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A PROSPECTIVE OBSERVATIONAL TRIAL OF FUSION IMAGING IN INFRARENAL ANEURYSMS

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Two Sentence Summary for Table of Contents In the first concise sentence please state the study design and the most important finding of this manuscript. In the second sentence state the most important conclusion. If accepted for publication, this summary will appear on the table of contents under the title of your article. **Example 1:** Intercostal artery reimplantation did not significantly decrease spinal cord injury in this retrospective study of 805 patients with	Adding 3D fusion imaging to conventional fluoroscopy in hybrid theatres or when using mobile system decreased radiation dose by 50% in 44 patients who underwent endovascular aortic aneurysm repair (EVAR), when compared to radiation dose in 21 historic control patients.

open repair of TAAs and TAAAs. The authors suggest physiologic interventions to reduce the rate of spinal cord ischemia. **Example 2:** This retrospective multicenter study analyzed presentation, etiology, management and outcome of 32 patients with post-EVAR aorta-enteric fistula (AEF). The study suggests that AEF is more frequent after EVAR performed for pseudoaneurysm or emergency and that treatment is associated with high mortality.	

A PROSPECTIVE OBSERVATIONAL TRIAL OF FUSION IMAGING IN INFRARENAL ANEURYSMS

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ABSTRACT

Objectives

Use of 3D fusion has been shown to significantly reduce radiation exposure and contrast utilization in complex endovascular aortic repair (FEVAR/BEVAR). Cydar software [CYDAR Medical, Cambridge, UK] is a cloud-based technology that can provide imaging guidance by overlaying preoperative 3D vessel anatomy from the CT scans onto live fluoroscopic images in both hybrid theatres and on mobile C-arms. The aim of this study is to determine if radiation dose reduction would occur with the addition of fusion imaging in infrarenal repair in all imaging environments.

Methods

All patients who consented to involvement in the trial, and treated with EVAR in our centre since March 2016 until April 2017 were included. A teaching session about radiation protection and Cydar fusion software use was provided to all operators before the start of the fusion group enrolment. This group was compared with a retrospective cohort of patients treated in the same centre from March 2015 to March 2016, after a dedicated programme of radiation awareness and reduction was introduced. Ruptured aneurysms as well as complex EVAR were excluded. Preoperative and perioperative characteristics were recorded, including parameters of radiation dose as Air Kerma (AK) and dose area product (DAP). Results were expressed in median and interquartile range.

Results

Forty-four patients were prospectively enrolled, and compared with 21 retrospective control

patients. No significant differences were found when comparing sex, body mass index [BMI] and age at repair. The median operation time (wire to wire) and fluoroscopy time were 90 minutes [75-105] and 30 minutes [22-34] respectively, without significant differences between both groups (P=.56 and P=.36). DAP was non significantly higher in the control group, 21.7 Gy.cm2 [8.9-85.9], compared with the Fusion group, 12.4 Gy.cm2 [7.5-23.4] (P=.10). AK product was significantly higher in the control group, 142 mGy [61-541] compared with 82 mGy [51-115] in the Fusion group (P=.03). The number of DSA runs was significantly lower in the Fusion group (8 [6-11]) compared with the control group (10 [9-14]) (P=.03). No significant differences in the frequency of adverse events, endoleaks or additional procedures required.

Conclusions

When used in simple procedures such as infrarenal aneurysm repair, image-based fusion technology is feasible in both hybrid theatres and on mobile systems, and leads to an overall 50% reduction in radiation dose. Fusion technology should become standard of care for centres attempting to maximize radiation dose reduction, even if capital investment of a hybrid theatre is not feasible.

INTRODUCTION

The endovascular repair of infrarenal aneurysm (EVAR) has surged since 1991,[1] and today even complex aneurysm morphology can be undertaken using complex devices, such as fenestrated (FEVAR) and branched (BEVAR).[2,3] This treatment is becoming more available, associated with low morbidity and good medium-term outcomes.[4-6] However, EVAR requires radiation exposure for both patients and staff and nephrotoxic contrast administration to the patient.[7,8]

A method to reduce both radiation and contrast use is to improve clinicians' perception of intraoperative 3D vascular anatomy. Advanced imaging techniques available in hybrid rooms allow the overlay of a 3D vascular mask from a pre-operative computed tomography angiography (CTA) onto the live 2D X-ray image using first generation, or hardware-based systems. This 3D vascular mask is synchronized to the table and gantry position and provides perioperative guidance as a "3D roadmap" to the operator during endovascular repair. It has been proven that using fusion imaging guidance during aortic endovascular repair reduce both contrast and radiation dose,[9-11] especially if the registration protocol is contrast and almost radiation free.[12]

The drawbacks of this advanced imaging application are twofold: First, it is currently available only in modern expensive hybrid theatres thus only in large centres. And second, using hardware-based, rather than patient-based tracking techniques can introduce inaccuracy if the patient shifts on the table during the procedure. However, in this study, next generation fusion software is tested that is suitable for any theatre including those equipped with mobile C-arm,

fully automated to register using patient-based images, and employs a radiation and contrast free overlay registration (Cydar imaging guidance, CYDAR medical, Cambridge UK).

The aim of this study is to assess the radiation exposure and patient safety during EVAR performed using Cydar imaging guidance in all imaging environments, compared with an historical cohort performed by the same operators, but without fusion guidance.

MATERIALS AND METHODS

This study was a prospective, single centre, nonrandomized trial registered at the www.ClinicalTrial.gov with identifier NCT02592733 and has been approved by the NHS Research Ethics Committee. Participation required informed consent and compliance with the study inclusion and exclusion criteria. The decision to use imaging guidance technology was made at the discretion of the implanting operator, and did not replace traditional, conventional methods of imaging.

Cydar RTRS EV technology

The Cydar RTRS EV is a cloud-based high-performance computing software that allows an automated 3D vascular mask overlay during X-ray guided surgery. The software, combined with secure and certified cloud high-performance computing, deduced the patient position by comparing the bony anatomy visible on the X-ray to that on the patient's CTA, enabling it to produce and update accurate and reliable overlays of the diagnostic CTA 3D vascular mask throughout the operation (www.cydar.co.uk). At least 2 vertebrae had to be visible on the screen and within 3 to 8 seconds, the vascular mask appeared. This new product presented as an

additional screen in theatre. It was suitable for any theatre including those equipped with a digital mobile C-arm; was radiation and contrast free for the overlay registration; and was fully automated. The 3D vascular masks were created prior to surgery by imaging specialists at the company.

Population

Fusion group. The trial population consisted of consecutive patients booked for an elective endovascular aneurysm repair (EVAR) of an infrarenal aortic aneurysm who have had a pre-operative diagnostic CTA. Other inclusion criteria were patients who were willing and able to give informed consent, aged 18 or older, able and willing to comply with the study requirements, and agreement of the surgeon to participate. Exclusion criteria were females under the age of 60 years old, patient requiring an associated procedure (iliac branch device implantation, renal or mesenteric angioplasty), ruptured aortic aneurysms and emergency procedures.

Control group. This consisted of a retrospective analysis of consecutive patients who underwent an EVAR without overlay imaging guidance during the procedure prior to the introduction of fusion software at our hospital. Exclusion criteria were patients with associated procedure (iliac branch device implantation, renal or mesenteric angioplasty) or ruptured AAA and emergency procedures.

Endovascular technique and physician training.

EVAR were performed using standard techniques by experienced radiologists or vascular surgeons, under regional or general anaesthesia. Prior to March 2015, all cases were performed in a dedicated hybrid operating room (Zeego, Siemens Healthcare, Erlangen Germany) without the use of the image fusion guidance from the system. Since then, cases were performed either in

the hybrid room, or in a theatre with a mobile motorized C-Arm (Cios alpha, Siemens Healthcare, Erlangen Germany). The endovascular devices used were either Zenith [Cook Medical, Bloomington Indiana, USA] or Endurant [Medtronic, Santa Barbara California, USA] at the discretion of the operator. The settings of the hybrid room were optimized February 2015 (prior to the control group) with the implementation of a low dose mode, and adjusted at the discretion of the operator.

Prior to the beginning of the Fusion group patient's enrolment, a teaching video remaining guideline on radioprotection, methods to decrease radiation doses and explaining how fusion should be used has been visualised by the operators. On the educational video and on the screen during the procedure, a message informed surgeons that the anatomy may have changed due to rigid guiding sheaths insertion or time to CTA, and that the operator must check the accuracy of the fusion prior to stent graft deployment. All physicians were aware that radiation dose reduction was the main focus of the study.

Trial assessments

Patient characteristics (age, sex, BMI), technical details of the equipment used, procedure details (date, access, anaesthesia, stent grafts, additional procedure, unexpected event, technical success, endoleaks) and outcomes of the trial (dose fundamentals, contrast use, procedure time) were prospectively collected for the Fusion group, and retrospectively collected from the medical charts for the control group, for planned analysis.

Endpoints

The primary outcome was the DAP (Dose Area Product, in $Gy.cm^2$) at the end of the procedure. The secondary outcomes were: the AK (Air Kerma, in Gy); the Fluoroscopy Time (FT, in min),

the number of digital subtraction angiography runs (DSA), the volume of iodinated contrast (in mL), and the operative time wire to wire (in min) at the end of the procedure.

Outcomes and Statistical analysis

Study design. This was an interventional trial comparing a prospective cohort undergoing standard of care EVAR with image guidance, to an historic cohort undergoing standard of care EVAR without image guidance. All intervention with the exception of the additional imaging guidance screen in the operating theatre were standard of care, and all techniques and operative decisions were at the discretion of the implanting surgeon. The pre-trial hypothesis was that the imaging guidance would provide a 20% reduction of radiation exposure during endovascular aortic repair, which is clinically relevant for both patient and staff safety.

Subgroup analysis. To assess the accuracy of this new automated overly technology when patient's movement on the table is greatest, we compared demographics and procedure related data within the Fusion group, between the procedures performed under local or regional anaesthesia with those performed under general anaesthesia.

Operator's perception of Fusion. By the end of each procedure, the operator was asked to fulfil a case report form about his opinion using the fusion overlay. The ease of the procedure, the self-confidence during the stent graft implantation and the accuracy of the fusion regarding the proximal landing zone were prospectively recorded for analysis.

Primary technical success was defined as successful introduction and deployment of the device in the absence of surgical conversion or mortality, the absence of type I or III endoleaks on completion angiography, and survival through 24 hours.[13]

Expression of the results. Continuous variables are expressed as median (25^{th} 75^{th} interquartile range). Categorical variables are presented as percentage and 95% confidence interval (CI) and compared with chi-square analysis. Comparisons between continuous variables were made with the Mann Whitney test. A p-value <.05 was considered as significant.

RESULTS

Population and procedure characteristics (Table I)

Forty-four consecutive patients treated for EVAR at a single centre were prospectively enrolled in the Fusion group from March 2016 to May 2017, and were compared with the 32 patients who underwent an EVAR procedure at the same centre during the 12 months prior (from March 2015 to March 2016). Data collection from the control group were retrospective. No significant differences were found regarding sex, BMI and age at repair. Regarding procedure parameters, no significant differences were found in terms of adverse events, technical success, endoleaks or additional procedures required. All of the four type Ia endoleaks in the Fusion group resolved on post-operative imaging (supplemental Table).

Exposure parameters (Table II)

The median operation time (wire to wire) and fluoroscopic time were 90 minutes [75-105] and 30 minutes [22-34], respectively, without significant differences between both groups. AK product was significantly higher in the control group, 142 mGy [61-541] compared to 82 mGy [51-115] in the Fusion group (P<.03), Figure I. The DAP in the control group was 21.7 $Gy.cm^2$ [8.9-85.9], non-significantly higher compared to the Fusion group, 12.37 $Gy.cm^2$ [7.48-23.63]

(P<.10), Figure II. The number of DSA runs was significantly lower in the Fusion group, 8 [6-11] than in the control group with 10 [9-14] (P<.03), Figure III. Volume of contrast use was 45 mL in Fusion group, but this data was not recorded in historic controls.

Fusion users' opinion

By the end of the procedure, 95% of Fusion users declared that the procedure was easier when performed under overlay guidance. To deploy the stent graft just distal to the renal arteries, 48% of the operators declared that the fusion was accurate enough.

Fusion user learning curve

Over the 10 first cases performed using Fusion, a trend to a reduced number of DSA runs was reported, underlying the learning curve associated with the fusion use despite the educational video projection.

Subgroup analysis excluding mobile C-arms (Table III)

To minimize the bias related to the implicit lower radiation dose intrinsic with mobile C-arm use, we performed a subgroup analysis comparing the control and Fusion group including only patients performed in the hybrid room (33 patients). No significant differences were found regarding sex, BMI and age at repair. The median operation time wire to wire was 90 minutes [70-105] and the fluoroscopic time was 29.5 minutes [22-35], without significant differences between both groups. DAP and AK product were significantly higher in the control group compare with the fusion group, 21.7 Gy.cm^2 [8.9-85.9] versus 9.17 Gy.cm^2 [6.83-14.74] (P<.03) and 142 mGy [61-541] versus 70 mGy [45-100] (P=.01), respectively. There was also a significant difference regarding the number of DSA, higher in the control group, 10 [9-14], compare to 8 [6-10] in the Cydar group (P=.005).

Subgroup analysis within Fusion group: local anaesthesia vs general anaesthesia (Table IV)

To assess the accuracy of this technique when patient movement is greatest, we compared the procedures performed under local or regional anaesthesia with those performed under general anaesthesia, including the number and the speed of the registration. We did not find significant differences in the DAP (9.2 [8.6-18.2] *vs* 12.4 [7.2-24.8] $Gy.cm^2$ in the local vs general anaesthesia group, respectively), AK (80 [56-183] *vs* 85 [51-112] mGy) and contrast used (38 [35-46] *vs* 45 [40-60] mL). No significant differences were found regarding fluoroscopy time, procedure time and number of DSA. About the accuracy of the software, no differences were found regarding the mean number of successful registrations (100±30 in the local anesthesia group vs 85±22 for the general anesthesia group) nor any difference in the mean registration speed (5925±965 *vs* 6125±1315 msec, respectively).

DISCUSSION

Due to the increasing use of endovascular aneurysm repair, radiation exposure for both patients and staff is becoming an important in choice of treatment. Several studies have reported a reduced radiation dose using fusion imaging guidance available in hybrid theatres during complex and infrarenal EVAR.[12] Our study is the first reporting a significant reduction in radiation exposure during infrarenal EVAR, using a new automated, patient-based image guidance process available in both hybrid theatres and on mobile systems.

Advanced imaging technologies such as 3D fusion imaging guidance has spread through the modernisation of theatre equipment as hybrid rooms become more prevalent. In most of the oldest proprietary systems, image fusion guidance is performed from acquisition of an

unenhanced intraoperative cone-beam CT (CBCT) study or from a preoperative CTA (computed tomography angiography). Those images are sent to a workstation where the 3D aortic volume is constructed. More recently, to save time and radiation exposure, the 3D vascular mask is constructed before the procedure using the preoperative CTA and sent to the hybrid room's workstation. At the beginning of the procedure, the overlap of the 3D vascular mask to the 2D live X-ray imaging is performed using bony or calcification landmarks. This 3D vascular mask is synchronized to the table and gantry position and provides perioperative guidance as a roadmap to the operator during endovascular repair. Depending on the system used, the mask is either fixed, or can be adjusted during the procedure to optimize the accuracy before stent graft implantation. Depending on the system and on the radiation cost of the 3D vascular mask registration, studies have shown a benefit of fusion guidance in contrast use,[10,14] or in both contrast use and radiation exposure.[12,15]

However, this technology has only been available in high-cost hybrid theatres, and therefor this benefit is enjoyed by patients at high volume centres. Moreover, the manual registration process for the fusion guidance is time consuming and may be cumbersome to use, leading physicians to give up on the fusion, especially for simple procedures. The Cydar RTRS EV software is a new technology able to supply similar fusion imaging guidance to any interventional equipment with digital imaging display. It is a Cloud based high performance computing and software that allows an automated 3D vascular mask overlay during X-ray guided surgery. The software, combined with secure and certified cloud high-performance computing, deduces the patient position by comparing the bony anatomy visible on the X-ray to that on the patient's preoperative CTA, enabling it to produce and update accurate and reliable overlays of the diagnostic CTA 3D vascular mask throughout the operation.[16] The registration is continuously updated employing

image matching techniques, and it works through a standard PC with its own monitor. This PC connects the video output of the live X-ray set to the cloud through an available network and functions with fixed fluoroscopic equipment as well as mobile C-arms. This new product provides several advantages including being suitable for any theatre including those equipped with mobile C-arm; being radiation and contrast free for the overlay registration; and being fully automated thus user friendly for the operator avoiding any additional requirement.

Our study is the first reporting a reduction in radiation exposure during EVAR using this new technology, in combination with the optimisation of the X-ray settings (low dose mode) and a brief teaching session on ALARA principles and fusion use.[17] The 3D imaging fusion is used during infra-renal EVAR for the placement of catheters and stent-graft prior to deployment without DSA or contrast, as well as during limb insertion to assess the iliac bifurcation. In theory, only one DSA is required to assess the accuracy of the fusion, then the procedure can be performed using the overlay guidance. We report almost 50% reduction of DAP and AK, respectively correlated to the stochastic and determinist risk, but did not show any reduction in fluoroscopy time. These results are partly explained by the significant reduction of the DSA runs, high quality and radiation consuming imaging record, which represent up to 80% of the radiation exposure during a standard procedure.[18] These image recordings allow the visualization of the vascular anatomy but are no longer necessary under fusion guidance, except prior to the stent graft deployment to check the accuracy of the fusion mask. Indeed, the location of the renal arteries ostia may be affected by deformation, mainly due to the large rigid sheath and stiff wire insertion.[19] Fluoro loops are usually sufficient to assess the accuracy of the iliac bifurcation, and the other steps of the procedure can be performed following fusion guidance.[17] We report a median of 8 DSA runs per procedure, which is lower than in the control group, but higher than

expected. An explanation could be the learning curve related to both the experience requested to trust the fusion guidance, and the early experience of Vascular Surgeon from our group with the technique (prior performed by the radiologists). This may also explain the high number of type Ia endoleak by the time of the completion angiogram; Our results concur with Hertault et al, reporting a 50% reduced DAP within EVAR performed in an hybrid room, compared with previous experience of EVAR performed using a mobile C-arm and without fusion guidance.[12]

To reduce the morbidity of the procedure, some operators replace general anaesthesia with loco regional anaesthesia. Few teams even offer outpatient EVAR.[20] In these cases, patient movements on the table are greater, implying that fixed hardware-based fusion registration processes cannot be used as they would quickly be rendered inaccurate, and adjustable fusion process requires more DSA runs to check the accuracy of the registration. We report in our study a similar success rate of fusion registration and use between general and loco regional anaesthesia, due to the continuous update of the registration using the image matching techniques, confirming that this technology would cover all EVAR repairs.

There are limitations of this study. First, the retrospective data used for the control group, even if performed with the same equipment and the same operators, may be flawed because important variables were not collected in a protocolized fashion. In addition, the small number of patients enrolled may misrepresent the findings. Another limitation is the cumulative effect on radiation dose reduction of the settings adjustments (low dose mode), the educational video (review of the ALARA principles) and the fusion use. Some critics may suggest that the inclusion of patients in which a mobile C-arm was used may be an unfair bias against the historic controls. However, we believe the ability of this fusion system to be used in a variety of imaging environments is a major factor in its benefit to deliver accurate fusion imaging to patients. A prospective

randomised study comparing controls and patients performed under fusion guidance is necessary to assess more precisely the role of this automated fusion on the radiation exposure reduction.

CONCLUSION

When used in simple procedures such as infrarenal aneurysm repair, automated image-based fusion technology is feasible in both hybrid theatres and on mobile systems, and leads to almost 50% reduction in radiation dose, in combination with the use of a low dose mode and the application of the ALARA principles. Fusion technology in association with ALARA principles implementation should become standard of care for any centre attempting to maximize radiation dose reduction for both patients and staff.

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JVS-D-17-01209R2, A PROSPECTIVE OBSERVATIONAL TRIAL OF FUSION IMAGING IN INFRARENAL ANEURYSMS
Type of Research: Retrospective cohort study of prospectively collected data
Take Home Message: Adding 3D fusion imaging to conventional fluoroscopy in hybrid theatres or using mobile system decreased radiation dose by 50% in 44 patients who underwent endovascular aortic aneurysm repair (EVAR), when compared radiation dose in 21 historic control patients.
Recommendation: The authors recommend using 3D fusion technology for EVAR in hybrid theaters or even when using mobile C-arm.

Figure 1 PRINT

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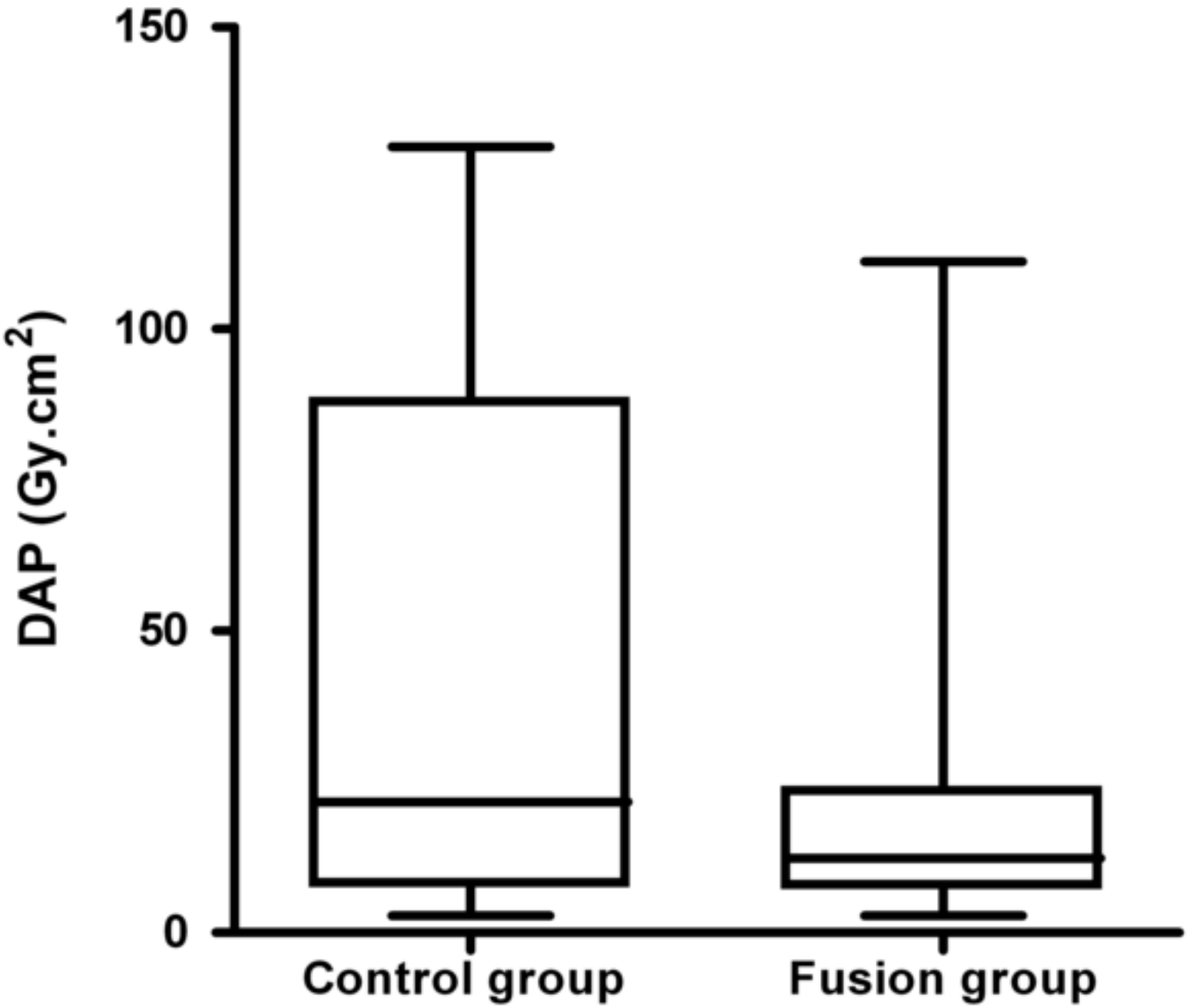

Figure 2 PRINT

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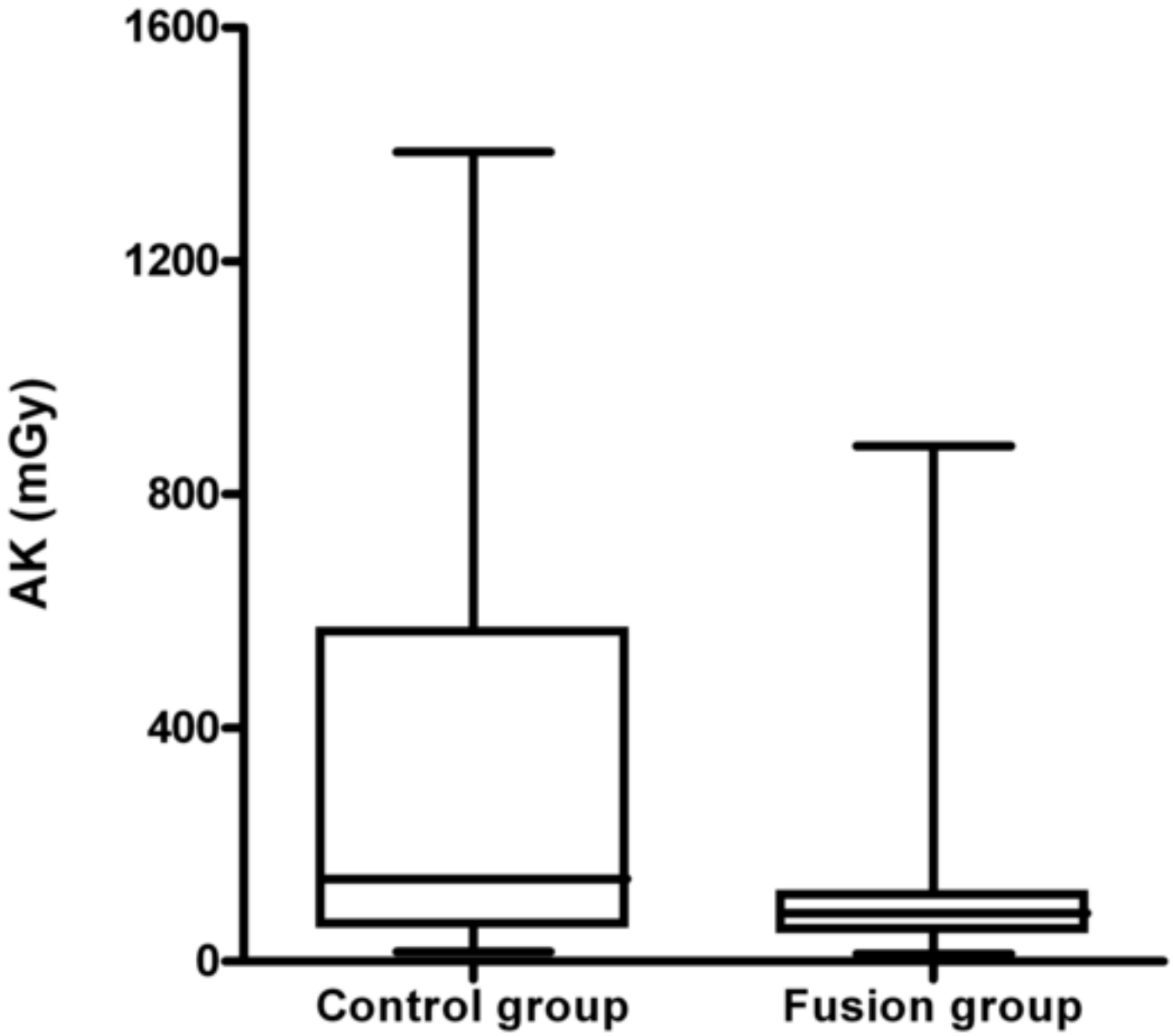

Figure 3 PRINT

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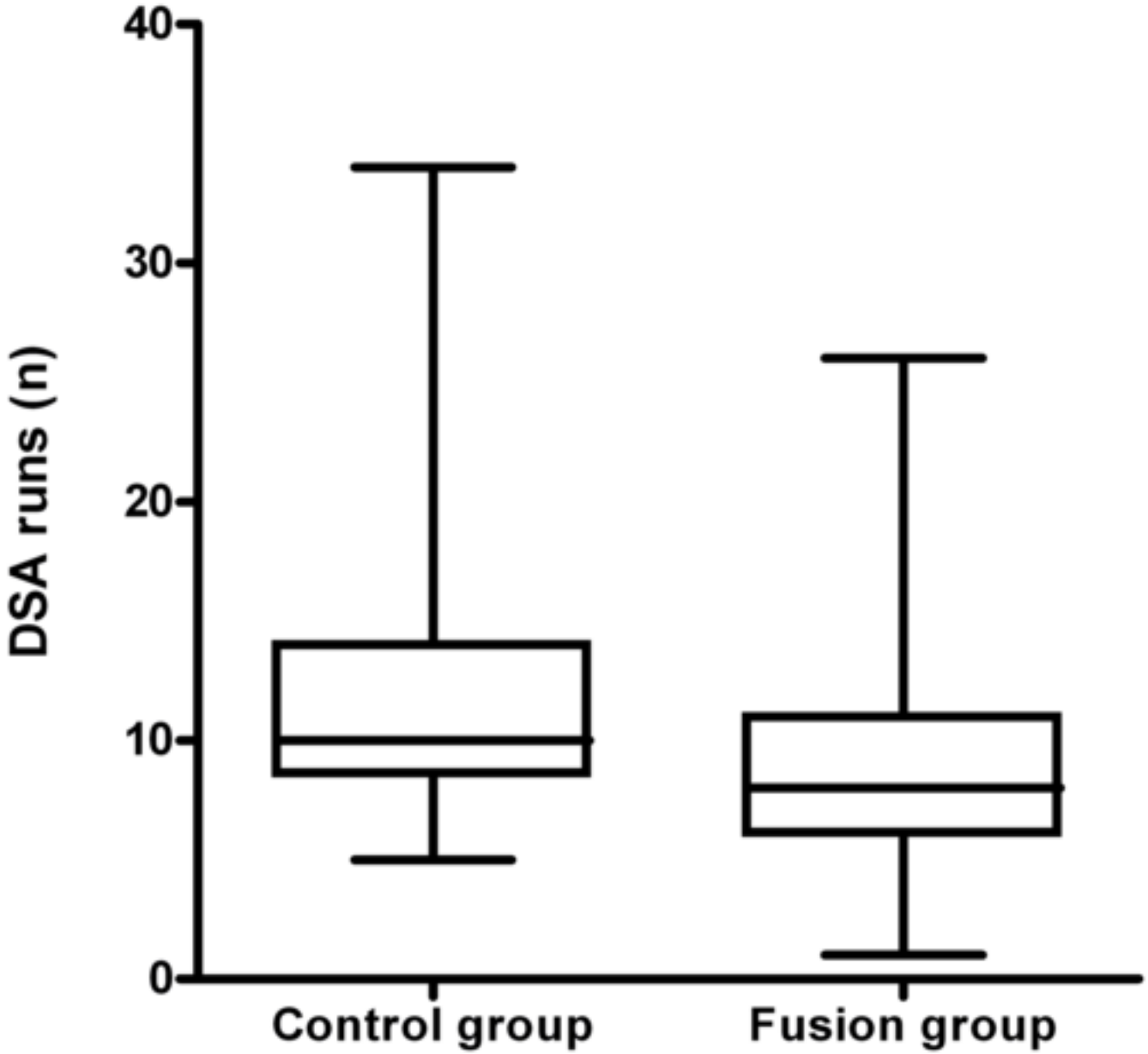

	FUSION group (n=44)	CONTROL group (n=21)
Male	41 (93%)	20 (95%)
BMI	27.3 ± 3.3	27.6 ± 4.2
Age at repair (yo)	75 ± 8.8	76.5 ± 8.5
Additional procedure	3 (7%) - accessory renal embolization (3)	0
Technical success	40 (91%)	19 (90.5%)
EDL total - **Type Ia** - **Type II** - **Type III**	9 (20%) - 4 - 5 - 0	3(14%) - 2 - 1 - 0
Endograft - **AUI** - **BIF**	 - 0 - 44 (100%)	 - 2 (9.5%) - 19 (90.5%)
Procedure performed in HR	33 (75%)	21 (100%)

Table I : population and procedure details. *BMI : body mass index ; yo : year old ; IIA : internal iliac artery ; EIA : external iliac artery ; EDL : endoleak ; AUI : aorto uni iliac ; BIF : bifurcated stentgraft. HR: hybrid room.*

	FUSION group (n=44)	CONTROL group (n=21)	P
DAP (Gy.cm2)	12.37 [7.48-23.63]	21.73 [8.92-85.94]	.105
AK (mGy)	82 [51-115]	142 [61-541]	.028
FT (min)	29.5 [22-33]	32 [23-38]	.357
Procedure time (min)	90 [75-100]	90 [75-110]	.563
DSA runs (n)	8 [6-11]	10 [9-14]	.026
Contrast (mL)	45 [36-60]		

Table II. Exposure parameters during the procedure. DAP: dose area product; AK: air kerma; FT: fluoroscopy time; DSA: digital subtraction angiography.

	FUSION group performed in HR (n=33)	CONTROL group (n=21)	P
DAP (Gy.cm^2)	9.17 [6.83-14.74]	21.73 [8.92-85.94]	.029
AK (mGy)	70 [45-100]	142 [61-541]	.011
FT (min)	27 [21-33]	32 [23-38]	.267
Procedure time (min)	85 [70-100]	90 [75-110]	.4411
DSA runs (n)	8 [6-10]	10 [9-14]	.0053
Contrast (mL)	45 [36-60]		

Table III. Exposure parameters during the procedure performed only in the hybrid room. DAP: dose area product; AK: air kerma; FT: fluoroscopy time; DSA: digital subtraction angiography.

	FUSION patients performed under Local (n=11)	FUSION patients performed under GA (n=33)	P
DAP (Gy.cm^2)	9.19 [8.61-18.21]	12.39 [7.25-24.78]	.5971
AK (mGy)	80 [56-183]	85 [51-112]	.9667
FT (min)	32 [25-36]	28 [21-33]	.1661
Procedure time (min)	92.5 [75-100]	90 [7.-100]	.399
DSA runs (n)	8 |6-9]	9 [6.5-12]	.3278
Contrast (mL)	38 [35-46]	45 [40-60]	.1022

Table IV. Exposure parameters within the Fusion group comparing local versus general anesthesia. GA: general anesthesia; DAP: dose area product; AK: air kerma; FT: fluoroscopy time; DSA: digital subtraction angiography.

Patient	Date of Surgery	Intraoperative Event	Follow up 1 month	Follow up 1 year
1	06/2016	T1a endoleak on final angiogram, no further intervention	No T1a endoleak, sac 5.9 cm	CTA no endoleak, sac 4.8 cm
2	04/2016	T1a endoleak, Medtronic cuff placed and endoleak resolved	No T1a endoleak, sac 5.5 cm	CTA no endoleak, sac 5.5 cm
3	03/2017	T1a endoleak on final angiogram, no further intervention	No T1a endoleak, sac 6.7 cm	Duplex at 6 months no endoleak, sac 6.1 cm
4	03/2017	T1a endoleak on final angiogram, no further intervention	No T1a endoleak, sac 6.2 cm	Not 1 year yet

Supplementary table: Fate of Endoleaks among patients from the Fusion group.

T1a: type 1a endoleak; CTA: computed tomography angiography

Figure I. Box plot figure comparing the values of dose area product (DAP) between the Control and Fusion groups.

Figure II. Box plot figure comparing the values of Air Kerma (AK) between the Control and Fusion groups.

Figure III. Box plot figure comparing the numbers of digital subtraction angiography (DSA) per procedure between the Control and Fusion groups.