Introduction of a Team Based Approach to Radiation Dose Reduction in the enhancement of the overall Radiation Safety Profile of FEVAR

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Conflict of Interest
Tara Mastracci does consultation and proctoring for Cook Medical Inc.

ABSTRACT

Objectives

Fenestrated endovascular aneurysm repair (FEVAR) exposes operators and patients to considerable amounts of radiation. Introduction of fusion of three-dimensional (3D) computed tomography (CT) with intraoperative fluoroscopy puts new focus on advanced imaging techniques in the operating environment and has been found to reduce radiation and facilitate faster repair. The aim of this study is to evaluate the radiation dose effect of introducing a team-based approach to complex aortic repair.

Methods

Procedural details for a cohort of 21 patients undergoing FEVAR after fusion-guided (Modern Group) imaging was introduced are compared with 21 patients treated in the immediate 12 months prior to implementation (Historic Group) at a centre with expertise in FEVAR. Non-parametric tests were used to compare procedure time (PT), air kerma, dose-area product (DAP), fluoroscopy time (FT), estimated blood loss (EBL) and pre- and post-operative estimated glomerular filtration rate (eGFR) between the groups.

Results

Change in operative approach resulted in a significant reduction in PT for the Modern group (median 285 mins; interquartile range 268-322) compared with the Historic group (450 mins; IQR 360-540 p=<0.001). There were reductions in skin dose for the Modern group (1.6 Gy; IQR 1.09-2.1) compared with the Historic group (4.4 Gy; 3.2-7.05 p=<0.001), and DAP (Modern 159 Gy.cm^2; IQR 123-226 vs 264.93 Gy.cm^2; 173.3-366.8 for Historic (p=0.006). Estimated blood loss was significantly reduced for Modern (350 mls; 250-580) compared with Historic (1000 mls; 420-2300 p=0.009). There were no significant differences in FT, and pre- and post-operative eGFR between the two groups. Weight and height were distributed equally across both groups.

Conclusions

Implementation of a team-based approach to radiation reduction significantly reduces radiation dose. These findings suggest that the radiation safety awareness that accompanies the introduction of fusion imaging may improve the overall radiation safety profile of FEVAR for patients and providers.

Key words: Fusion, complex aneurysms, radiation, performance

What this paper adds:

This paper investigates the implementation of a team-based approach to radiation safety in complex aneurysm repairs. The importance of a systematic approach to radiation safety and the procedure itself, with improvement in the safety-profile of FEVAR must not only rely on specific imaging modalities but also on a systematic and integrated approach to all cases.

INTRODUCTION

Imaging technology has evolved since the introduction of endovascular aneurysm repair (EVAR).[1] Modern hybrid rooms have the capacity to combine pre-operative computed tomography (CT) with cone-beam computed tomography (CBCT) to assist intra-operative navigation and graft deployment (Fusion).[2,3] Fusion usually employs rigid co-registration of consistent bony landmarks,[4,5] but could employ orthogonal 2D acquisitions[6] and computational algorithms in real time.[7] Fenestrated endovascular aneurysm repair (FEVAR) has increased the complexity of endovascular repair[12,13], exposing the patient and surgeon to more radiation.[8–10,11]

Existing data supports fusion imaging in complex aneurysm repair to reduce contrast volume and radiation dose.[4–6,14] We believe the effect is augmented by an emphasis on dose reduction that introduction of a new technology can provide. We review our experience with a new systematic and team-based approach to the routine use of advanced technologies like fusion, and hypothesize that this awareness is responsible for dose reduction.

METHODS

All patients who underwent complex endograft between January 2014 and May 2015 were included in this before and after comparison study. This study documents a period of clinical change at our institution during which time Fusion Imaging techniques were introduced as standard of care, and there was a change in clinical leadership. Guidance from HRA advised that this study did not fall under the remit

of the NHS Research Ethics Committee, thus it is registered with the Royal Free NHS Foundation Trust as an audit in line with clinical guidelines.

At our centre, all patients who are deemed clinically suitable for complex endovascular repair of aortic aneurysm undergo pre-operative high-resolution computed angiography (CTA) and selective pre-operative assessment including stress-echocardiography, pulmonary function testing, and CPEX testing, according to our care pathway. Following multi-disciplinary team discussion, custom fenestrated or branched devices are designed and ordered.

For this study, the Historic Group was a consecutive retrospective cohort of patients who received fenestrated grafts from January 2014 to October 2014, prior to the implementation of routine fusion imaging. These were identified from one surgeon's personal log, and verified against data in the national vascular registry for our centre to ensure consecutive patients were captured. Patients were operated on by a senior experienced operator. Procedural data, including measures of radiation output, and short-term outcome data were gathered from the PACS system and from the patients' medical records.

After a change in clinical leadership, fusion imaging was implemented at our centre, and with it, a systematic approach to radiation safety that involved surgeons, nurses and radiographers. Consecutive patients who received fenestrated stent grafts after fusion was introduced were included in the Modern Group. For these patients, procedural and perioperative data was collected by the investigators [AER, SR, MD,

MD] as part of routine clinical auditing practice. Reporting of consecutive cases was ensured by comparing against the national vascular registry.

Fusion Protocol and Fluoroscopic Settings

All patients were treated in the same hybrid suite, using the same fixed imaging equipment (Siemens Artis Zeego, Siemens Healthcare, Erlangen, Germany). All procedures were performed by an experienced surgeon, following ALARA principles, with a radiographer present in every case. In all cases, the senior surgeon/radiologist was operating the radiation pedal.

In the Modern cohort, prior to the procedure, the surgical team imported the pre-operative CTA onto the workstation and marked the target vessels using Syngo™ (Siemens Healthcare, Erlangen, Germany) software (fig.1a). All fluoroscopy used standardized low-dose settings of 32 nGy per pulse (which was changed to 18 nGy as of March 2015 in an effort to continually refine the technique and decrease dose), at 3 pulses per second, unless modified at the surgeon's discretion based on intraoperative judgement. The patients were fully prepared and draped to prevent patient movement after registration has been performed, and an additional temporary drape covered the entire operative field prior to rotational CBCT in order to maintain sterility. All staff retreated to a shielded area prior to CBCT. A 5sDR (5 seconds, 133 frames at 30 f/s) was used (fig. 1b). The bony landmarks of the pre-operative CTA were fused to the CBCT (fig. 1c). The rings identifying the target vessels were superimposed on the fluoroscopy screen and were not adjusted after index registration (fig. 1d). One surgeon with experience using the system provided

technical support to radiographers. During the procedure, senior level radiographers worked with the surgeon to ensure tight collimation, filtering and lowest-possible dose settings (fig. 2). In the Historic Group similar anticoagulation and draping methods were employed, but the radiographic protocols did not include fusion, and they were not standardized, recorded or consistent between cases.

Procedure

All patients underwent repair with Zenith Fenestrated devices (Cook Medical, IN, USA). Major differences in operative techniques between cohorts did exist: before device deployment, some target-vessels were pre-marked with catheters in the Modern cohort, and an axillo-bi-femoral bypass was performed in the Historic cohort. In Modern cases, an initial digital-subtraction angiogram (DSA) was omitted. The 3D overlay image was used selectively to guide catheterization of the target vessels, and the use of selective DSA and hand-injections was kept to an absolute minimum. Contrast (Visipaque 320) for hand-injections was diluted to 50% strength. The power injector was not used until the completion angiogram. There was no systematic approach to radiation reduction in the Historic cohort.

Procedural Data, Outcomes and Statistics

Radiation exposure was reported as air kerma at the interventional reference point of 15 cm towards the tube from the radiological isocentre (Gy) and dose-area product [DAP] ($Gy.cm^2$). Contrast volumes were recorded for all patients in the Modern Group, but not for the Historic Group. Therefore, the total number of angiograms was obtained for each case as a surrogate marker to provide a

descriptive comparator, although the differences in technique does not make this a reliable method of comparison. Rapidity of cannulation was not available and thus was not an outcome measure.

Recorded secondary outcome measures included 30-day mortality, permanent spinal cord injury and non-surgical complications. Peri-operative renal function was recorded as estimated glomerular filtration rate (eGFR) on pre-procedure, post-operative day 1, and on the day of discharge.

Data analysis was performed using SPSS statistics version 22.0 (IBM corporation, Chicago, Ill) and reported as per guidelines.[16] Procedural data were not-normally distributed and non-parametric tests were used: results expressed as median and inter-quartile range. Differences in the distribution of continuous variables between the Modern Group and Historic group were tested using the Mann-Whitney U test. The Kruskal-Wallis test was used to identify any difference in renal function across the three different time-points for each group. Categorical variables were analyzed using the Fisher exact test. P values less than 0.05 were considered significant.

RESULTS

A total of 42 patients who underwent FEVAR were reviewed in this study, 21 in each cohort. Demographic data are given in Table 1Table 2. Fusion of pre-operative CTA with the bony volume acquired during rotational CBCT was successful at first attempt in 19 of the 21 cases in the Fusion Imaging Group, the remaining two cases,

the CBCT was not possible due to technical failure attributed to the learning curve of performing CBCT.

Procedural Data and Radiation Dose Outcomes

Median procedure time for the Modern Group was 285 mins (inter-quartile range; 268-322) versus 450 mins (IQR; 360-540) for the Historic Group (*p*=<0.001) (fig.3). In terms of radiation parameters, median air kerma was 1.59 Gy (IQR; 1.09-2.11) for the Modern Group and 4.4 Gy (IQR; 3.2-7) for the Historic Group (*p*=<0.001), whilst median dose-area product for the Modern group was 158 $Gy.cm^2$ (IQR; 123-226) compared to 264 $Gy.cm^2$ (IQR; 173.3-366.8) for the Historic Group (*p*=0.006) (fig.4). Breakdowns based on CBCT and the remainder of the procedure are included in Table 4, and depicted in a per-patient illustration in Figure 5. Significantly fewer angiograms were used in the Modern Group (10.5, IQR; 7-14.5) compared with the Historic Group (24, IQR; 21.5-32.5) (*p*=<0.001). There was no significant difference in fluoroscopy time (*p*=0.372). Median length of stay for the Modern group was 5 days (IQR; 4-7.5) compared with 9 days (7-17) for the Historic group (*p*=0.001). The imaging quality did not differ (fig.2).

Secondary outcomes

There were no aneurysm-related deaths within 30 days of the procedure in either group. There were no differences in eGFR across the three time-points for either the Modern Group or the Historic group: pre-op 67 (IQR; 44-90), day 1 post-op 60 (47-86.5), discharge 66 (38-87) (*p*=0.91), and pre-op 68 (49.2-84.7), day 1 post-op 67 (43.5-85), discharge 71 (52.5-84) (*p*=0.87), respectively. Renal complications

described in Table 5. There was no permanent spinal cord ischaemia in either group. In the Historic group, 2 patients required laparotomies on the same admission: in the first instance for small bowel obstruction, and in the second case for infected haematoma. The former patient had a prolonged stay on the intensive care unit and received haemofiltration, also suffered a posterior circulation cerebral infarct and severe chest sepsis. One patient in the Historic group suffered a cardiac arrest, however was revived successfully. There were no conversions to open repair. The frequency of complications is given in table 3.

Technical Success

In the Modern group, a total of 63 vessels were catheterized. One patient sustained a left renal artery dissection that was recognized intra-operatively and treated with a self-expanding stent (Zilver, Cook Medical, IN, USA). There were nine type II endoleaks identified on the final angiogram in the Modern group. In the Historic group, one renal artery was partially covered by a misaligned fenestration, preventing branch stent deployment, however was found to be patent on completion angiogram. A further attempt was made six weeks later to catheterize this target but was abandoned. Another patient sustained a left external iliac artery dissection requiring patch angioplasty of the common femoral artery and re-lining of the external iliac with a self-expanding stent (Zilver, Cook Medical, IN, USA). Four type II endoleaks were observed intra-operatively.

DISCUSSION

The results of this study demonstrate that introduction of advanced imaging techniques like fusion and a team based approach is technically feasible, and may

provide an element of radiation safety awareness that improves the overall safety of complex aortic procedures. We observed significant reductions in radiation parameters, procedure-time and estimated blood loss in the Modern group, compared with the Historic cohort. We also reflect an ongoing dedication to refining our technique by decreasing our pulse rate through the Modern cohort. Other immediate and short term benefits are more likely attributable to a change in the approach to the Aortic practice at our centre.

A first report comparing fusion assistance to standard fluoroscopic imaging in complex aortic endografting was published in 2011.[17] An Artis Zeego (Siemens Healthcare, Erlangen, Germany) and an 8sDR protocol, consisting of 397 frames taken at 60 f/s, in the majority of cases (80%). Although there was a significant difference in the radiation output using CBCT, the overall amount of radiation emitted did not differ from the historic control, which led the authors to postulate that this technique may aid in dose reduction. A different technique was adopted by Hertault et al to fuse pre-operative CTA with intra-operative imaging and were able to effect a significant reduction in radiation dose compared with historic controls, and report the lowest radiation output across a range of contemporary studies (table 1).[6] By contrast, McNally et al document higher radiation doses in their study, but again emphasize its utility.[5] The finding in this study that fluoroscopy time is not significantly reduced despite reductions in radiation dose is in keeping with two of the studies described above,[5, ,1517] and suggests that radiation dose can be affected by radiation settings more than simply “time on the pedal”. Furthermore, radiation output differed significantly across studies using the same fusion imaging system

(Siemens Zeego) implies that reductions in radiation are multifactorial and not dependent on fusion alone.

Given the complexity of modern imaging systems and hybrid rooms, close collaboration between specialist radiographers and vascular surgeons is crucial to ensure optimal outcomes.[18] For our new approach, radiographers received two-day training sessions and were closely supported by a surgeon with extensive prior experience with the Artis Zeego system. Radiographers worked closely with the surgeon to ensure tight collimation, filtering and the use of low-dose radiation settings.

A major limitation to current fusion techniques used by most moderns systems is that CBCT exposes the patient to considerable radiation.[19] Carrell et al[7] have developed a registration system that utilizes pre-operative CTA to create a series of digitally reconstructed radiographs (DRR) at progressive degrees of virtual C-arm rotation, precluding the need for CBCT. The system used by Hertault and colleagues in their paper of the same conclusion (Discovery IGS 730), GE, Chalfont, UK) was able to reliably fuse pre-operative CTA with intra-operative fluoroscopy using orthogonal antero-posterior and lateral single acquisitions only.[6] There is clearly scope for further development of novel registration techniques.

Although this study is an accurate clinical audit of our change in practice, there are some issues that may limit its generalizability. We acknowledge that comparing new practice with historic controls is a weak study design and introduces bias: there is a

different in style and technique between different practitioners that will bias the results. We recognize that these weaknesses may introduce bias into the conclusions, but we also feel that the significant change in radiation dose is worthy of report. The use of retrospective data is always a challenge: recording of contrast volumes was not routine in the historic cohort, making a valuable comparison between the two study groups impossible for this important outcome variable. Total number of angiograms was collected as a surrogate marker, although we acknowledge that this data is not as robust as contrast volume, since contrast type and concentrations are not accounted for in such a comparison. The concept of the 'Aortic Team' did vary across the two cohorts and there was more standardization of operators in the modern experience. This makes a strict comparison of imaging modalities difficult, since it was not possible to control for variation in operative strategy and imaging protocols in the historic group. Most specifically, the lack of consistency in frame rate in the historic cohort compared with the modern cohort could alone contribute to a large portion of radiation dose reduction. We feel that the significant reductions in radiation dose strongly supports the practice of using a standardized and integrated approach to these procedures.

CONCLUSION

The introduction of fusion imaging by a team of surgeons and radiographers is feasible, and may contribute to an overall improved awareness of radiation safety practices that lead to significant reduction in radiation overall.

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Table 1: Studies to-date of fusion-assisted complex aortic complex aortic endografting.

Study	*n*	Procedure	Imaging System	DAP (Gy.cm^2)	Air Kerma (Gy)
Dijkstra, 2011	8 (5sDR)	FEVAR	Siemens Zeego	-	7 (4-12)
Hertault, 2014	18 (2D fusion)	FEVAR	GE Inspiron	43.7 (24.7-57.5)	
McNally, 2014	12 19	FEVAR-2 fen FEVAR-3,4 fen	Siemens Zeego	- -	1.38 (+/- 0.52) 2.7 (+/- 1.4)
Sailer, 2014	31	FEVAR/BEVAR	Phillips Allura Xper	143 (120-166)	-

Table 2: Demographics, co-morbidities and aneurysm morphology. COPD- Chronic obstructive pulmonary disease, IHD- Ischaemic heart disease, CRF- Chronic renal failure, ESRF- End stage renal failure, CCF- Congestive cardiac failure

	Modern group	Historic Group	*P* value
Total	21	21	
Demographics			
Male:Female	17:4	18:3	-
Age [mean (SD)]	72.9 (8.02) yrs	74 (7.4) yrs	0.64
Height [mean (SD)]	171 (6.5) cm	170 (8.2) cm	0.72
Weight [mean (SD)]	82 (10.8) kg	79 (10.3) kg	0.38
BMI	27.9 (IQR 25.5-30.5)	27.6 (IQR 24.2-30.3)	0.56
Comorbidities			
Hypertension	19 (90%)	18 (85%)	1
Dyslipidaemia	19 (90%)	20 (95%)	1
Smoking (current)	6 (28%)	8 (38%)	0.74
COPD	7 (33%)	12 (57%)	0.21
IHD	9 (42%)	15 (71%)	0.11
Diabetes Mellitus	4 (19%)	4 (19%)	1
CRF	6 (28%)	5 (23%)	1
ESRF	0 (0%)	0 (0%)	-
CCF	3 (14%)	3 (14%)	1
Arrhythmia	1 (.04%)	2 (.09%)	1
Aneurysm Morphology			
Sac Size [median (IQR)]	6.2 cm (5.8-7.7)	6.5 cm (5.8-7.9)	0.9
Juxtarenal	17 (81%)	20 (95%)	-
Thoracoabdominal	4 (19%)	1 (5%)	-
Number of Fenestrations (not including scallops)			
4x	5	5	-
3x	12	11	-
2x	3	4	-
1x	1	1	-

Table 3: Rate of complications

Complication	Modern group	Historic Group	P value
Cardiac	0 (0%)	3 (14%)	0.23
Pulmonary	0 (0%)	4 (19%)	0.1
Renal	4 (19%)	3 (14%)	1
Bleeding	0 (0%)	2 (9%)	0.48
Gastrointestinal	0 (0%)	2 (9%)	0.48
Stroke	0 (0%)	1 (5%)	1

Table 4: Median Dose and DAP for the CBCT and Procedure

	CBCT	Fluoroscopy	Acquisition (DSA)	Total
Median Radiation Dose (Gy)	**0.13**	**1.07**	**0.50**	**1.59**
Median DAP ($Gy.cm^2$)	**36.9**	**86.7**	**44.9**	**159**

**Spin doses calculated using a local conversion for kV and mGy. Assuming uncollimated beam and 0 mm Cu. Fl doses calculated using a local conversion for DAP. Assuming a mix of PA and lateral at ~100 kV and 0.9 mm Cu. Acq doses calculated using a local conversion for DAP. Assuming a mix of PA and lateral at ~85 kV and 0 to 0.1 mm Cu.

Table 5: Renal Complications, online only

Historic Group
Post-op AKI, treated with IV hydration
Right renal artery fenestration misaligned, acute deterioration in renal function, but responded to aggressive hydration
Acute occlusion of right renal stent with deterioration in renal function, managed conservatively
Modern Group
Background of CKD II. Post-op AKI creat 223, managed medically, no haemofiltration
Post-op AKI, resolved with hydration
Background CKD stage III with known bilateral hydronephrosis in inflammatory aneurysm. Treated bilateral JJ stents, Creat 298 at peak
LRA dissection, treated intraop with additional Zilver Stent, but still poor flow. On follow up, EGFR 39 and creat 157 with atrophy of left kidney

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