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National Diagnostic Reference Levels for Standard Descending Thoracic Endovascular Aortic Repair and Optimisation Strategies

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WHAT THIS PAPER ADDS

The International Commission on Radiological Protection has highlighted the lack of radiation protection programmes in various medical specialties. Thoracic endovascular aortic repair (TEVAR) is a complex procedure necessitating radiation protection guidance. This paper establishes national diagnostic reference levels (DRLs) for TEVAR using both mobile and hybrid Xray systems, recommends optimisation measures, and highlights the increased DRL factors in hybrid rooms compared with mobile Xray systems. It also emphasises the importance of dose audits to enhance imaging protocols.

Objective: The International Commission on Radiological Protection has highlighted the large number of medical specialties that use fluoroscopy outside diagnostic imaging departments without radiation protection programmes for patients and staff. Vascular surgery is one of these specialties. Thoracic endovascular aortic repair (TEVAR) is a complicated procedure requiring radiation protection guidance and optimisation. The recent EU Basic Safety Standards Directive requires the use and periodic updating of diagnostic reference levels (DRLs) for interventional procedures. The aim of this study was to determine doses for patients undergoing TEVAR with mobile Xray systems and hybrid rooms (fixed Xray systems) to obtain national DRLs and to suggest optimisation actions.

Methods: This was a retrospective cross sectional study. The Spanish Chapter of Endovascular Surgery conducted a national survey in 11 autonomous communities representing around 77.6% of the Spanish population (47.33 million inhabitants). A total of 266 TEVAR procedures from 17 Spanish centres were analysed, of which 53.0% were performed in hybrid operating rooms. National DRLs were obtained and defined as the third quartile of the median values from the different participating centres.

Results: The proposed national DRLs are: for kerma area product (KAP), 113.81 Gy·cm^2 for mobile Xray systems and 282.59 Gy·cm^2 for hybrid rooms; and for cumulative air kerma (CAK) at the patient entry reference point, 228.38 mGy for mobile systems and 910.64 mGy for hybrid rooms.

Conclusion: Based on the requirement to know radiation doses for standard endovascular procedures, this study of TEVARs demonstrated that there is an increased factor of 2.48 in DRLs for KAP when the procedure is performed in a hybrid room compared with mobile C-arm systems, and an increased factor of 3.98 in DRLs for CAK when the procedure is performed with hybrid equipment. These results will help to optimise strategies to reduce radiation doses during TEVAR procedures.

Keywords: Diagnostic reference level, DRL, European Directive, Optimisation, Patient dose, TEVAR
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INTRODUCTION

The International Commission on Radiological Protection (ICRP) has drawn attention to the large number of medical specialties that use fluoroscopy for diagnostic and therapeutic purposes without adequate radiation protection programmes for patients and staff, which includes vascular surgery.[1] One of the examples of procedures requiring more attention to radiation safety is endovascular aneurysm repair (EVAR). The ICRP recognises that there is a substantial need for radiation protection guidance, due to the increased use of radiation in this surgical specialty and the lack of radiation safety training.[1] In 2020, the Spanish Chapter of Endovascular Surgery (SCES) published the Spanish national diagnostic reference levels (DRLs) for EVARs and optimisation strategies to improve radiation protection.[2] It should also be noted that the European Directive on Basic Safety Standards for protection against the dangers arising from exposure to ionising radiation[3] is mandatory for all the Member States in the European Union (EU). This directive contains the obligation of using DRLs for interventional procedures. The EU Member States shall ensure the establishment and regular review of DRLs as well as the appropriate investigation whenever DRLs are exceeded.

The ICRP initially proposed DRLs in 1990[4] and they were later refined in several publications[5] and updated in 2017 with ICRP publication 135 on diagnostic reference levels in medical imaging.[6]

A DRL is a form of investigation level to identify unusually high patient dose levels, which calls for local review if consistently exceeded. In principle, there could also be a lower level (i.e., below which there is insufficient radiation dose to achieve a suitable medical image or diagnostic information). To determine whether protection has been adequately optimised, any local review should include the protocols used during the clinical procedures and the equipment setting. For interventional practices, it is recommended to consider complex procedures and their impact on patient dose values. In addition, DRLs should not be applied to individual patients or considered as a dose limit. A DRL can be used to improve a regional, national, or local distribution of results observed for a general medical imaging task. The aim is to reduce the frequency of unjustified high or low dose values.[7,8]

This study aimed firstly to report the results of a survey carried out by the SCES to collect patient dose values for standard thoracic endovascular aortic repair (TEVAR) procedures and to suggest initial national DRLs; and secondly to formulate some optimisation actions to help improve the radiation protection aspects in hospitals and for future updates of national DRLs.

MATERIALS AND METHODS

Study design

The SCES launched a working group (Spanish DRLs Vascular Collaborators Group) to address these issues and the impact of the implementation of the new EU regulations. The working group prepared a national survey to collect patient doses for TEVAR procedures, to analyse differences between the hospitals involved (and between mobile Xray systems and hybrid rooms), and to suggest optimisation actions. The term mobile C-arm refers to mobile image flat panels in the operating room that are able to set a wide range of possible setups and with high flexibility, but not able to perform 3D fusion. A hybrid room refers to an operating room with a high performance imaging system with the latest processing software applications to perform 3D fusion and the possibility of intra-operative C-arm computed tomography. A data collection sheet was designed based on a previous publication[2] and modified according to specific TEVAR procedure characteristics, and was shared within participating centres to collect demographic data, indication, and precise radiation exposure measurements.

The survey included patient dose values from consecutive elective TEVAR procedures performed during 2018 — 2020 at 17 different hospitals with tertiary characteristics. The procedures included standard endovascular treatment of the descending thoracic aorta from the subclavian artery to, at most, the coeliac trunk. The indication for TEVAR was classified into three categories: aortic dissection, thoracic aneurysm, and blunt traumatic aortic injury. To achieve a homogeneous sample, urgent, fenestrated, multistenting, or procedures with chimney or snorkel techniques were not included. Data on age, sex, number of stents deployed, and type of stent were also collected.

Specific training and certification in radiation protection has been required in Spain since 1999[9] for all medical specialists (included vascular surgeons) performing interventional procedures guided by fluoroscopy.[10]

In addition to the SCES initiative to conduct a national survey to collect dose values for patients undergoing TEVAR, some hospitals are conducting pilot activities on staff protection using active electronic dosimeters.[11] The aim is to obtain data on occupational lens doses to prevent cataracts induced by prolonged exposures during endovascular procedures and to assist in global optimisation strategies managing together the patient and occupational dose values as recommended.[12]

The total population of Spain is currently 47.33 million inhabitants and the survey carried out by the SCES involved 11 autonomous communities (from a total of 17) representing around 77.6% of the Spanish population, of which all were public and university hospitals.

The data collected included age, body mass index (weight and height), kerma area product (KAP) in $Gy \cdot cm^2$ (total and for fluoroscopy mode), cumulative air kerma (CAK) in mGy, fluoroscopy time, and contrast volume. The initial national DRLs have been obtained, as recommended by the ICRP, as the third quartile of the median values from the different centres involved in the survey.[3,6] Data from mobile Xray systems were available from five hospitals, and data from hybrid rooms (fixed Xray systems) were available from four hospitals, whereas eight hospitals reported data both for mobile C-arm and hybrid rooms. All hospitals included dosimetric data from at least 15 consecutive treated patients.

Statistical analysis

Data were anonymised and processed at the Vascular Surgery Unit of University Hospital of Valladolid (Valladolid, Spain). All the ethics committees of the different participating hospitals in the study approved this work. Continuous data are presented as the mean ± standard deviation (SD) or median.

A descriptive univariable analysis was conducted wherein quantitative variables were summarised using mean and SD, respectively. Categorical variables were expressed through percentages. The descriptive univariable analysis provided a comprehensive overview of the dataset. The mean and SD for quantitative variables offers insights into the central tendency and variability, while the frequency distribution and percentages for categorical variables reveals the distribution across different categories. Statistical analysis was carried out using IBM SPSS Statistics Version 29.0 (IBM Corp., Armonk, NY, USA).

RESULTS

The total sample in the survey was 266 procedures: 141 in hybrid rooms (from 12 hospitals) and 122 with mobile C-arms (from 13 hospitals); data were missing for 3 cases. Among the patients treated, 72.9% were men and the mean patient age was 67.54 ± 22.77 years. The most frequent indication for TEVAR was thoracic aortic dissection with 157 cases (59.0% of the cases treated), followed by thoracic aneurysm with 73 patients (27.4%) and traumatic thoracic aortic rupture with 12 cases (4.5%); data were missing for the remainder of the cases. Regarding the number of implanted stent grafts, most patients were treated with one stent (54.9%), followed by 30.8% with two stent grafts, and 8.6% requiring three or more stent grafts; the number of stent grafts was unknown or not specified for 5.7%. In this sample, five different aortic thoracic endoprosthesis devices were deployed, namely Zenith Alpha Thoracic Endovascular Graft (Cook Medical Inc., Bloomington, IN, USA), GORE TAG Conformable Thoracic Stent Graft (W.L. Gore & Associates, Newark, DE, USA), Evita Thoracic 3G Endovascular Stent Graft (Jotec GmbH, Hechingen, Germany), Valiant Medtronic Stent Graft (Medtronic, Minneapolis, MN, USA), and RelayPro (Cardiva-Bolton, Sunrise, FL, USA). No differences were found regarding dosimetric values between different manufacturers.

The median values of patient doses were obtained independently for mobile C-arms and hybrid rooms with fixed Xray systems (Table 1).

The two main dosimetric quantities for patient doses were analysed, namely: KAP (also known as the dose area product) and CAK at the patient entrance reference point. These are the main quantities recommended by the ICRP to set DRLs for interventional procedures (Table 2).[5]

It should be noted that TEVAR procedures performed using hybrid rooms resulted in national DRL values for KAP 2.48 times higher than DLRs in mobile Xray systems (282.59 Gy·cm^2 *vs.* 113.81 Gy·cm^2), and in DRLs for CAK 3.98 higher in hybrid rooms than using mobile Xray systems (910.64 mGy *vs.* 228.38 mGy). The results of patient doses obtained for TEVAR procedures are presented in Figures 1 and 2, and the calculated initial national DRLs are presented in Figures 3 and 4.

The fluoroscopy time and volume of contrast used in the different procedures performed with mobile C arms and in hybrid rooms were also collected (Table 3; Fig. 5). Fluoroscopy time was slightly higher with mobile Xray systems. Contrast volume was markedly lower when the procedure was performed in a hybrid operating room, with the difference being statistically significant ($p < .001$).

DISCUSSION

This work is the first study published in relation to national DRLs in a standard TEVAR procedure. The survey evaluated standard, non-complex TEVAR procedures, excluding those procedures that required debranching or another associated endovascular procedure at the level of the digestive, renal, or mesenteric arteries in order to homogenise the sample so that heterogeneity would not affect the results obtained. These results showed consistently higher levels of DRLs for TEVARs in hybrid rooms compared with mobile Xray systems. This group previously published their results for EVAR,[2] and other authors have published studies on complex procedures in abdominal aortic aneurysm with visceral artery involvement.[13,14] With the increased use of endovascular procedures, radiation protection is an issue that has grown in importance.[15]

According to the previous study, an increased factor of 3.2 for KAP and 4.8 for CAK in DRLs was observed when TEVAR procedures were performed in hybrid rooms rather than with mobile Xray systems.[2] Both increases were also confirmed in the present study when TEVAR was performed in a hybrid room, but with a slightly smaller increase. These factors were reduced to 2.48 in the case of KAP for procedures in hybrid rooms and to 3.98 for CAK when TEVAR was performed in a hybrid room. In the current study,

Table 1. Values of patient doses obtained independently for mobile C-arms and hybrid rooms with fixed Xray systems in various hospitals in Spain.

Dose	C-arm	Hybrid room	*p* value
KAP, total − Gy·cm^2	113.81 ± 176.27	282.59 ± 324.49	<.001
KAP, fluoroscopy − Gy·cm^2	51.84 ± 103.65	100.95 ± 135.31	.027
CAK − mGy	228.38 ± 248.75	910.64 ± 1 180.97	<.001

Data are presented as mean ± standard deviation. KAP = kerma area product; CAK = cumulative air kerma.

Table 2. Total kerma area product (KAP) and cumulative air kerma (CAK) values of patient doses for mobile C-arms and hybrid rooms with fixed Xray systems in various hospitals in Spain.

	C-arm		Hybrid room	
	KAP – Gy·cm^2	CAK – mGy	KAP – Gy·cm^2	CAK – mGy
Mean	113.81	228.38	282.59	910.64
Median	51	149	171	528
SD	176.27	248.75	324.49	1 180.97
Minimum	7	23	14	39
Maximum	908	1 698	2 094	8 448
75th percentile	107.75	248.75	338	1 053

KAP = kerma area product; CAK, cumulative air kerma; SD = standard deviation.

hospital 7 exhibited higher levels of DRL compared with the other hospitals examined. It was chosen not to exclude any collected data, as we believe that including all data, even those that may appear unexpectedly high, more accurately reflects the diversity of clinical fluoroscopy practice.

In most studies and a meta-analysis carried out on radiation doses, it is observed that more modern and powerful equipment with more features, such as those installed in hybrid rooms, have higher KAP and CAK levels than C-arms.[16–21] Only limited data are available on the radiation dose associated with TEVAR. Haga *et al.*[22] explored the radiation dose indicators (KAP and CAK) delivered during TEVAR and EVAR performed in hybrid rooms and compared their results with seven previous similar studies. Their CAK levels for TEVARs were comparable with the current study. It must be remembered that better image quality, in most cases, means more radiation. However, other papers have not found differences between C-arms and hybrid rooms, although doses were lower in fixed equipment.[23] Some of the features in fixed equipment can contribute to dose reduction, such as post-processing digital image management, Xray settings, and image fusion. Proper training in the capabilities of the devices could reduce this gap between hybrid equipment and C-arms. The learning curve and the number of cases performed annually probably play a strong part in the dose levels reached in each centre.[24,25] Unfortunately, no study has specifically evaluated these factors, and they are not commonly reported. Regardless of the reasons for this dose difference between C arms and fixed equipment, the important thing is to set DRLs for each technology and therapeutic group.

The wide distribution of the obtained results suggests the need to standardise the criteria for TEVAR complexity. The ICRP recommends that the comparison with DRLs (and patient dose audits) should always be made using the median values of a representative sample of clinical procedures performed for a specific clinical task.[6]

It is important to determine the DRLs for endovascular procedures to protect patients from excessive radiation doses that could lead to serious complications. Vascular

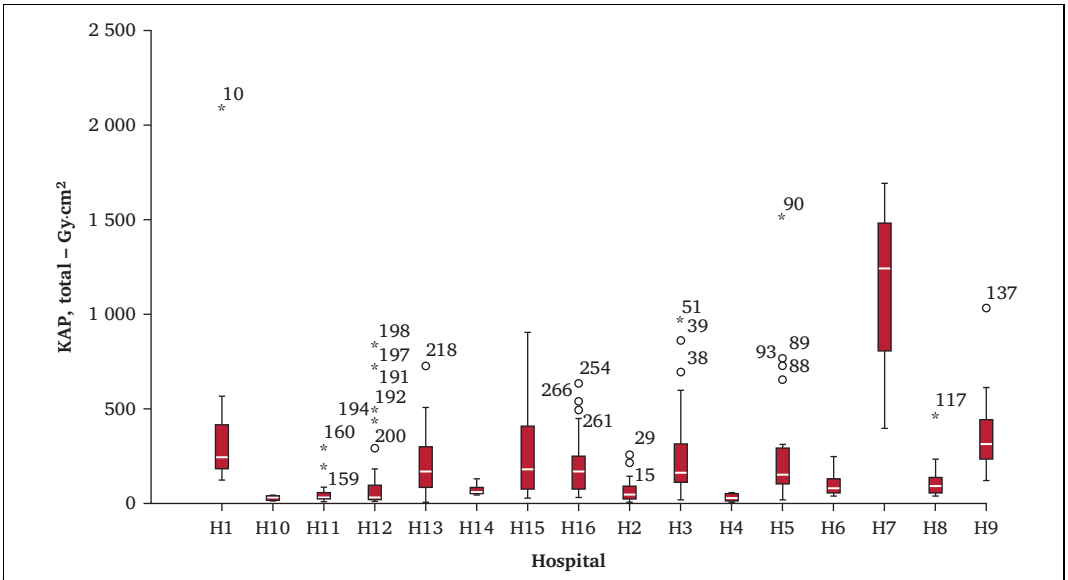

Figure 1. Boxplot showing total kerma area product (KAP) levels in different hospitals across Spain. Red boxes indicate the range, the horizontal lines indicate the median, and whiskers the quartiles. Potential outliers are shown as asterisks (*).

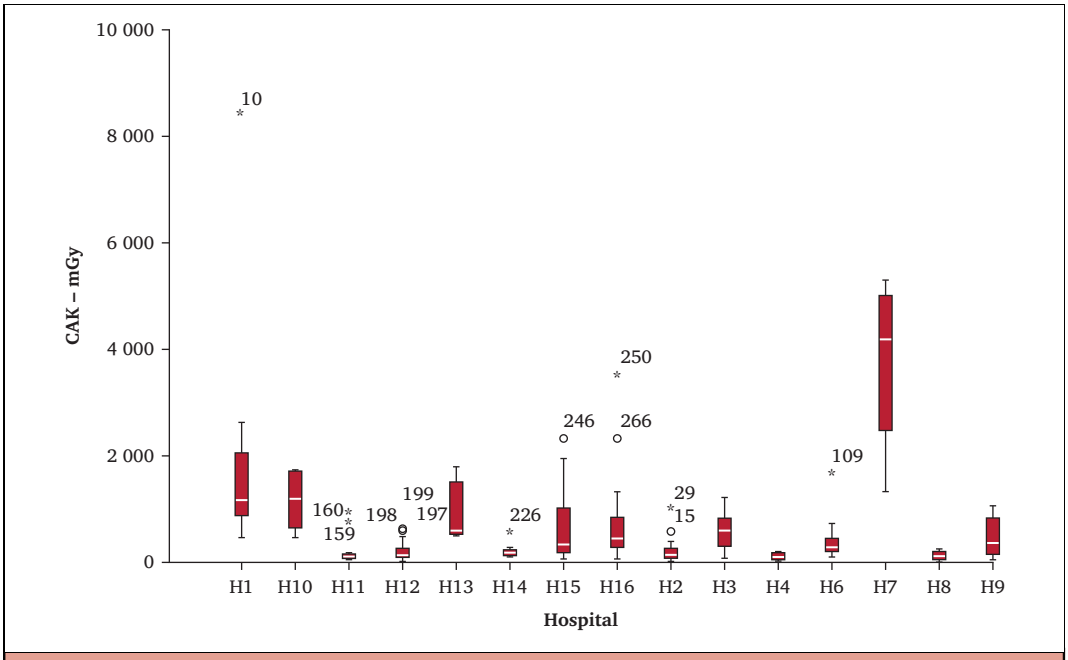

Figure 2. Boxplot showing cumulative air kerma (CAK) doses in different hospitals across Spain. Red boxes indicate the range, horizontal lines indicate the median, and whiskers the quartiles. Potential outliers are shown as asterisks (*).

interventional procedures are associated with high doses of radiation, as demonstrated by Kuhelj *et al.*,[13] who evaluated the maximum skin doses of patients ($n = 7\,607$) undergoing interventional radiological procedures. All procedures that exceeded 3 Gy in CAK were vascular procedures, including hepatic radio-embolisation, transjugular intrahepatic portosystemic shunt, EVAR, adrenal venous sampling, TEVAR, and embolisation in the abdominal and or pelvic area.[13]

Kirkwood *et al.* showed that EVARs with fenestrated stent grafts were the cases with higher radiation doses; 34.42% of the cases reached a reference air kerma of 5 Gy, and 52% of patients had multiple endovascular procedures within six months of the substantial radiation dose level event.[14]

The benefit of new post-processing and patient dose reduction techniques is clear. Rohlffs *et al.* showed that the technological advances implemented for image noise reduction result in a reduction in the radiation absorbed by the patient and professionals during complex endovascular procedures.[26]

Budtz-Lilly *et al.* analysed the relationship between the number of catheterised vessels and multiple operative

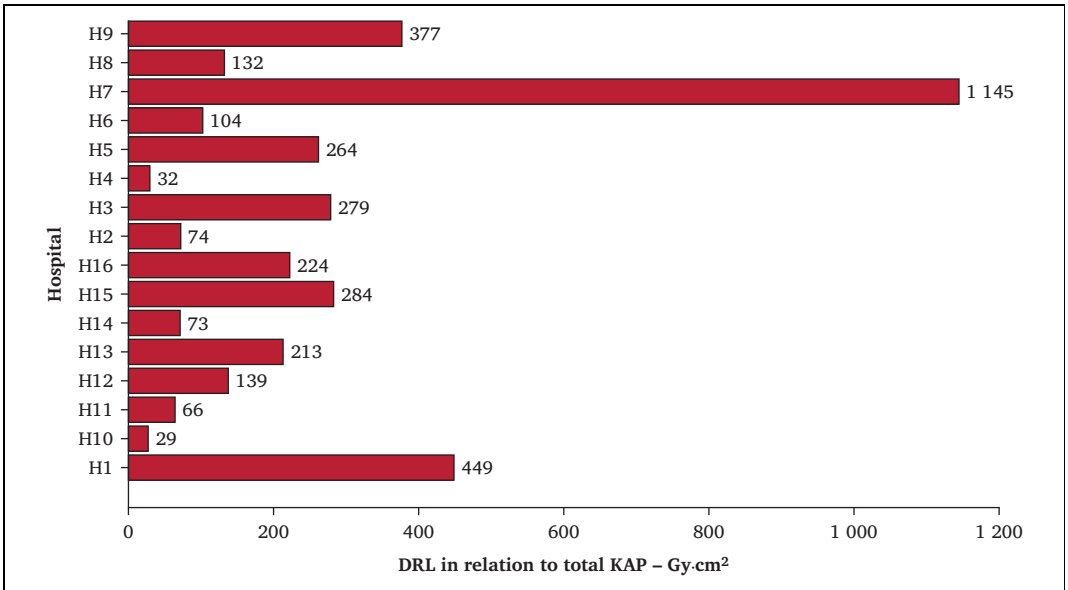

Figure 3. Calculated diagnostic reference levels (DRLs) in relation to total kerma area product (KAP) in different hospitals across Spain.

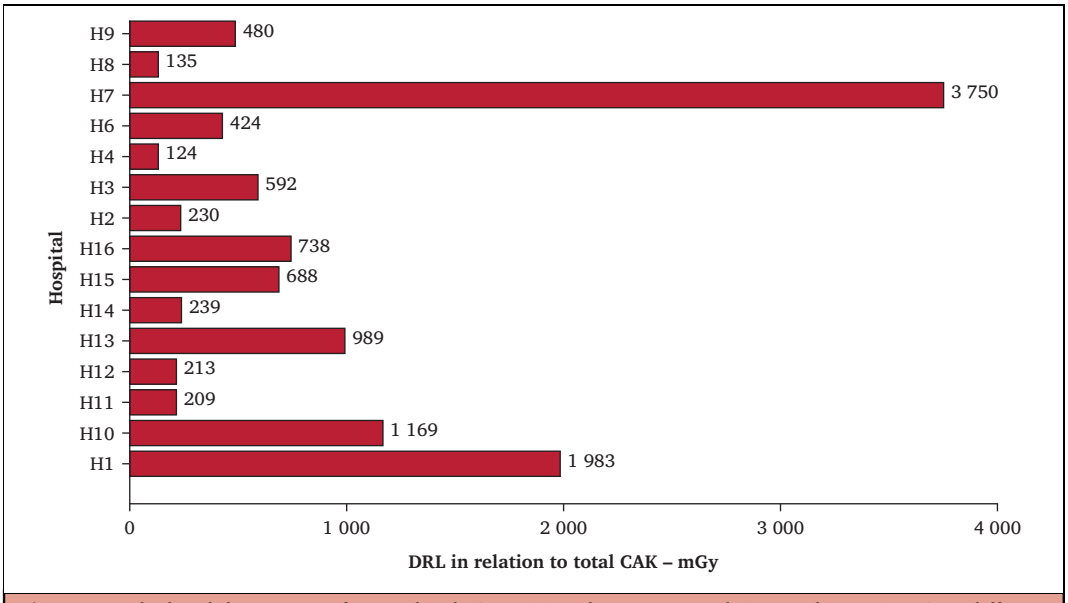

Figure 4. Calculated diagnostic reference levels (DRLs) in relation to cumulative air kerma (CAK) in different hospitals across Spain.

variables as a means of evaluating procedural complexity (contrast volume, fluoroscopy duration, number of angiography series, etc.).[27] One of the relevant aspects to be considered when comparing patient dose values is that the diagnostic information and the image documentation of the procedures that can be obtained in hybrid rooms is much better than those obtained in mobile Xray systems.

Vascular surgery societies should define criteria for justification, balancing these improvements in diagnostic information with the increases in patient doses. Recently, the European Society for Vascular Surgery (ESVS) has published a crucial clinical practice guideline in radioprotection safety.[28] Based on international consensus, TEVAR procedures should be differentiated into a variety of complexities. This could provide the opportunity to compare patient dose values when setting DRLs and to establish different DRL values for mobile Xray systems and hybrid rooms. Perhaps the use 3D image fusion should be considered as one of the options to reduce patient doses, and to have specific DRLs when using this imaging modality. An important aspect to emphasise is the need to perform analysis in complex procedures, which should be considered in the future, and the medical societies should define criteria to score the complexity and to determine the impact on patient dose values.

The defined DRLs should not be used straightaway in other settings, but each country or region should develop their own DRLs. It is hoped that this work could be an inspiration and benchmark for other countries in Europe.

Table 3. Values of fluoroscopy time and contrast volume obtained independently for mobile C-arms and hybrid rooms with fixed Xray systems in various hospitals in Spain.

	C-arm	Hybrid room	*p* value
Fluoroscopy time − s	1 016.08 ± 783.79	998.03 ± 878.56	.86
Contrast volume − mL	140.55 ± 114.86	80.30 ± 61.69	<.001

Data are presented as mean ± standard deviation.

Study limitations

This study had some limitations. Firstly, it was a retrospective study on a limited number of cases. However, DRLs are obtained retrospectively. They are a snapshot of how we are acting in daily clinical practice, without introducing

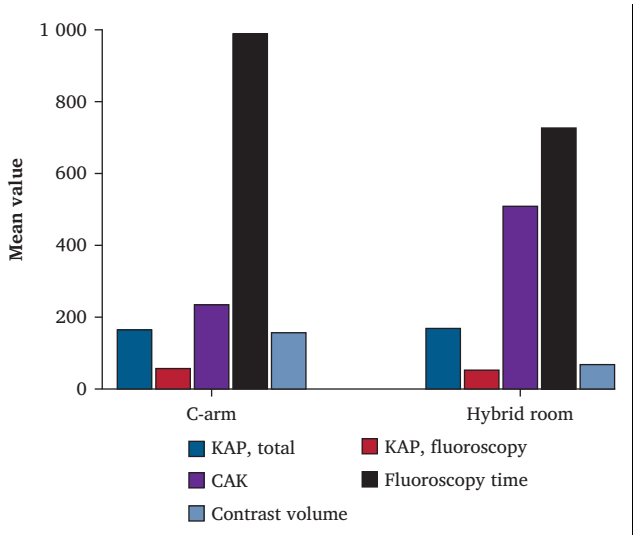

Figure 5. Mean total kerma area product (KAP; in Gy·cm^2), KAP for fluoroscopy (in Gy·cm^2), cumulative air kerma (CAK; in mGy), fluoroscopy time (in seconds), and contrast volume (in millilitres) in mobile C-arms and hybrid rooms with fixed Xray systems in different hospitals across Spain.

radioprotection actions that are not normally used, in order to implement those and at the same time serve as a reference to other similar communities. Secondly, this study evaluated standard, non-complex TEVAR procedures. Procedures that required debranching or another associated endovascular procedure at the level of the digestive, renal, or mesenteric arteries were excluded. Despite this, there was significant heterogeneity probably attributed to some degree of variability in equipment used, procedures performed, and methods to acquire the exposure values. This also highlights the importance of defining national reference levels for endovascular procedures in order to provide vascular surgeons with an approximation of acceptable levels of radiation for standard TEVARs and to implement strategies to reduce radiation when necessary.

Conclusions

From the patient dose data, TEVAR procedures performed in hybrid rooms resulted in national DRL values with a KAP 2.48 times higher than those obtained with mobile Xray systems (282.59 Gy·cm^2 *vs.* 113.81 Gy·cm^2), and the DRLs for CAK 3.98 higher in hybrid rooms (910.64 mGy *vs.* 228.38 mGy). The complexity of the procedures in patient radiation doses should be considered in the future update of DRLs. These data are valid for TEVAR procedures in Spain. Image optimisation strategies that allow radiation dose reduction should be one of the main priorities of optimisation strategies, which could help to reduce the differences found between the hospitals participating in the survey. For these optimisation actions, the support of medical physics experts is important, as indicated by European regulations.

ETHICAL STATEMENT

Data were anonymised and processed at the Vascular Surgery Unit of University Hospital of Valladolid (Valladolid, Spain). All the ethics committees of the different participating hospitals in the study approved this work.

CONFLICTS OF INTEREST

None.

FUNDING

None.

APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvs.2024.05.012.

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COUP D'OEIL

Endovascular Repair and Immunosuppressants as a Multidisciplinary Approach for an Often Forgotten Vasculitis

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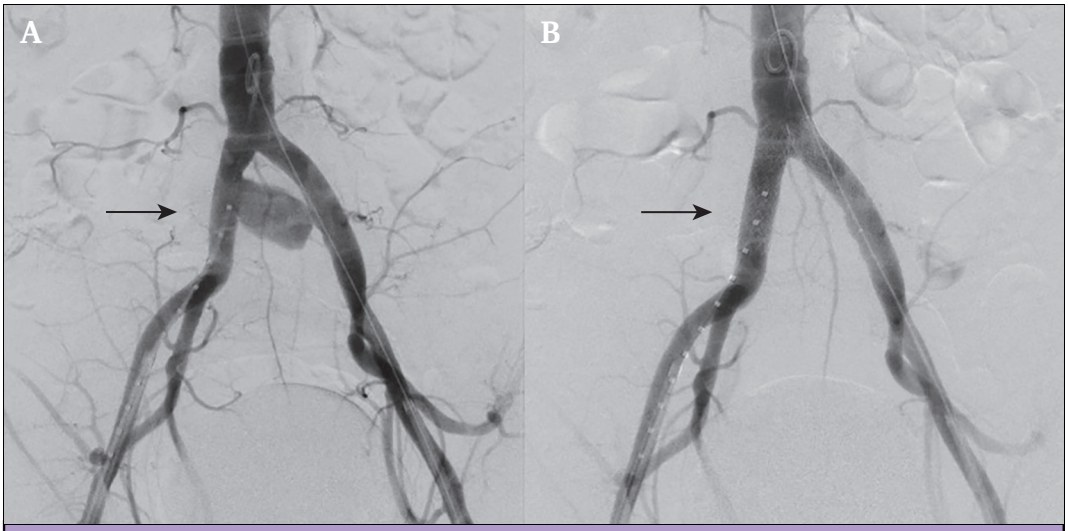

A 56 year old male with Adamantiades–Behçet disease presented with abdominal pain and weight loss. Computed tomography angiography revealed a saccular aneurysm of the right common iliac artery (29 × 27 × 42 mm), caused by underlying vasculitis given his personal history. Angiography (A) and endovascular repair using the kissing stenting technique (B) with 12 × 49 mm (right) and 12 × 42 mm (left) covered, balloon expandable Begraft stents (Bentley InnoMed GmbH, Germany) of both common iliac arteries was performed. Mycophenolate mofetil was stopped and high dose corticosteroids and cyclophosphamide were initiated to obtain remission. Seven months post-operatively, he remains asymptomatic with triphasic signals distally on duplex ultrasonography.

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