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ABSTRACT

Introduction: hybrid rooms (HR) provide advanced imaging capabilities within an optimal open surgical environment. The technology associated with hybrid rooms facilitates endovascular navigation and enhances technical success during endograft implantation and other endovascular procedures. However, radiation exposure remains a significant concern.

Objective: this study aims to compare the recommended national Diagnostic Reference Levels (DRLs) with the local DRLs of a tertiary hospital.

Material and methods: a retrospective study was conducted on patients undergoing endovascular aortic repair (EVAR) from January 2016 to September 2022. Patient demographics, radiation dose, type of C-arm, and contrast use were analyzed.

Results: a total of 245 patients were included: 136 in the MCA group (Group 1) and 109 in the HR group (Group 2). Patients in Group 2 received double the mean kerma air product compared to Group 1 (112.29 Gy·cm² vs. 53.8 Gy·cm², $p < 0.001$), as well as a higher cumulative air kerma (361.11 mGy vs. 221.40 mGy, $p < 0.001$) and greater contrast volume (71.45 mL vs. 64.71 mL, $p = 0.039$).

Conclusions: patients undergoing EVAR in the HR with fixed imaging received higher KAP and contrast doses compared to those treated with a mobile C-arm. However, radiation exposure and contrast usage remained below national Diagnostic Reference Levels.

Keywords: Abdominal aortic aneurysm. Endovascular aneurysm repair. Diagnostic reference levels. Radiation dose.

RESUMEN

Introducción: las salas híbridas ofrecen capacidades avanzadas de imagen dentro de un entorno quirúrgico abierto óptimo. La tecnología asociada a las salas híbridas facilita la navegación endovascular y mejora el éxito técnico en la implantación de endoprótesis y en otros procedimientos endovasculares. No obstante, la exposición a la radiación sigue siendo una preocupación relevante.

Objetivo: comparar los niveles de referencia de dosis nacionales recomendados con los locales de un hospital terciario.

Material y métodos: se realizó un estudio retrospectivo en pacientes sometidos a reparación endovascular del aneurisma de aorta abdominal (EVAR, por sus siglas en inglés) entre enero de 2016 y septiembre de 2022. Se analizaron las características demográficas de los pacientes, la dosis de radiación, el volumen de contraste utilizado y el tipo de arco en C: arco en C móvil o sala híbrida.

Resultados: se incluyeron un total de 245 pacientes: 136 en el grupo de arco en C móvil (grupo 1) y 109 en el grupo de sala híbrida (grupo 2). Los pacientes del grupo 2 recibieron una dosis de radiación significativamente mayor en comparación con los del grupo 1 en términos de “producto-dosis-área” (112,29 Gy·cm^2 frente a 53,8 Gy·cm^2, $p < 0,001$), así como kerma acumulado en aire (361,11 mGy frente a 221,40 mGy, $p < 0,001$) y un mayor volumen de contraste (71,45 mL frente a 64,71 mL, $p = 0,039$).

Conclusiones: los pacientes sometidos a EVAR en la sala híbrida recibieron dosis más altas de radiación en comparación con aquellos tratados con un C-arm móvil. Sin embargo, la exposición a la radiación y el uso de contraste se mantuvieron por debajo de los niveles de referencia de dosis nacionales.

Palabras clave: Aneurisma de aorta abdominal. Reparación de aneurisma endovascular. Niveles diagnósticos de referencia. Dosis de radiación.

INTRODUCTION

Over the past two decades, advancements in endovascular devices, X-ray equipment, and techniques have significantly transformed the management of vascular diseases, with endovascular aortic repair (EVAR) becoming a prominent procedure.

Multiple strategies have been implemented to mitigate radiation exposure, including modern X-ray equipment and hybrid operating rooms (HR) with enhanced imaging capabilities. However, limited published data exist on the impact of these systems on radiation exposure, and fixed systems are still reported to be associated with higher radiation levels compared to mobile C-arms (MCA) (1-6). Despite these advancements, the increased use of ionizing radiation during EVAR poses substantial risks to both patients and healthcare providers.

Given the growing popularity of endovascular aortic interventions, ensuring optimal safety protocols and equipment in surgical environments is crucial. One such strategy is the establishment of Diagnostic Reference Levels (DRLs) to optimize radiological exposure (1,7). The aim of this study is to compare the recommended national DRLs with the local radiation dose in a tertiary hospital.

METHODS

This retrospective comparative study analyzed all patients who underwent EVAR at a tertiary care hospital between January 2016 and September 2022. The patients were divided into two groups: Group 1 included those who underwent EVAR in a conventional operating room with mobile C-arm (MCA), while Group 2 comprised patients who underwent EVAR in a hybrid room (HR).

Inclusion and exclusion criteria

All patients with infrarenal aortic aneurysms with neck lengths greater than 10 mm were treated with scheduled or urgent EVAR performed with MCA or HR during the study period.

The exclusion criteria were Patients without recorded radiation dosage, patients with juxtarenal or pararenal aneurysms requiring more complex procedures and patients who refuse informed consent.

Data collection

Data were collected from medical records and radiation dose reports. All patients underwent preoperative angiographic computed tomography (angioCT) for surgical planning on a 3D workstation. Procedures were performed under either general or local anesthesia. All procedures were performed in accordance with ALARA ("As Low as Reasonably Achievable") principles.

Both dosimetric and non-dosimetric parameters were recorded, including kerma area product (KAP), cumulative air kerma (CAK), fluoroscopy time (FT), contrast volume, and the type of arterial approach described as percutaneous or open. The procedures were distributed according to their complexity, based on their technical difficulty and patient anatomy. This classification has been described in our published protocol (8) (Table I).

Table I. Complexity levels of endovascular aortic aneurysm repair

Medium Complexity
1. An arterial approach without incidents (open or percutaneous) 2. Non-hostile anatomy (neck length >15 mm and/or neck diameter < 32 mm, length of iliac arteries > 15 mm and/or diameter < 20 mm) 3. Implantation of the device without incident 4. Easy catheterization of the contralateral limb 5. Absence of endoleaks in the final angiographic control (except type II)
High complexity
1. Complication of the arterial access (open or percutaneous)

2. Hostile anatomy (neck length < 15 mm and/or neck diameter > 32 mm, length of iliac arteries < 15 mm and/or diameter > 20 mm)
3. Complex catheterization of the contralateral limb requiring extra procedures (for example, single-loop snare)
4. Additional procedures for endoleak treatment (such as central cuff extension or additional iliac limb)
5. Additional procedures as embolization of inferior mesenteric/internal iliac artery, placement of endo-anchor, etc.
6. Chimney or snorkel technique
7. Fenestrated or branched aortic endograft
8. Iliac branch

Equipment

All interventions were performed by a team of 1-2 experienced vascular surgeons in two different surgical settings: a hybrid room (HR) equipped with a fixed C-arm (Philips Azurion 7®, Philips Healthcare, Best, The Netherlands) and a standard operating room with a radiolucent table, utilizing a mobile C-arm (MCA) Zenition 70® (Philips Healthcare, Best, The Netherlands). The same team of surgeons operated in both settings. Additionally, the hospital's physics department conducts regular evaluations of all radiological equipment to ensure compliance with safety standards and optimal performance.

Statistical analysis

Data were entered and analyzed using RStudio 4.2.2. The Shapiro-Wilk test was applied to all continuous variables to assess normality. As the results were $p < 0.05$, the data did not follow a normal distribution, requiring the use of non-parametric tests, such as the

Mann-Whitney U test. For categorical variables, Chi-square tests were performed. A P-value < 0.05 was considered statistically significant.

RESULTS

During this period, 283 infrarenal aorta EVARs were performed. Two hundred and forty-five met the inclusion criteria and were included in the study cohort. The number of cases performed per year are shown in figure 1. There were 136 patients in Group 1 (MCA, 2016 to 2020) and 109 in Group 2 (HR, 2019-2022).

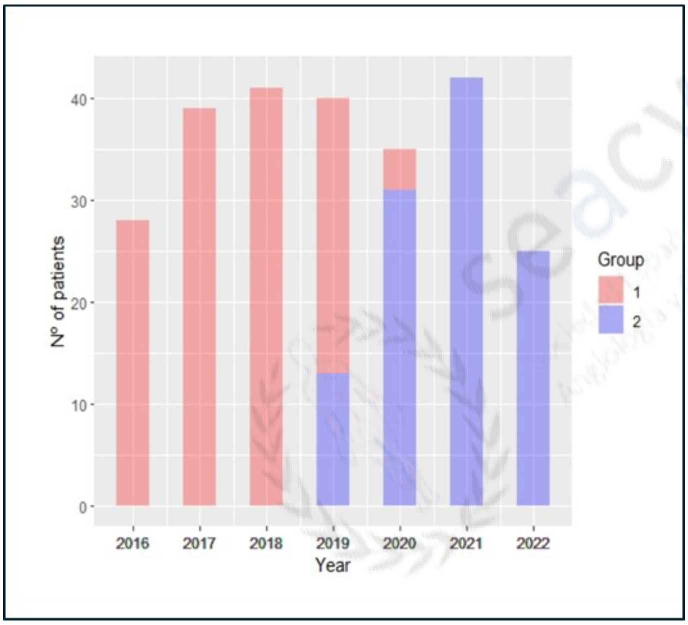

Figure 1. Number of EVARs performed per year.

There were no differences noted in the demographic details of the patients, except for a higher level of hemoglobin in group 2 (9,51g/dL vs. 11,99g/dL, p = 0,028) (Tables II and III).

Variables	**Group 1 (*n* = 136)**	**Group 2 (*n* = 109)**	***p***
Age (years) (95 % CI)	75.16 ± 7.13	75.30 ± 6.78	NS (0.21)
Male gender (%)	53.06	43.27	NS (0.73)
Currently smoking (%)	13.47	11.02	NS (1.00)
Diabetes mellitus (%)	10.61	10.61	NS (0.45)
Hypertension (%)	42.86	34.69	NS (1.00)
Ischemic heart disease (%)	21.63	15.51	NS (0.60)
COPD (%)	16.33	11.02	NS (0.34)
Dyslipidemia (%)	33.47	27.35	NS (0.96)
Chronic kidney failure (%)	13.47	9.80	NS (0.80)
Hematocrit (%)	38.03 ± 8.84	37.34 ± 10.19	NS (0.21)
Hemoglobin (g/dL)	9.51 ± 3.29	11.94 ± 2.35	**0.028**
Creatinine (µmol/L)	128.02 ± 89.65	117.73 ± 77.37	NS (0.43)
Glomerular function (mL/min/1.73 m2)	56.67 ± 20.80	59.88 ± 21.76	NS (0.42)

Data are presented as percentages, and as mean ± standard deviation (SD). NS: not significant; COPD: Chronic Obstructive Pulmonary Disease.

Table III summarizes the variables related to the procedure comparing MCA and hybrid room.

Table III. Comparison of data related to EVAR procedure between the MCA group (Group 1) and HR group (Group 2).

Variables	**MCA (n = 136)**	**HR (n = 109)**	***p***
Bi-iliac (%)	43.72	34.46	NS (0.33)
Uni-iliac (%)	9.72	6.07	NS (0.47)
Others (%)	1.62	0.40	NS (0.65)
Percutaneous femoral access (%)	14.17	31.98	**< 0.001**
Length of hospital stay (days)	6.29 ± 9.82	5.62 ± 7.19	**0.03**
Local anesthesia (%)	**10.53**	**7.29**	NS (0.67)

Data are presented as percentages, and as mean ± standard deviation (SD). NS: not significant.

General radiographic data

Mean KAP in the MCA was lower compared to the HR (53,80 Gy·cm^2 vs. 112,29 Gy·cm^2, p < 0,001). Furthermore, the MCA group received less mean cumulative air kerma compared to HR group (221,40 mGy vs. 361,11 mGy, p < 0,001) and less mean contrast volume (64,71mL vs. 71,45 mL, p < 0,039) (Table IV).

Variables	**MCA (n = 136)**	**HR (n = 109)**	***p***
KAP total (Gy·cm^2)	53.80 ± 39.92	112.29 ± 110.37	**< 0.001**

Cumulative AK (mGy)	221.40 ± 183.95	361.11 ± 312.39	**< 0.001**
Fluoroscopy time (s)	1339.30 ± 910.65	1480.30 ± 1030	NS (0.35)
Contrast volume (mL)	64.71 ± 27.72	71.45 ± 29.43	**0.049**

Data are presented as percentages, and as mean ± standard deviation (SD). NS: not significant.

Table V. represents the comparison of radiographic variables related to the complexity of the procedures in both C-arms. The mean KAP was significantly higher in HR compared to MCA.

Median complexity			
Variables (mean. SD)	**MCA (*n* = 83)**	**HR (*n* = 59)**	***p***
KAP total (Gy·cm²)	39.02 ± 27.40	69.48 ± 47.52	**< 0.001**
Cumulative AK (mGy)	219.85 ±137.14	240.56 ± 164.02	0.542
High complexity			
Variables (mean. SD)	**MCA (*n* = 53)**	**HR (*n* = 50)**	***p***
KAP total (Gy·cm²)	80.91 ± 58.97	162.63 ± 143.43	**< 0.001**
Cumulative AK (mGy)	323.68 ± 265.13	494.97 ± 388.01	**0.042**

Data are presented as percentages, and as mean ± standard deviation (SD). NS= not significant.

Radiographic data in relation with DRLs

Subsequently, the data were compared with the Diagnostic Reference Levels (DRLs) established in the study by Rial et al. (8). This comparison is shown in table VI for both the C-arms.

Variables	**MCA**		**HR**	
	Our study (*n* = 136)	**National DRLs (8)**	**Our study (*n* = 109)**	**National DRLs (8)**
Mean age (years)	75.16	77	75.30	75
Mean KAP total (Gy·cm^2)	53.80	80	112.29	333
Mean Cumulative AK (mGy)	221.40	307	361.11	1.404
Mean Fluoroscopy time (s)	1339.30	1761	1480.30	2052
Mean contrast volume (mL)	64.71	124	71.45	95

DISCUSSION

This study shows that patients undergoing EVAR in an HR received nearly double the radiation compared to a mobile C-arm. It also revealed that procedures performed in an HR require higher cumulative AK and contrast volume.

Following the inauguration of the HR in September 2019, priority was initially given to scheduling procedures in the HR to enhance image quality and streamline workflow. However, shortly afterward, scheduled procedures were paused due to the COVID-19 pandemic, which disrupted regular interventions. Regarding demographic data, a higher hemoglobin level was observed in procedures performed in Group 2. This may be attributed to the implementation of the ERAS (Enhanced Recovery After Surgery) protocol in September 2021, which includes, among other measures, improved blood management for all surgical patients (9).

Furthermore, it is notable that the HR group underwent more percutaneous access procedures and had a shorter hospital stay than the C-arm group. The ERAS program in AAA surgery could account for the reduced hospital stay duration in the HR group.

Regarding dosimetric parameters, several studies have described higher KAP levels in HR compared to MCA. However, with proper adherence to ALARA principles and the routine application of fusion imaging guidance for EVAR, radiation exposure may be reduced (3).

Our results align with the findings of Kendrick et al. (11), who reported a five-fold increase in radiation exposure in cases performed with an HR compared to a mobile C-arm system. These results, however, differ from those of Rehman et al. (12), who reported lower radiation exposure in HR than in MCA. This discrepancy may be attributed to the exclusion of high-complexity EVAR procedures in their analysis.

Additionally, we observed that more complex procedures were performed in the HR than in the MCA. This difference in patient selection could partially explain the discrepancy between our study and that of Rehman et al. (12), who excluded data from the initial 18 months of the HR program to mitigate the ‘learning curve’ effect. In contrast, our study included data from all patients, which may also contribute to the differing results.

Regarding procedural complexity, HR consistently demonstrated higher radiation doses than MCA across all complexity levels. Therefore, HR does not have higher radiation doses solely due to the performance of more complex procedures. Kendrick et al. (11)

observed a similar trend in scattered radiation between HR and mobile C-arm systems, suggesting that a MCA imaging system could be used for less complex procedures to reduce radiation exposure while maintaining comparable surgical outcomes. However, it is important to note that Kendrick et al.'s study did not analyze EVAR procedures.

A direct statistical comparison with the study by Rial et al. (8) was not possible due to a lack of access to their database. However, our results demonstrated significantly lower radiation dose levels, even when including the learning curve stage. The age distribution in both studies was similar.

Our findings showed lower radiation values across all DRLs categories. Notably, the total KAP and cumulative AK in the HR were approximately one-third of the values reported in the national DRLs for the same equipment, while MCA procedures exhibited approximately 32.75 % lower radiation levels. The mean contrast volume was also comparatively lower in our study than in the results of Rial et al. (8), particularly in MCA, reducing potential nephrotoxic risks. However, these results could be further improved by diluting the contrast with physiological saline solution.

These findings suggest improvements in procedural efficiency and safety, likely due to advancements in equipment and refined operator techniques compared to national DRLs standards. Regular updates to the DRLs should be implemented to continuously lower dose thresholds, reflecting ongoing technological advancements and further enhancing patient safety during vascular procedures.

STUDY LIMITATIONS

This study has inherent limitations associated with its retrospective design. Another limitation is the learning curve during the first 24 months following HR implementation. Additionally, the possibility that more complex procedures were preferentially performed in the HR should be considered, as this may have influenced both dosimetric and procedural outcomes.

CONCLUSIONS

Our results suggest that patients undergoing EVAR in HR may be exposed to up to twice the radiation dose and require greater contrast volume compared to MCA. Radiation dose tends to increase with procedural complexity, particularly in the HR group. However, radiation exposure and contrast usage were lower than national DRLs values.

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