular™ software (3mensio Medical Imaging BV, Bilthoven, Netherlands). Other than the change to OCI, there was no change in operative protocol during the study period, nor any additional training with regard to radiation safety (that might have influenced the dose delivered by the operator).

Results

122 patients underwent elective EVAR for infra-renal AAA between 4th January 2011 and 17th December 2011. Of these, 57 patients had their intervention prior to installation of OCI and 65 patients underwent EVAR after installation of OCI. Mean values for age, BMI, and maximum aneurysm diameter were not significantly different before and after the change in theatre configuration. The male/female ratio was also unchanged (Table 1).

Median DAP values before and after change in theatre configuration were 6.9 mGy m^2 and 4.9 mGy m^2 respectively, representing a 29% reduction in median emitted radiation dose ($p = 0.005$). Notably, the range of values was far greater prior to the introduction of OCI, with DAP values exceeding 23.5 mGy cm^2 in 9 of 57 cases. After introduction of the new system, the highest recorded DAP was 13.3 mGy m^2 (Table 2).

Median total screening time was also significantly lower after installation of OCI (16.2 min) than before installation (20.0 min) ($p = 0.027$), though there was no significant correlation between total screening time and DAP ($r = 0.13$). Operative duration was also reduced following the change to OCI (130 min before; 120 min after), as was contrast dose (100 ml before; 90 ml after), but both of these were non-significant ($p = 0.28$ and $p = 0.21$ respectively) (Table 2).

Consultant interventionalists performed the majority of cases both before (65%) and after (62%) installation of OCI.

Zenith® endografts (Cook Medical Inc., Bloomington, USA) were the most frequently used device both before ($n = 40$) and after ($n = 49$) the change to OCI. All remaining cases were performed using Endurant™ devices (Medtronic, Minneapolis, USA).

Discussion

Exposure to radiation is an undesirable yet inevitable consequence of all fluoroscopic procedures, particularly those that involve complex endovascular intervention. Although other authors have attempted to quantify the level of radiation exposure during EVAR[3,8,9] little work has been done to assess whether more

Table 1
Patient characteristics.

	Before installation of OCI (SD) $n = 57$	After installation of OCI (SD) $n = 65$	p[b]
Mean age (yrs)	76.1 (7.5)	76.6 (8.3)	0.73
Gender (n = male/n = female)	49/8	57/8	0.79[c]
Mean Body Mass Index[a]	26.5 (3.8)	27.4 (4.7)	0.29
Mean maximum aneurysm diameter (mm)	62 (9.1)	63 (10.2)	0.52

[a] $n = 48$(before)/45(after).
[b] Student's t-test.
[c] p-value based on Fisher's exact test.

Table 2
Median values before and after change to OCI.

	Median value before OCI (range)	Median value with OCI (range)	*p* value[b]
Dose area product (mGy m^2)	6.9 (1.91–95.0)	4.9 (1.25–13.3)	0.005
Screening time (min)	20.0 (4.8–49.3)	16.2 (3.1–51.1)	0.027
Contrast dose (ml)[a]	100 (60–300)	90 (50–180)	0.21
Operative duration (min)	130 (65–240)	120 (60–205)	0.44

[a] $n = 45$(before)/51(after).
[b] Mann-Whitney *U* test.

modest changes in operative protocol and theatre configuration could reduce radiation exposure for both patient and surgeon.

Radiation levels recorded during this study were in keeping with those reported elsewhere, with median DAP values after installation of OCI being comparable to the optimum series in the literature.[8,10,11] Whilst DAP does not provide a direct measure of absolute radiation dose received by the patient or interventionalist, it has been shown to have a strong correlation with peak skin dose (PSD) during EVAR ($r^2 = 0.923$).[10,11] PSD is a direct measurement of radiation dose derived from radiochromic films placed beneath the patient throughout the procedure. This strong correlation therefore supports the use of DAP as a surrogate measure of received radiation dose. Furthermore, whilst entrance skin dose (ESD) or effective dose (ED) are often reported for angiographic procedures, both of these alternative measures are dependent upon the position of the X-ray tube relative to the patient. Since this relative position varies so significantly during EVAR, DAP was considered to be the most useful surrogate of radiation exposure in this setting.

What is most notable from our results is that the change to OCI not only reduced median DAP, but also dramatically reduced the *range* of DAP values observed (Fig. 1). Prior to introduction of OCI, the range of DAP values was 1.9–95.0 mGy m^2 (with only a single DAP value over 78.3 mGy m^2), which is broadly similar to figures presented by Kuhelj et al. and Weerakoddy et al., who observed ranges of 3.5–70 mGy^2 m^2 and 9–66 mGy m^2 respectively.[3,7] After installation of OCI, however, the maximum recorded DAP during 65 consecutive cases was only 13.3 mGy m^2, which is lower than the maximum recorded DAP in any series of bifurcated endografts published to date.[8,10,12]

Scrutiny of the nine cases in which DAP exceeded 20 mGy m^2 (all prior to OCI) did not reveal any clear intraoperative difficulty, nor any significant differences in BMI, gender, maximum aneurysm diameter or type of endograft compared to patients who received lower radiation doses. The mean age of these higher-dose patients was greater than in the low-dose group (80.1 yrs versus 76.6 yrs), but this alone does not explain the dose differences. Operator inexperience was also excluded as a sole cause of higher radiation exposure, since six of the nine higher-dose cases were performed by consultant interventionalists (which is in keeping with the total proportion of cases performed by consultants). Furthermore, the same group of interventionalists performed the majority of procedures both before and after the change to OCI, confirming that reduced DAP values were not simply the result of change in operator.

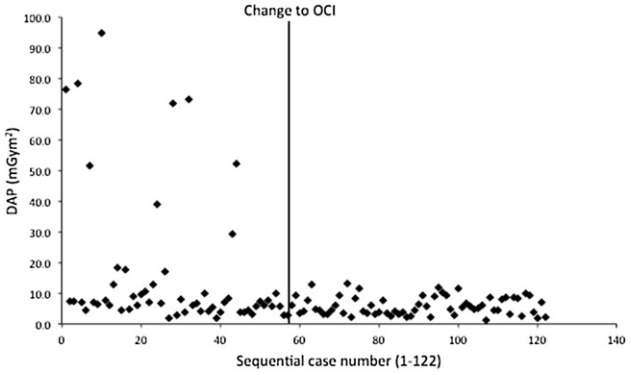

Figure 1. Radiation exposure in cases before/after change to OCI.

This reduction in maximum delivered dose is particularly relevant in attempts to reduce the impact of radiation on patients. Whilst mean/median DAP values give a useful guide to likely cumulative exposure for the interventionalist, it is the cases at the upper end of the dose range that are most likely to result in deterministic effects for the patient. Since a significant proportion of patients undergoing EVAR may exceed the theoretical threshold for deterministic tissue damage,[3] every effort must be made to reduce the number of these 'high-dose' cases.

In contrast to other authors,[13–15] our results showed no correlation between DAP and overall screening time (i.e. low-dose fluoroscopy and high-dose digital acquisition combined) or BMI. Nor was there any correlation between DAP and the volume of contrast used. Whilst median DAP was reduced by nearly 30% following introduction of OCI, there was only a 19% fall in overall screening time ($p = 0.027$) and a 10% reduction in contrast dose ($p = 0.28$). This suggests that there was a reduction in the number or duration of high-dose digital acquisition 'runs' after introduction of OCI, since this would significantly reduce DAP whilst having relatively little effect on overall screening time. This may be because OCI provides improved anatomical clarity by allowing the operator to position the patient more accurately before performing high-dose 'runs', thereby limiting the number/length of runs necessary to assess graft position during deployment. Prospective data collection would be necessary to confirm these assertions since this was a retrospective study and number and length of runs were not routinely recorded.

Although high-dose cases may be responsible for possible deterministic effects, the risk of stochastic effects – and the need to reduce routine radiation exposure – should not be underestimated. It has been suggested that the lifetime fatal-cancer risk may be greater than 1% for patients undergoing EVAR,[16] and whilst some patients may be very elderly and not live long enough for stochastic effects to manifest (typically 10–20 yrs),[17,18] the introduction of AAA screening programmes has meant that increasing numbers of patients are being treated at 65–70 yrs of age. In addition, thoracic endografts are now being used with increasing frequency to treat young trauma patients who will require life-long surveillance. The risk of stochastic effects must therefore be minimized whenever possible.

The low DAP values and reduced screening times achieved in this study demonstrate that interventionalists working in adapted operating theatres can enhance the safety and efficiency of EVAR by changing to OCI. This technique not only reduces radiation exposure to both patient and interventionalist, but also implies that fewer staff are required to perform the procedure – a factor particularly beneficial in the emergency setting when availability of staff is often low. Although these results were achieved with a mobile C-arm, it is likely that future progression to full-hybrid theatres with fixed, high-quality imaging under operator control may offer further improvements in performance.

With increasing evidence that EVAR can be performed with consistently low radiation doses, it may also be feasible to establish clearer guidelines for acceptable exposure during this procedure and ensure that it is 'as low as reasonably practicable' (ALARP).[19] Though there will always be a balance between image quality and radiation dose, greater awareness of the issues would allow

interventionalists to monitor radiation levels just as they monitor other operative outcomes and ensure high doses are not being delivered unnecessarily.

Conclusion

Operator-controlled imaging allows surgeons and interventional radiologists to perform EVAR with greater independence while significantly reducing the delivered radiation dose. Further data are necessary to verify whether changing to OCI is sufficient to completely eliminate 'high-dose' cases during infra-renal EVAR and clarify whether similar improvements can be achieved in the treatment of more complex aneurysms.

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Conflict of Interest

None.

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