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Patient dose in angiographic interventional procedures: A multicentre study in Italy



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ABSTRACT

Purpose: The Council Directive 2013/59/EURATOM considers interventional radiology to be a special practice involving high doses of radiation and requiring strict monitoring to ensure the best quality assurance programs. This work reports the early experience of managing dose data from patients undergoing angiography in a multicentre study.

Materials and methods: The study was based on a survey of about 15,200 sample procedures performed in 21 Italian hospitals centres involved on a voluntary basis. The survey concerned the collection of data related to different interventional radiology procedures: interventional cardiology, radiology, neuroradiology, vascular surgery, urology, endoscopy and pain therapy from a C-Arm and fixed units. The analysis included 11 types of procedures and for each procedure, air-kerma, kerma-area product and fluoroscopy time were collected.

Results: The duration and dose values of fluoroscopic exposure for each procedure is strongly dependent on individual clinical circumstances including the complexity of the procedure; the observed distribution of patient doses was very wide, even for a specified protocol. The median values of the parameters were compared with the diagnostic reference levels (DRL) proposed for some procedures in Italy (ISTISAN) or internationally. This work proposes local DRL values for three procedures.

Conclusion: This first data collection serves to take stock of the situation on patient's dosimetry in several sectors and is the starting point for obtaining and updating DRL recalling that these levels are dependent on experience and technology available.

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1. Introduction

Interventional radiology is a non-invasive technique used in various fields of medicine to diagnose or treat numerous diseases of the heart, brain, and vascular, urogenital and musculoskeletal systems. When the interventions are long and complex, the radiation dose to the patient could exceed the threshold of tissue reactions [1–4]; the patient's skin, in particular, receives the highest dose, leading to undesirable effects [5,6]. The threshold value for the first reaction of the skin, erythema, is 2 Gy [7]. As far as concerns effects on the crystalline lens (cataract), the International Commission of Radiological Protection (ICRP) has set an induction threshold of 0.5 Gy [8]. Lens opacities and cataracts may be induced during neurointervention procedures [9–11].

It is also important to consider the risk of inducing stochastic effects, especially for low-dose exposures [12]. It is, therefore, useful to define an optimization process, which is the key to ensuring high-quality procedures and high levels of protection for the patient and staff involved.

The ICRP was the first body to introduce the term diagnostic reference level (DRL) and, in 2007, recommended the introduction of these levels for interventional procedures [13]: their introduction and use in clinical practice has contributed and will continue to contribute to raising the level of optimization of radiological techniques.

The European Directive 2013/59/EURATOM of December 5, 2013 [14] underscores the need for justification of exposure to radiation, emphasizes the importance both of recording the doses to which patients are exposed during clinical exposures and of using reference levels, and extends their application to interventional radiology, a rapidly developing practice that represents one of the most critical scenarios for protection from radiation.

Some European countries have already introduced DRL for some frequent interventional procedures that benefit from fluoroscopic guidance. In Italy it was considered important to provide a set of DRL values for national radiological practice, including interventional procedures, derived mainly from studies recently conducted in Italy by scientific associations and the National Institute of Health (Istituto Superiore di Sanità, ISS) in collaboration with National Institute for Occupational Accident Insurance (INAIL), and to indicate how they are used [15].

The ICRP Report 135 [16] on DRL states that DRL values for x-ray procedures are often set, arbitrarily but reasonably, at the 75th percentile of the distribution of quantity under review (e.g. kerma-area product (KAP), fluoroscopy time (FT) and cumulative air kerma ($K_{a,r}$)), and the Commission now recommends this practice. “The purpose of a DRL is to identify facilities in which investigation of practices is advisable because protection is not optimized (i.e. where the local median value of the DRL is higher than the national or regional DRL)” [16]. If median values are higher than DRL values, the investigation should start with the evaluation of the equipment, the evaluation of procedure protocols, and also the evaluation of operator's technique. Higher values can be justified by considering the complexity of the procedure. However, even at lower DRL values, improvements may still be possible.

In 2001, it was proposed establishing reference levels for interventional procedures [17], starting from three dosimetric indicators, fluoroscopy time, number of images and kerma-area product, from which a patient's dose can be evaluated [18–20]. The ICRP Report 135 [16] recommends expressing the DRL for interventional procedures in terms of KAP, the cumulative air kerma, fluoroscopy time and the number of radiographic images (e.g., cine images in cardiology and digital subtraction angiography (DSA) images in vascular procedures), if available.

The aim of this study was to evaluate the exposure of adult patients subjected to interventional procedures in order to compare the results, in terms of the kerma-area product (KAP), air kerma at the interventional reference point ($K_{a,r}$) and fluoroscopy time (FT), between

different Italian centres. In this study we did not analyse the number of images since not all centres provided this information. The median values of the distributions of the individual centres were compared to the DRL proposed at a national level in Italy [15] or, in the absence of national data, to an international level [21–26]. This work proposes local DRLs for three procedures (cerebral angiography, CA and PTCA) as suggested by ICRP 135; these values could also be considered an updating because these levels are dependent on experience and technology available.

2. Methods

A retrospective study was conducted collecting data from procedures performed in the period between January 2015 and January 2019 in several Italian hospitals. The data were collected differently from centre to centre: in some centres the data were obtained from radiation dose index monitoring (RDIM) systems, in others the radiation dose structured report (RDSR) and paper records. Most of the medical physicists who contributed to the data collection are involved in the Digital Radiology Working Group of the Italian Association of Medical Physics (AIFM). The centres were located in a wide geographical area of northern and central Italy (17 and 4 centres, respectively). Forty-four angiographic systems with flat panel technology and 16 mobile units, partly image intensifier and partly flat panel technology, were selected to be representative of all major vendors and different years of installation (2002–2017).

With the collaboration of medical physicists and medical specialists (who use fluoroscopy inside and outside imaging departments), a list of 25 selected procedures was created, taking into account (a) the most widespread ones, such as coronary angiography, cardiac angiography, cerebral angiography, embolization of cerebral aneurysm, pacemakers, and endoscopic retrograde cholangio-pancreatography (ERCP), (b) some emerging procedures, such as transcatheter aortic valve implantation (TAVI), Mitraclip, and endovascular aortic repair (EVAR), and (c) others because of the lack of data in the literature.

Only the 11 procedures reported in Table 1 were analysed in detail; data relating to the other 14 procedures were not analysed because the data collected were not statistically significant (less than 20 cases per procedure) and, in some cases, were provided only few centres.

Twenty-one Italian centres joined this study, and each of them collected data related only to the procedures of the list carried out in their hospitals. The procedures were performed with fixed angiographic systems and mobile C-arm units of different brands. The hospitals that participated were asked to provide information about the radiological equipment used: the manufacturer, model, commissioning year, number and type of detector - flat panel or image intensifier and fluoroscopy mode used (low/normal/high), pulse rate (pps) during fluoroscopy, image acquisition frame rate (fps); use of magnification, and filtration (fixed and variable).

In this study, the KAP and $K_{a,r}$ results were not corrected to take into account the KAP meter deviation, which was checked to be in agreement with the national criteria on each installation (a deviation of less than $\pm 35\%$ [27,28]). This choice was made to be consistent with daily practice in Italian imaging departments, in which dosimetric indicators are checked annually.

The hospitals were requested to collect data on a sample of at least twenty patients for each procedure (without any selection criteria regarding the age, weight or height of the patients because in some centres these data were not available). No upper limit was set for the sample size. The data collected were FT, number of images, number of runs, fluoroscopy KAP, acquisition KAP and cumulative air kerma at the interventional reference point ($K_{a,r}$).

The total air kerma for the biplanes was calculated by adding the contribution of the front and side tubes. The total KAP was obtained by summing the acquisition and fluoroscopy KAP when the total value was not provided directly. All data were anonymized. The distributions of

each dosimetric indicator for each procedure are represented in Figs. 1–11 by box-plots (MedCalc Statistical Software version 17.2 (MedCalc Software bvba, Ostend, Belgium; <http://www.medcalc.org>; 2017)). In a Box-and-Whisker plot, the central box represents the values from the lower to upper quartile (25 to 75 percentile). The middle line represents the median. A line extends from the minimum to the maximum value. Comparisons between acquisition KAP and fluoroscopy KAP are shown in Fig. 12 for four procedures (cerebral angiography, embolization in the head for aneurysm, CA and TACE).

The procedures have been divided into two groups: for the first group data were received from more than 10 participating centres, in the latter the data were collected from less than 10 centres. DLRs could have been estimated only for the first group. Median values of the second group have been used to compare with published DRLs for the listed procedures. Cerebral angiography, CA and PTCA procedures were part of the first group. The remaining 8 procedures fell in the second category.

Basic statistical analysis has been performed (median, mean, standard deviation, range) for FT, Total KAP (KAPtot), and Ka,r. It is preferable to use median values and not mean values to perform comparisons because the mean values can be strongly influenced by the high-dose tails of the distribution, in particular for interventional radiology.

For the first group the 75th percentiles of the distribution of the median values has also been derived for each of the procedures to establish local DRLs and to compare to published DRLs. For the second group, considering the low number of centres sending data, only a comparison of the median values with the published DRLs could be performed. The DRL values taken as reference are those reported in the ISTISAN 17/33 report [15] and, for procedures not included in the report, reference was made to other published data [21–26].

The patient’s exposure to radiation is strongly linked to the level of complexity of the procedure. It is not always possible to analyse the complexity of procedures, because to do so requires clinical data that are not always available in a retrospective study.

3. Results

Twenty-one centres agreed to take part in this study and 15,182 data related to 11 procedures were collected and analysed (Table 1). The number of the data provided by the individual centres was related to the data collection methods: the centres with RDIM systems were obviously able to provide more significant samples compared to those that collected the data using paper records or RDSR. The size of the samples provided by each single centre is only relevant to the accuracy of the median value, but it does not affect the distributions of the medians. Therefore, the different samples size was not considered as confounding factor.

The set of fixed equipment used consisted of Philips Healthcare (68.2% of which 23.3% equipped with the Clarity system¹), Siemens Healthcare (15.9%), GE Healthcare (11.4%) and Canon Healthcare (4.5%) instruments; all of them are flat panel systems and only 11.4% are biplane. The portable systems (C-arm) were Philips (23.5%), GE (23.5%), Eurocolumbus (17.7%), Ziehm (11.8%), SIAS (5.9%) and Siemens (17.7%).

Table 2 summarizes the comparisons between local DRL obtained in this study, the ISTISAN DRL [15] and other DRL data in the literature [21–26] for cerebral angiography, CA and CA + PTCA procedures; Table 2 also shows the DRL or 75th percentile values proposed in the

¹ Clarity is a new generation fluoroscopy system designed to reduce radiation without compromising image quality for patients of all sizes; consists of a novel x-ray imaging technology that combines noise reduction algorithms with state-of-the-art hardware to enable real-time image processing and to reduce patient entrance dose significantly.

Table 1
List of the 11 procedures analysed. N: number of procedures; ND: number of centres.

| DEPARTMENT | PROCEDURE | N | ND | Number fixed machine with flat panel | Number fixed machine with Image Intensifier | Number C-arm with flat panel | Number C-arm with Image Intensifier |
|-------------------|---|------|----|--------------------------------------|---|------------------------------|-------------------------------------|
| VASCULAR | Angioplasty and stenting for peripheral arterial disease of the lower limbs | 1221 | 7 | 6 | 1 | 1 | 1 |
| | Endovascular aortic repair (EVAR) | 254 | 4 | 3 | 1 | 1 | 1 |
| | Coronary angiography (CA) | 6143 | 15 | 16 | 1 | 1 | 1 |
| HEMODYNAMIC | Percutaneous transluminal coronary angioplasty (PTCA) or CA + PTCA | 3747 | 15 | 16 | 1 | 1 | 1 |
| | Transcatheter aortic valve implantation (TAVI) | 379 | 7 | 9 | 1 | 1 | 1 |
| ELECTROPHYSIOLOGY | Radiofrequency ablation | 352 | 5 | 5 | 1 | 1 | 1 |
| | Pacemaker (PM) | 655 | 8 | 7 | 1 | 1 | 2 |
| ABDOMINAL | Hepatic chemoembolization (TACE) | 418 | 7 | 7 | 1 | 1 | 1 |
| | Cerebral angiography | 981 | 10 | 10 | 1 | 1 | 1 |
| NEUROLOGY | Embolization in the head for aneurysm | 489 | 7 | 7 | 1 | 1 | 1 |
| | Endoscopic retrograde cholangio-pancreatography (ERCP) | 542 | 8 | 8 | 2 | 2 | 6 |

Table 2
Comparisons between the local DRL obtained in this study, the ISTISAN DRL and other published DRL or 75th percentiles. Where no local DRLs can be defined, the median value of the distribution is shown in brackets.

| PROCEDURE | Local DRL of this study [15] | ISTISAN DLR DRL Switzerland [25] | ECRP 180 - part 2 of 2 DRL Austria [25] | ECRP 180 - part 2 of 2 DRL of 2 DRL Finland (2017) [24] | DRL C. Etard (2017) [24] | 75th percentile Tuthill et al. (2017) [21] | DRL Switzerland (2016) (rev 2) [22] | DRL T. Siskonen (2018) [26] | DRL STUK (2016) [34] |
|---|---|----------------------------------|---|---|--------------------------|--|-------------------------------------|-----------------------------|----------------------|
| CEREBRAL ANGIOGRAPHY | FT (min) | 10 | - | - | 11 | - | 15 | - | - |
| | KAPTot (Gy ^{cm} ²) | 159 | 150 | - | 90 | - | 150 | - | - |
| | Ka,r (Gy) | 1.401 | - | - | 0.63 | - | - | - | - |
| Embolization in the head for aneurysm | FT (min) | 45 | - | - | 58 | - | - | - | - |
| | KAPTot (Gy ^{cm} ²) | 180 | 350 | - | 190 | - | - | - | - |
| | Ka,r (Gy) | (2.197) | - | - | 2.77 | - | - | - | - |
| CA | FT (min) | 7 | - | 8 | - | - | 8 | - | - |
| | KAPTot (Gy ^{cm} ²) | 33 | 70 | 60 | - | - | 50 | 35 | 30 |
| | Ka,r (Gy) | 0.434 | - | - | - | - | 0.575 | 0.460 | - |
| CA + PTCA | FT (min) | 14 | - | - | - | - | 20 | - | - |
| | KAPTot (Gy ^{cm} ²) | 94 | 100 | 130 with stent | 100 | - | 100 | 85 | 75 |
| | Ka,r (Gy) | 1.45 | - | - | - | - | 1.32 | 1.20 | - |
| TAVI | FT (min) | (21.850) | - | - | - | - | 30 | - | - |
| | KAPTot (Gy ^{cm} ²) | (109.987) | - | - | - | - | 100 | 130 | 90 |
| | Ka,r (Gy) | 0.694 | - | - | - | - | 0.98 | 1.20 | - |
| ABLATION | FT (min) | 40 | - | - | - | - | 25 | - | - |
| | KAPTot (Gy ^{cm} ²) | (45.213) | - | - | - | - | 150 | - | - |
| | Ka,r (Gy) | (0.212) | - | - | - | - | 2.25 | - | - |
| Pacemaker | FT (min) | 8 | - | - | - | - | 7 | - | - |
| | KAPTot (Gy ^{cm} ²) | (14.945) | - | - | - | - | 30 | - | - |
| | Ka,r (Gy) | (0.102) | - | - | - | - | 0.45 | - | - |
| TACE | FT (min) | 20 | - | - | 28 | - | 20 | - | - |
| | KAPTot (Gy ^{cm} ²) | (162.430) | 300 | - | 250 | - | 300 | - | - |
| | Ka,r (Gy) | (0.761) | - | - | 1.00 | - | - | - | - |
| Angioplasty and stenting for lower limb | FT (min) | (11.00) | - | - | - | - | 14 | - | - |
| | KAPTot (Gy ^{cm} ²) | (11.962) | - | - | - | - | 350 | - | - |
| | Ka,r (Gy) | (0.101) | - | - | - | - | - | - | - |
| EVAR | FT (min) | (15.083) | - | - | - | 18.13 | - | - | - |
| | KAPTot (Gy ^{cm} ²) | (104.998) | - | - | - | 158.49 | - | - | - |
| | Ka,r (Gy) | (0.559) | - | - | - | - | - | - | - |
| ERCP | FT (min) | (4.742) | - | - | - | - | 10 | - | - |
| | KAPTot (Gy ^{cm} ²) | (21.889) | 30 | 45 | - | - | 30 | - | - |
| | Ka,r (Gy) | (0.104) | - | - | - | - | - | - | - |

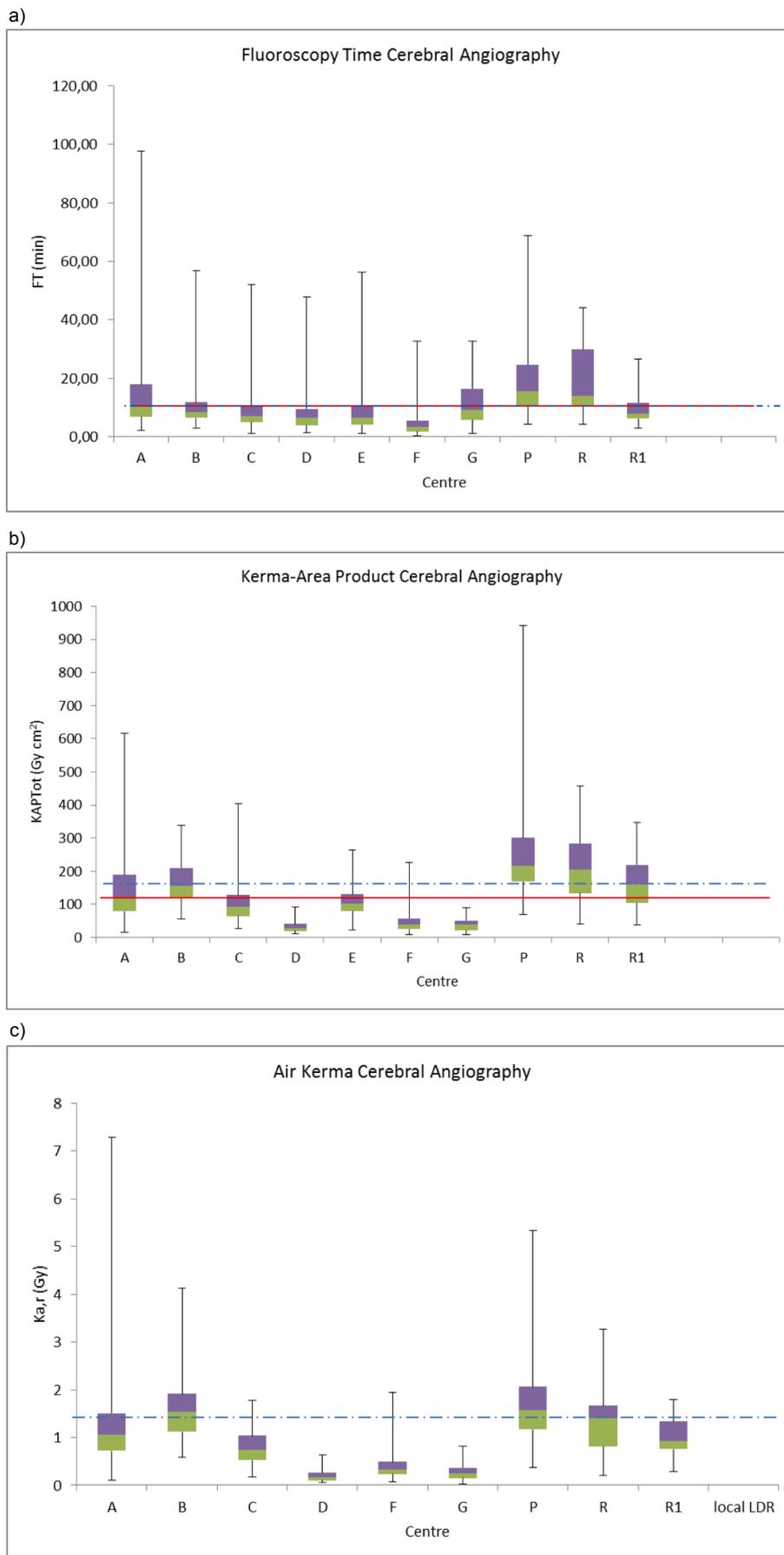


Fig. 1. Box plots of fluoroscopy time (a), total KAP (b) and air Kerma (c) values for cerebral angiography procedures in the different centres. The continuous line represents the ISTISAN DRL; dashed line represents local DRL of this study.

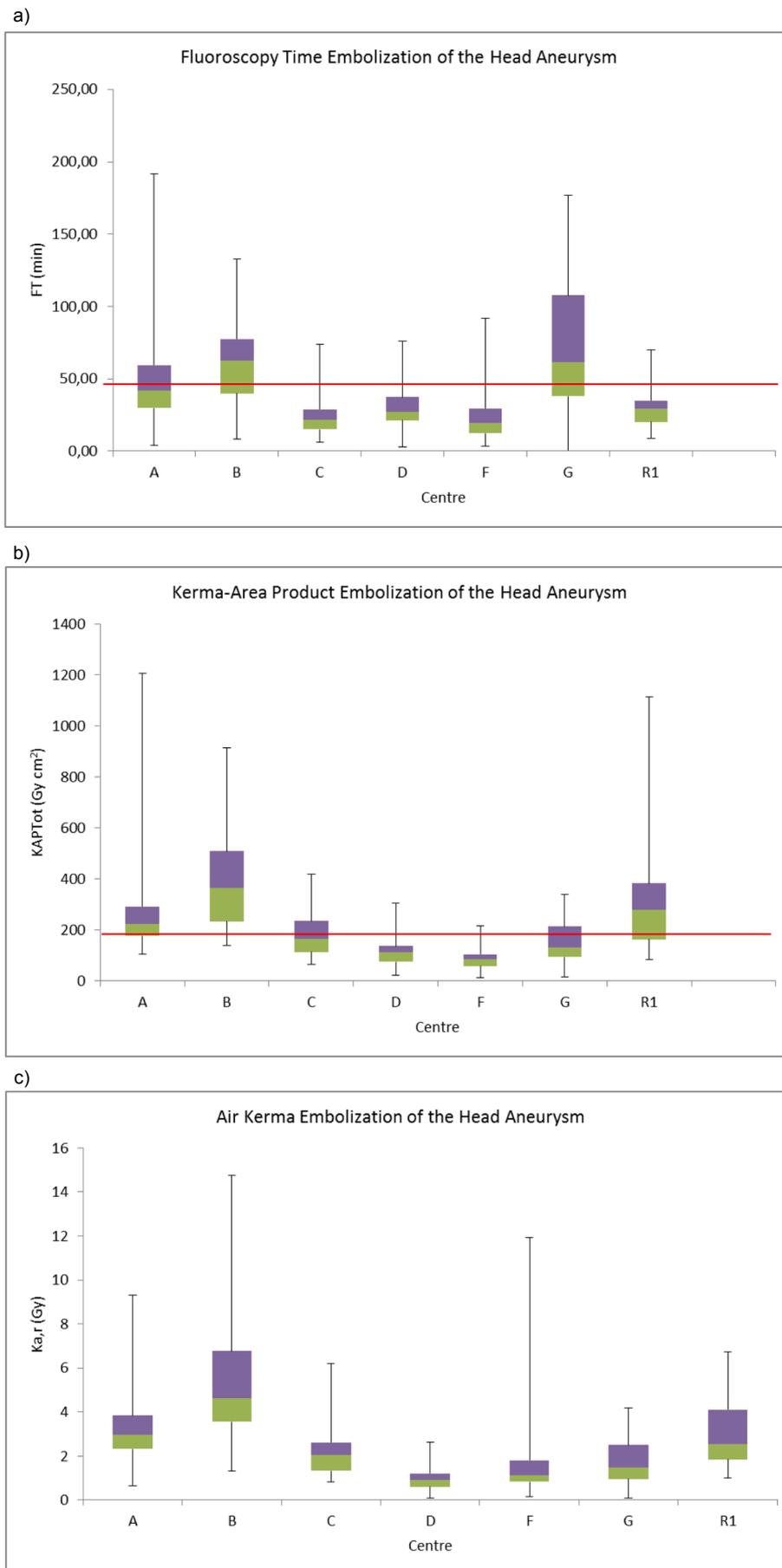


Fig. 2. Box plots of fluoroscopy time (a), total KAP (b) and air Kerma (c) values for embolization in the head for an aneurysm in the different centres. The continuous line represents the ISTISAN DRL.

literature for the remaining procedures studied.

The distributions of each dosimetric indicator for each procedure are represented in Figs. 1–11 by box-plots (MedCalc Statistical Software version 17.2 (MedCalc Software bvba, Ostend, Belgium; <http://www.medcalc.org>; 2017)). In a Box-and-Whisker plot, the central box represents the values from the lower to upper quartile (25–75 percentile). The middle line represents the median and a line extends from the minimum to the maximum value.

4. Discussion

4.1. Cerebral angiography

Observing the data on FT (Fig. 1a), it can be seen that the median values of the P and R centres were higher than the ISTISAN DRL; the local DRL estimated in this study was equal to the value published in the ISTISAN report [15]. With regards to KAP_{tot} (Fig. 1b), the local DRL of our study is significantly higher than the ISTISAN DRL (159 Gy_{cm}² vs 115 Gy_{cm}²), so a large number of centres (5 out of 10 centres) had values that were higher than the ISTISAN DRL. Fig. 12a shows the comparison between the median values of the fluoroscopy and acquisition KAPs highlighting how in the 5 centres (A, B, P, R and R1) the contribution to the KAP_{total} in the acquisition mode is not negligible.

As far as concerns K_{a,r} (Fig. 1c), the values from centres B and P were higher than the local DRL estimated in this study.

The comparison of the data reveals that there was a clear dose reduction in the centres with advanced technology system (the Philips Clarity system in centres D and G, the Siemens Care + Clear system in centre F). However, the results of centre C are also comparable: in this case optimization was achieved by privileging a low-dose technique (low-dose fluoroscopy and DSA acquisition with echo dose) and reducing the number of fps in DSA without having an adverse impact on clinical outcomes. The dose reduction in centre C was obtained without employing an image noise reduction algorithm. However, the comparison with data from a French multicentre study [24] shows that the local DRL of KAP and K_{a,r} in our study are higher (Table 2). However, it should be noted that the median values of centres D, F and G are below the DRL of the French study and the optimized value for the C centre is borderline.

This study confirms what is reported in the literature: the new systems result in a significant reduction of exposure to radiation during procedures in the field of neuroradiology [29,30] but it is also possible to obtain significant dose reductions in this sector through basic modifications of factory settings on neurointerventional X-ray equipment without an increase in procedural complexity or rate of complications [31–33].

4.2. Embolization in the head for aneurysm

The FT values from centres B and G (Fig. 2a) were higher than the ISTISAN DRL and those proposed in France [24]. Centres A, B and R1 had higher KAP_{tot} values (Fig. 2b) than ISTISAN DRL and the values proposed in France [24]. Fig. 12b shows the comparison between the median values of fluoroscopy and acquisition KAPs, highlighting how in the A, B and R1 centres the contribution to the KAP_{total} in the acquisition mode is not negligible. Centre B also exceeded the reference value for K_{a,r} proposed in France [24].

Centres D, G and F centres are equipped with innovative technology (centres D and G with Clarity technology and centre F with the Siemens Care + Clear system): in these centres, technology has certainly had a significant influence on patient dose reduction. As highlighted in the section dedicated to cerebral angiography, the dose reduction in the C centre is not due to the technology but to the practice of favouring a low-dose technique during fluoroscopy and radiography and reducing the number of fps in DSA. In centre B, which appears to be the centre with the highest dose values, a biplane system similar to that of centre C

is used but with the standard mode (DSA with 4 fps vs. DSA echo dose 2 fps, fluoro normal 12.5 pps vs fluoro low 12.5 pps).

4.3. Coronary angiography

The results are shown in Fig. 3. In general, the distribution of median FT values (Fig. 3a) shows that the different centres are comparable to each other and their values are below local DRL of our study (with the exception of centres B, I and M) and those proposed in literature (Table 2).

The median KAP values (Fig. 3b) of each centre were lower than the ISTISAN DRL, with the exception of those from centre M that is borderline. An analysis of the acquisition modes revealed that the M centre used 15 fps in acquisition and 15 pps in fluoroscopy and the Normal mode with a field of view (FOV) of 15 cm. The trend in other centres is to work with a FOV of 22/25 cm, in Low mode and reduce the number of pps from 15 to 7.5 in fluoroscopy and in one centre decrease the number of fps in acquisition from 15 to 10. The comparison between the contributions of the fluoroscopy and acquisition KAP (Fig. 12c) shows that there is an excess of the acquisition modality in centre M. Since the local DRL results clearly lower than ISTISAN DRL (33 Gy_{cm}² vs 70 Gy_{cm}²), three centres (F, M and Z) exceed the local DRL while two centres are borderline (G, L). Our local DRL is comparable to the one recommended at European level by Siiskonen et al. [26] (35 Gy_{cm}²) who obtained DRL as the third quartile of the median values distribution and it is comparable to 30 Gy_{cm}², which is the value reported by the Finnish national set of DRLs in cardiology [34].

As showed in Fig. 3c, in three centres (F, M, Z) the local DRL value established in this study for K_{a,r} is exceeded, and in three other centres (B, G, L) median values are close to it; however, the value of centre F was higher than that of the DRL of references 22 (0.575 Gy): in centre F a normal or high fluoroscopy mode is used, often at 30 pps and rarely at 7.5, with 15 fps in acquisition and sometimes even 30 fps. The value of 1 Gy is not exceeded in any centre. The angiographic systems used in centres D, I and V are Philips with Clarity.

K_{a,r} Local DRLs is similar to the most recent literature values [26] as reported in Table 2.

4.4. Coronary angiography and percutaneous transluminal coronary angioplasty

The results are shown in Fig. 4. In general, the distribution of median FT values (Fig. 4a) shows that the different centres have comparable values, three centres (A, I, M) have higher values than the local DRL of this study and only one (M) that has a value higher than found in the published data (Table 2).

The median values of the KAP (Fig. 4b) were lower than the ISTISAN DRL in all centres except for centre Z which also exceeded the reference level of this study. The local DRL of this study were also exceeded by centres F and M: the analysis of the acquisition methods revealed that centre M uses 15 fps in acquisition and 15 pps, normal mode with a FOV of 15 cm in fluoroscopy; in centre F, normal or high fluoroscopy modalities are used, often at 30 pps rarely at 7.5, with 15 or 30 fps in acquisition, while in centre Z a normal fluoroscopy mode is used with 15 pps, 15 fps in acquisition and a FOV of 20 or 17 cm.

Comparing K_{a,r} values (Fig. 4c) with the local DRL of this study it can be seen that almost all the centres had values below our levels, except for centres F, L and M. From the comparison with the published data, it emerges that 5 out of 15 centres (A, F, G, L, M) had median values that exceed the DRL (1.32 Gy) proposed in Switzerland [22]. The K_{a,r} did not exceed 2 Gy: 50% of the centres had values below 1 Gy.

Centres D, I and V use Philips with Clarity angiographic systems. KAP_{tot} and K_{a,r} Local DRLs are slightly higher than the most recent literature values [26,34] (see Table 2).

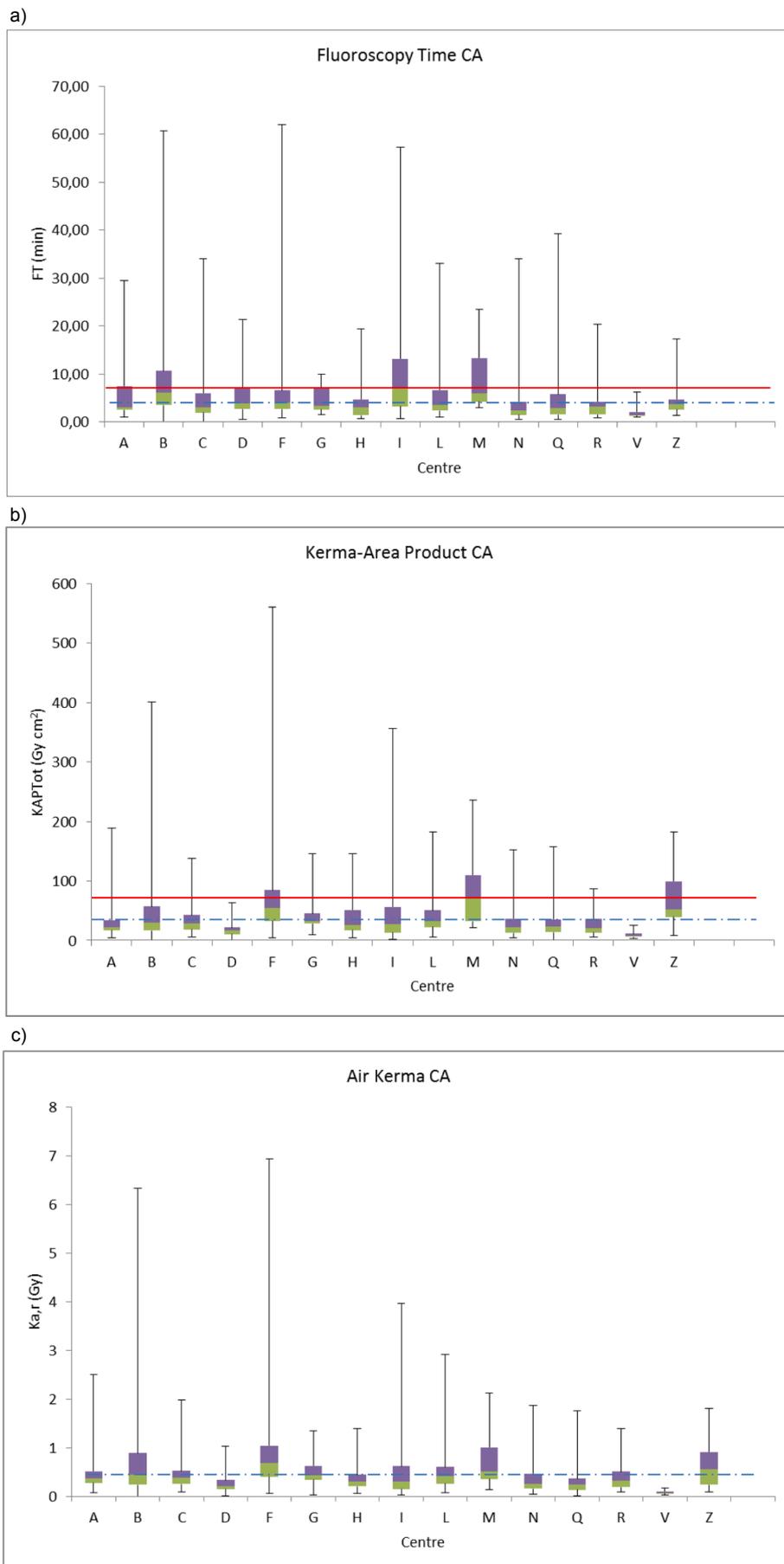


Fig. 3. Box plots of fluoroscopy time (a), total KAP (b) and air Kerma (c) values for the coronary angiography procedures in the different centres. The continuous line represents the ISTISAN DRL; dashed line represents local DRL of this study.

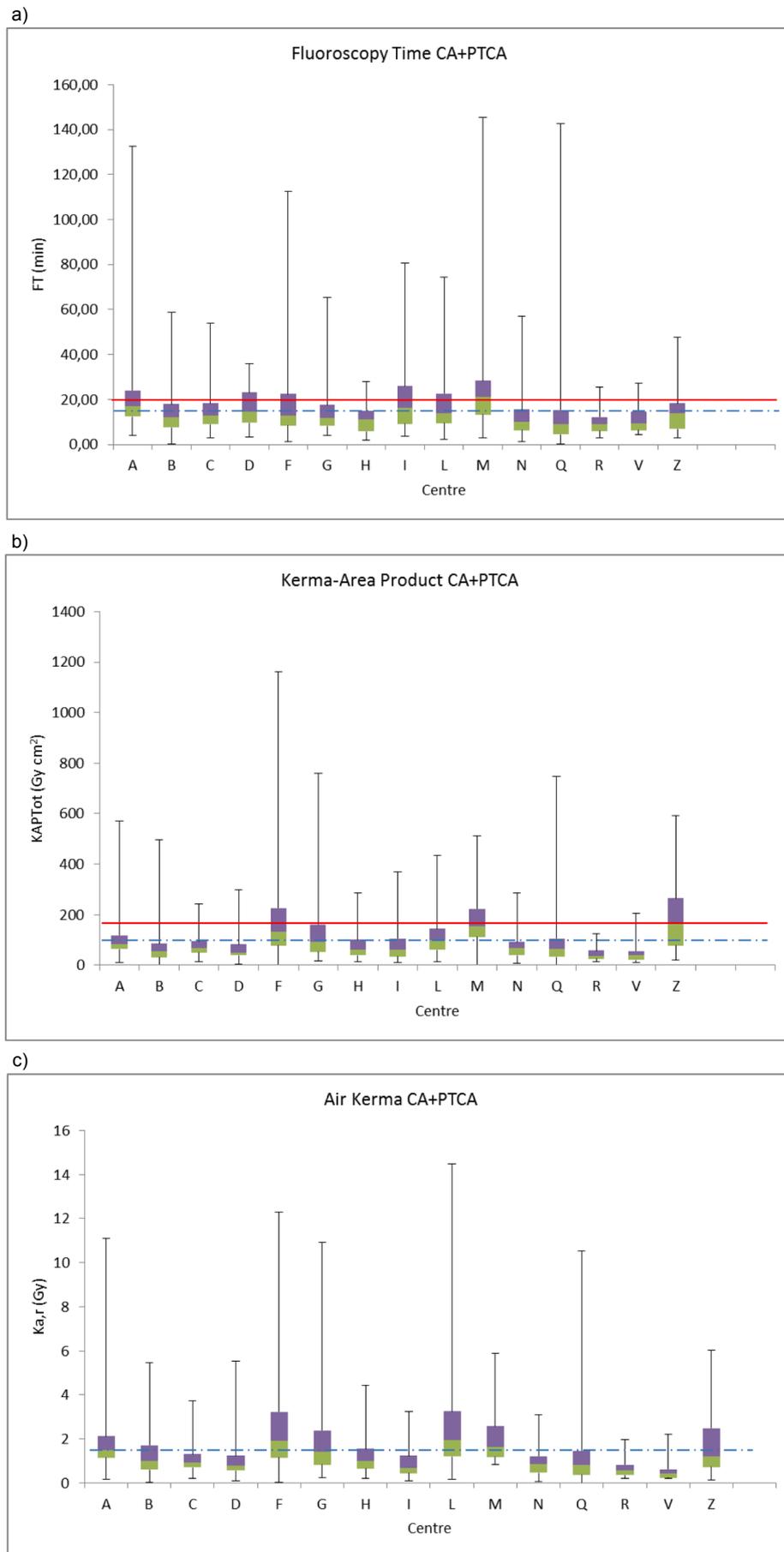


Fig. 4. Box plots of fluoroscopy time (a), total KAP (b) and air Kerma (c) values for coronary angiography + percutaneous transluminal coronary angioplasty procedures in the different centres. The continuous line represents the ISTISAN DRL; dashed line represents local DRL of this study.

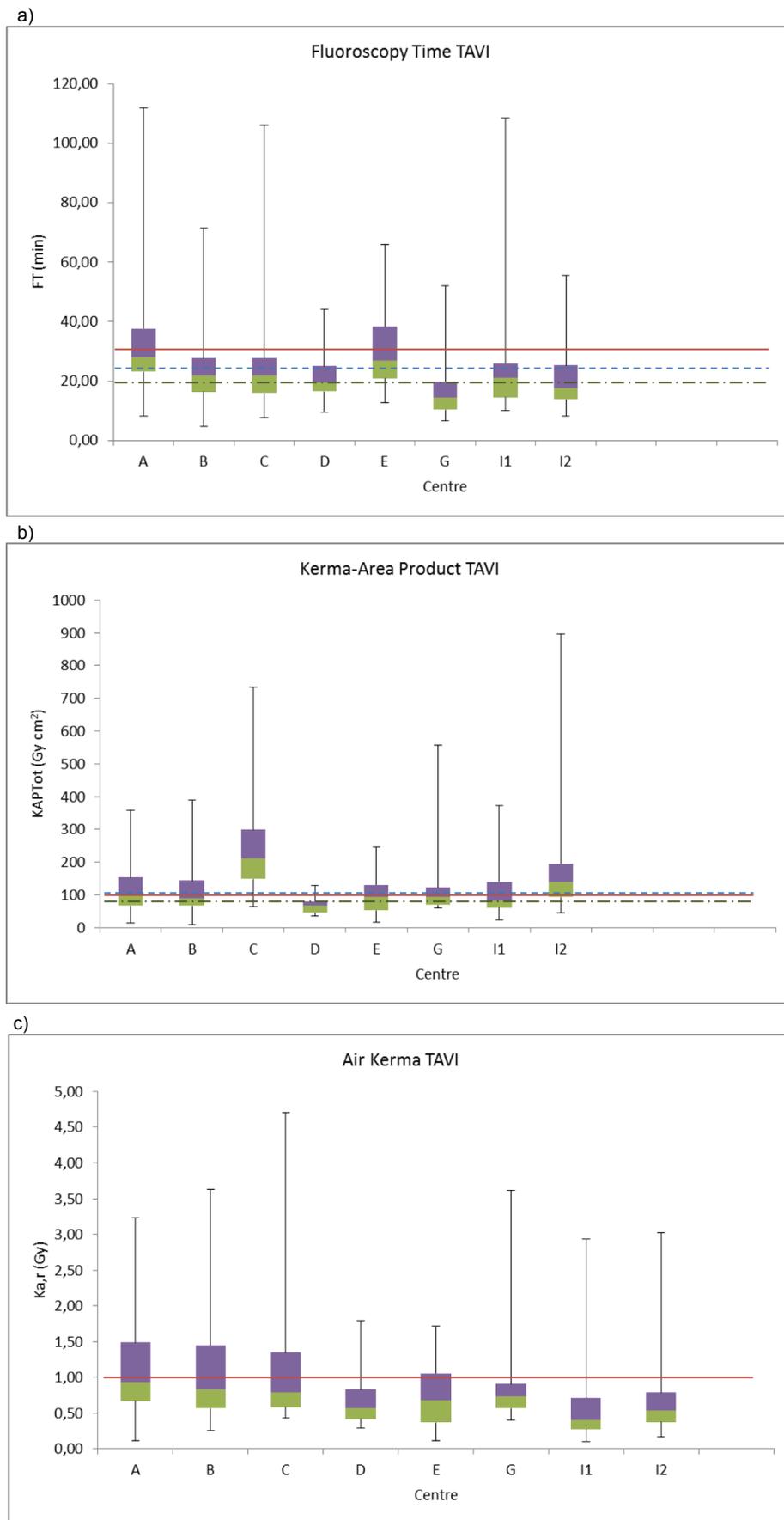


Fig. 5. Box plots of fluoroscopy time (a), total KAP (b) and air Kerma (c) values for transcatheter aortic valve implantation procedures in the different centres. The continuous line represents the Switzerland DRL [22]; the dashed line - - - represents the median value of non optimized procedures and - · - · the median value of optimized procedure provided by Sharma et al. [11].

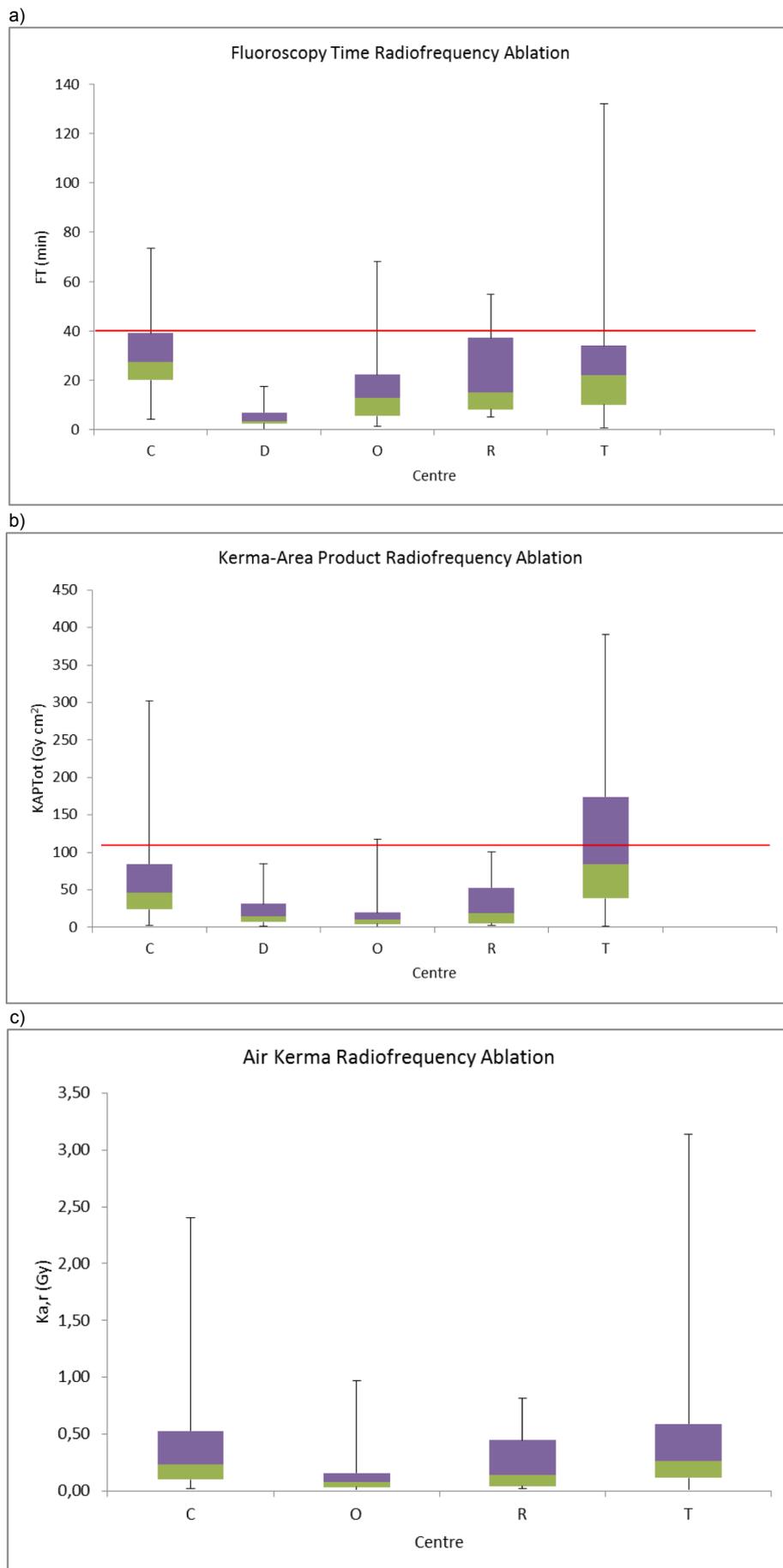


Fig. 6. Box plots of fluoroscopy time (a), total KAP (b) and air Kerma (c) values for the radiofrequency ablation procedures in the different centres. The continuous line represents the ISTISAN DRL.

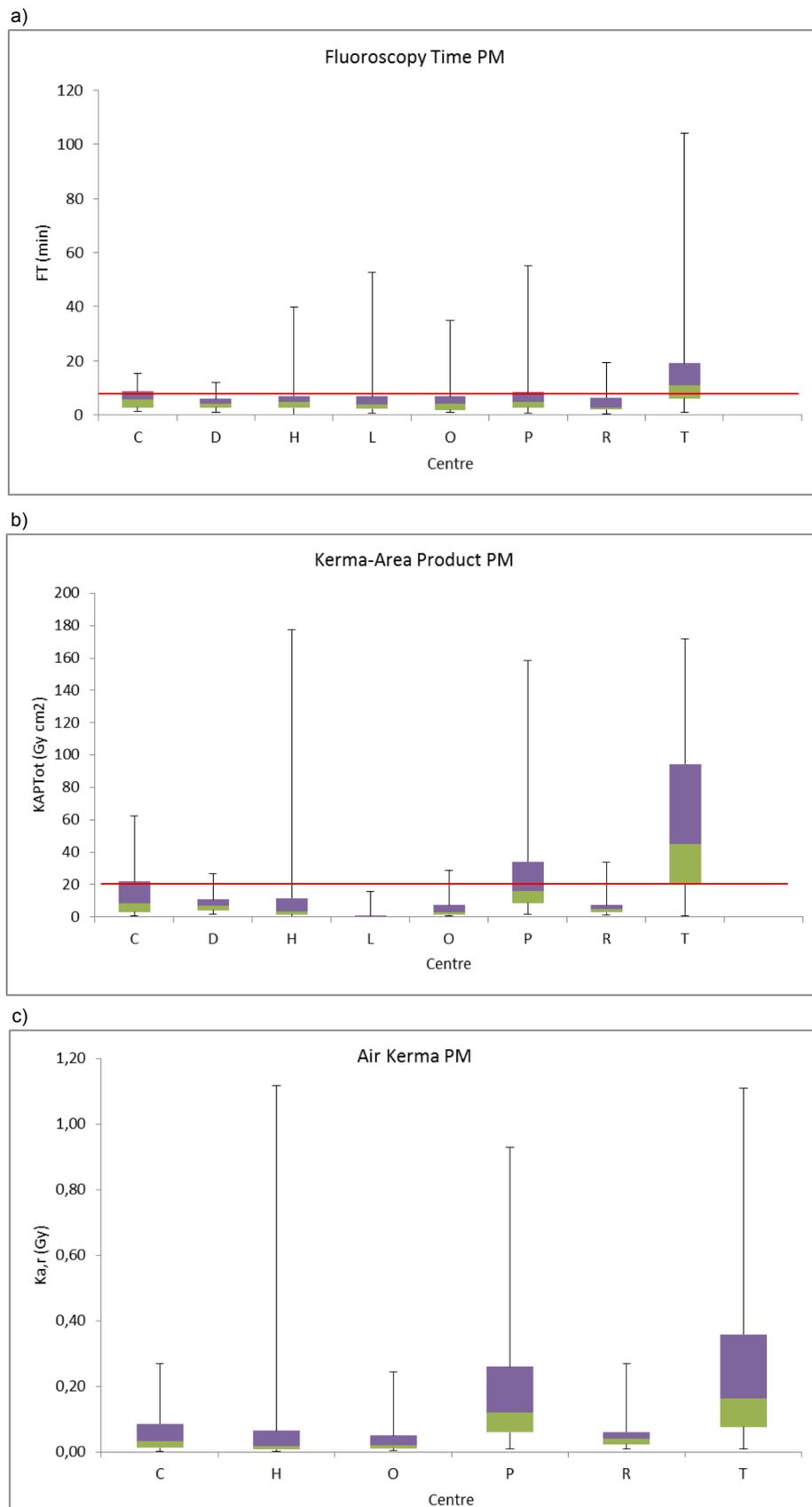


Fig. 7. Box plots of fluoroscopy time (a), total KAP (b) and air Kerma (c) values for the pacemaker procedures in the different centres. The continuous line represents the ISTISAN DRL.

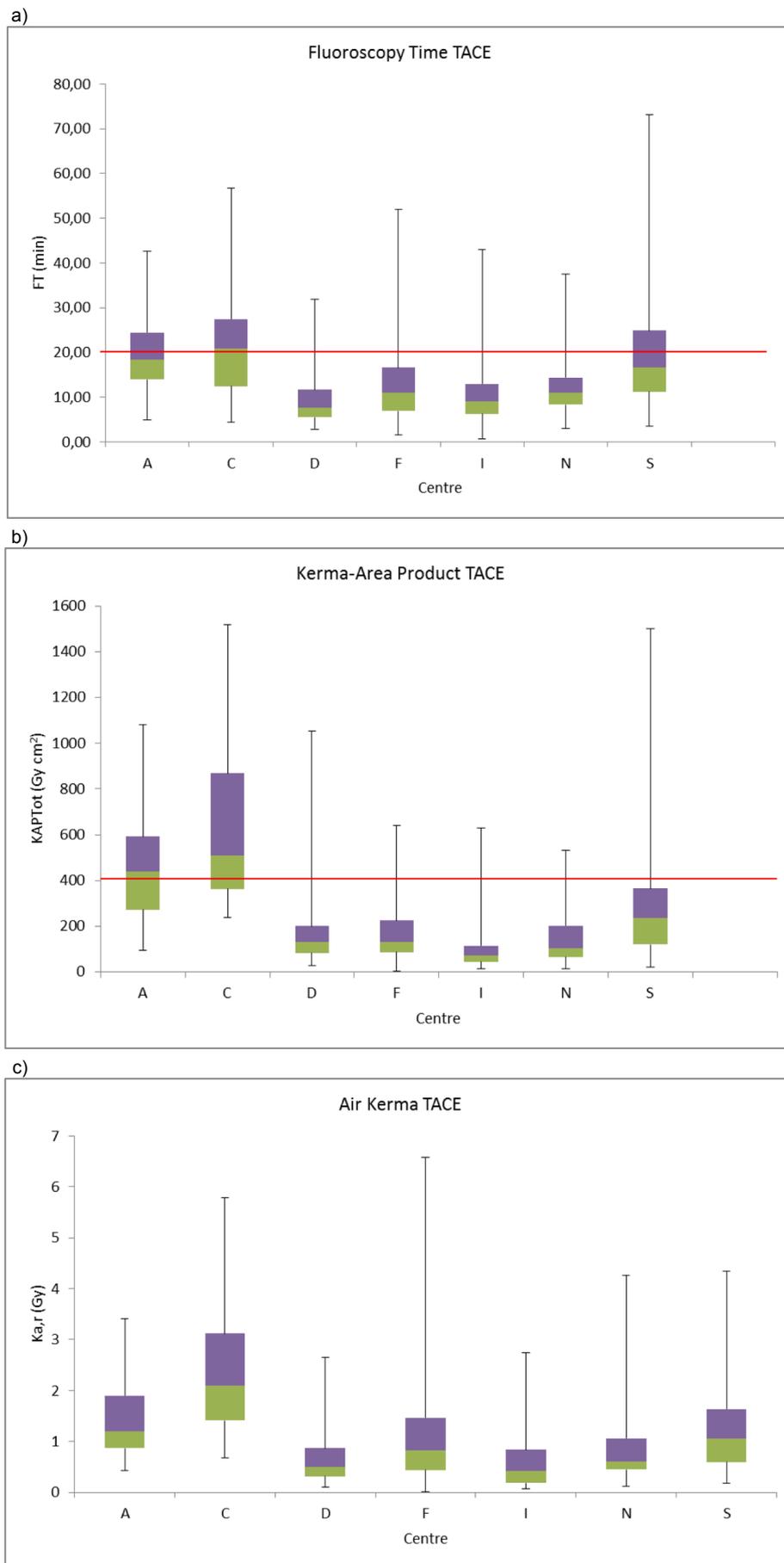


Fig. 8. Box plots of fluoroscopy time (a), total KAP (b) and air Kerma (c) values for hepatic chemoembolization procedures in the different centres. The continuous line represents the ISTISAN DRL.

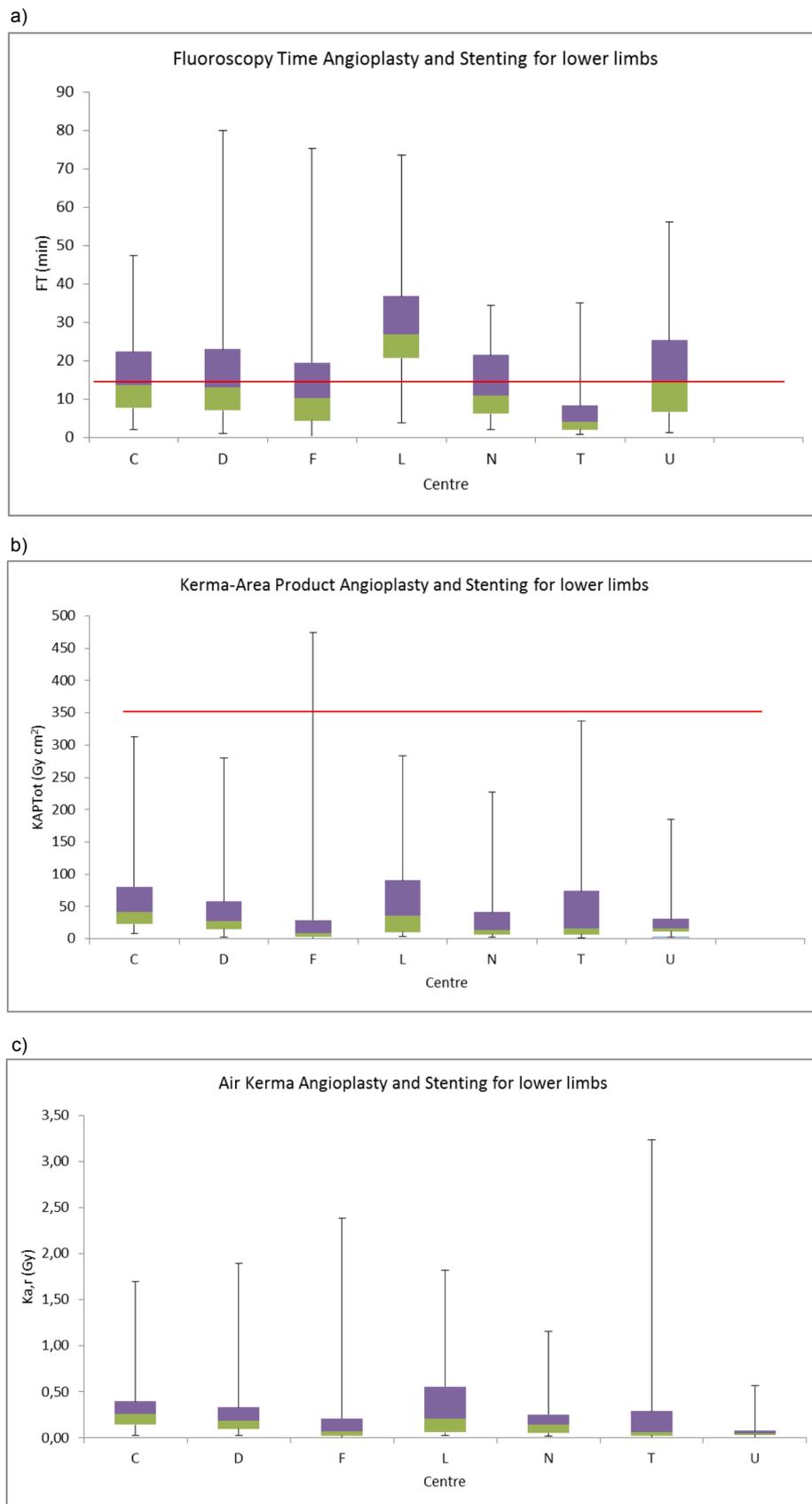
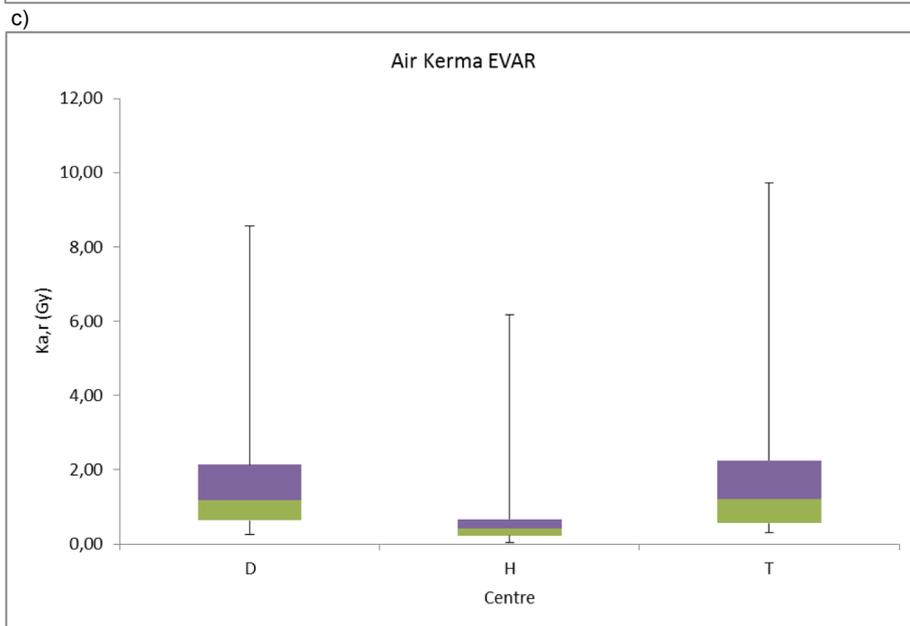
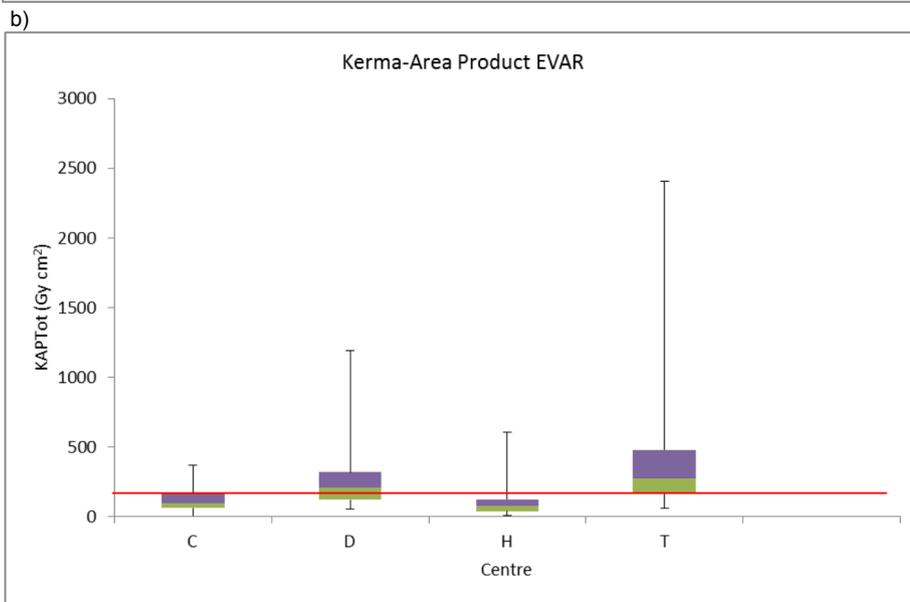
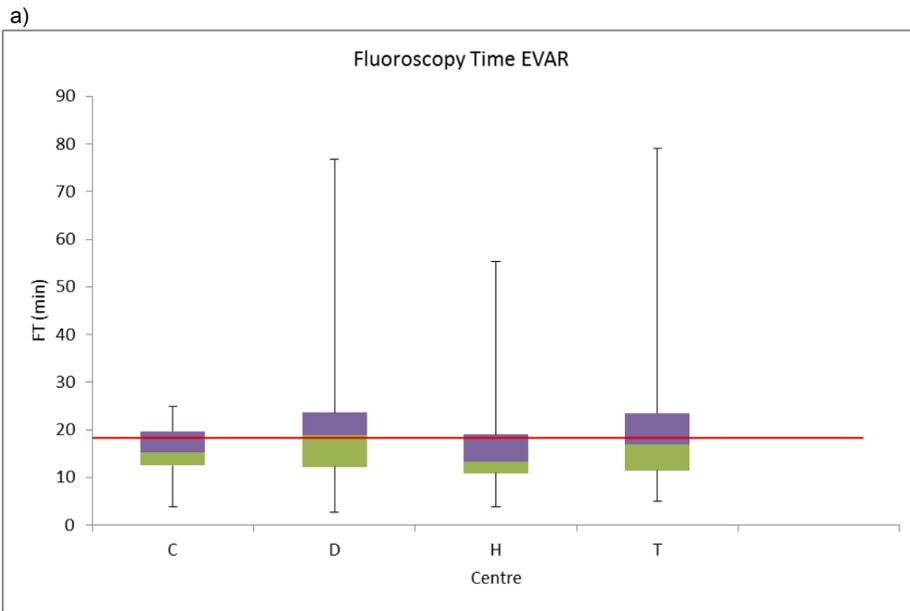


Fig. 9. Box plots of fluoroscopy time (a), total KAP (b) and air Kerma (c) values for angioplasty and stenting for peripheral arterial disease of the lower limbs in the different centres. The continuous line represents the Switzerland DRL [22].



(caption on next page)

Fig. 10. Box plots of fluoroscopy time (a), total KAP (b) and air Kerma (c) values for endovascular aortic repair procedures in the different centres. The continuous line represents the 75th percentile provided by Tuthil et al. [21].

4.5. Transcatheter aortic valve implantation

The ISTISAN 17/33 report does not provide DRL values for TAVI procedures. We compared our data with those reported in the study by D. Sharma et al. [11] which provides median values for FT and KAP, differentiating between optimized and non-optimized procedures. The non-optimized procedures were those performed using standard image acquisition settings (SS): SS included 15 ppf and 15 fps for cine-acquisition. The optimized setting (LS) included reductions in fluoroscopy from 15 to 3.75–7.5 ppf and in cine acquisition from 15 to 3.75–7.5 fps. SS were used for the “aortogram to identify the aortic annular plane for valve implantation and during the key valve deployment steps“. The median dose-area product in the SS group was 102.4 Gy cm^2 as compared to 74.6 Gy cm^2 in the LS group, which was a statistically significant difference ($P = 0.008$). There were no significant differences in

the fluoroscopy time (23.9 min vs 19 min, $P = 0.14$).

An evaluation of the FT median values (Fig. 5a) shows that two centres (A and E) exceeded the median value reported by Sharma et al. [11] for the non-optimized procedures. Only centres G and I2 gave comparable values for optimized procedures. As for the KAP (Fig. 5b), centres C and I2 exceeded the median values reported by Sharma et al. [11] for the non-optimized procedures. It was not possible to compare the median values of fluoroscopy and acquisition KAPs because centre C doesn't have this data available. Only centre D had values below the value set by Sharma et al. [11] for the optimized procedures.

Centres D and I1 use Philips with Clarity angiographic systems: advances in image post-processing may be beneficial for the patient exposure also for TAVI as reported in literature [35,36]. The median values of the kerma in air are all lower than 1 Gy and are lower than DRL proposed in literature [22,26].

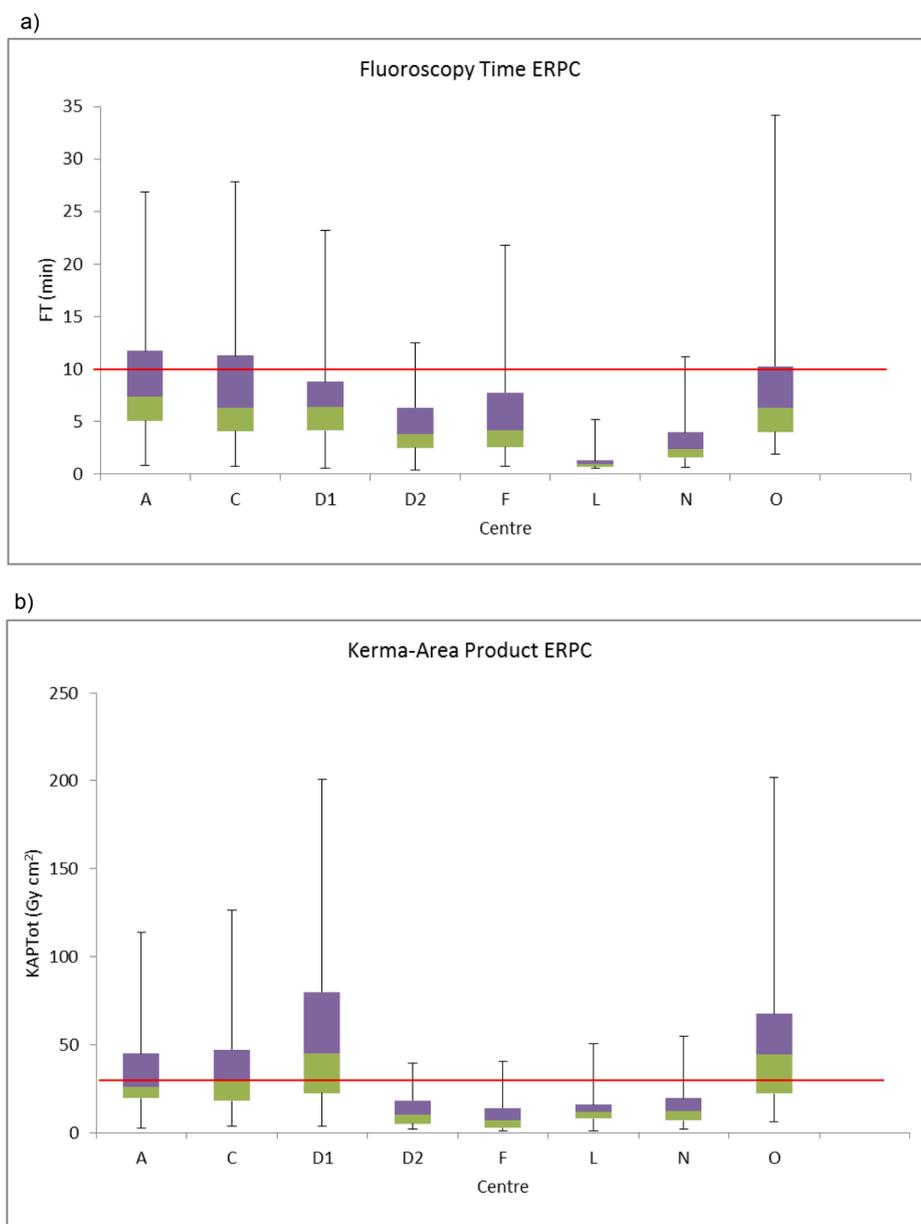


Fig. 11. Box plots of fluoroscopy time (a) and total KAP (b) values for endoscopic retrograde cholangiopancreatography procedures in the different centres. The continuous line represents the Switzerland DRL [22].

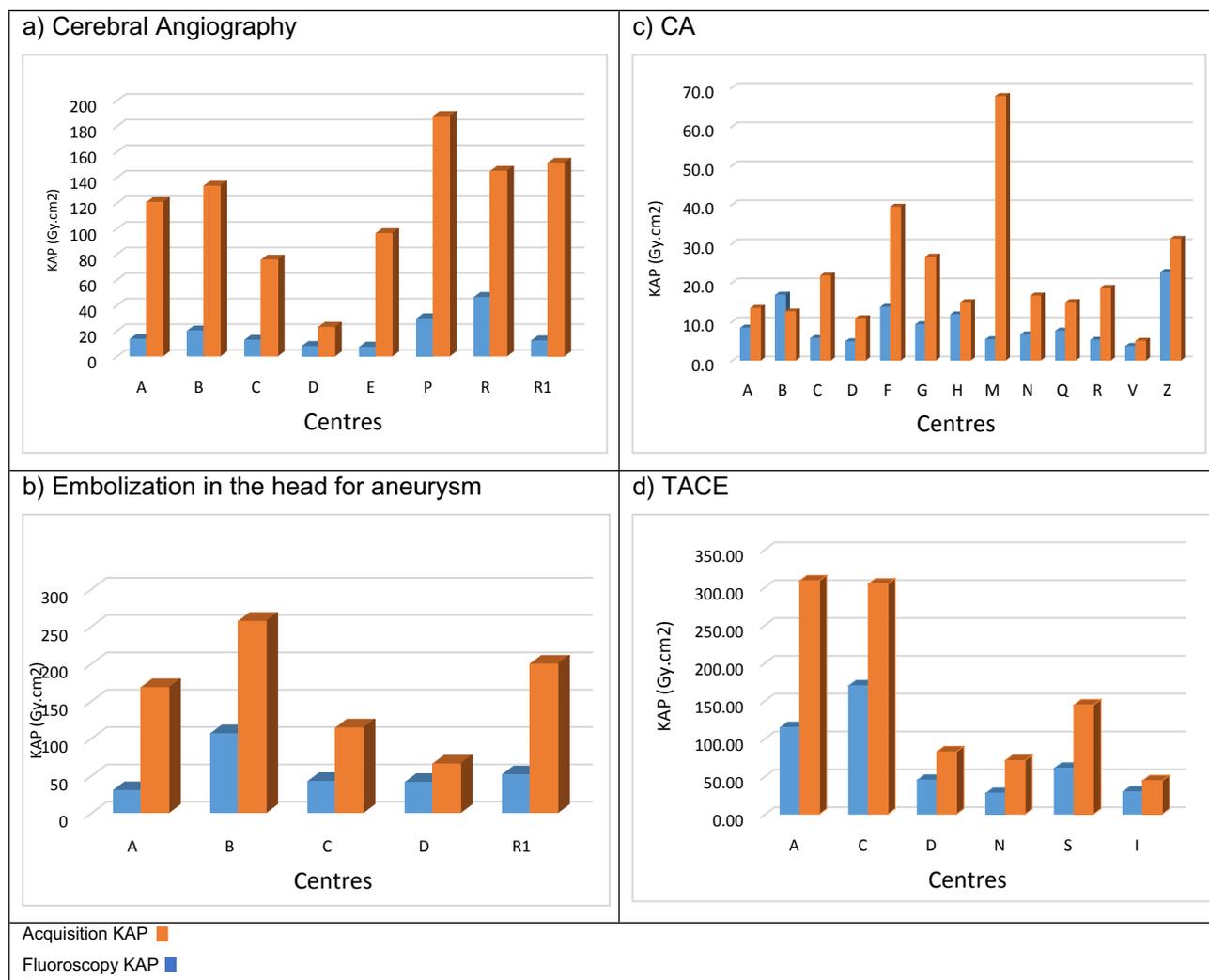


Fig. 12. Comparison between median fluoroscopy KAP and acquisition KAP values for some procedures.

Comparisons with DRL values [22,26] often allow identification of aspects of a procedure that can be optimized or staff who, due to lack of training or attention, need to be invited to change the technical mode of executing of the procedure. In the particular case of centres C and I2, in which the KAP level was high but the $K_{a,r}$ value was acceptable, is probably due to lack of attention to the collimation of the X-ray beam.

4.6. Radiofrequency ablation

For this type of procedure, no centre exceeded the ISTISAN DRL values for either FT or KAP (Fig. 6a and b). The $K_{a,r}$ values were between 100 and 300 mGy.

Radiofrequency ablation procedures can be performed with an electro-anatomical mapping system that enables the use of radiation to be limited. The reduction in FT and, therefore, the patients' exposure to radiation thanks to this electro-anatomical mapping is as much as 25% according to See [37] and about 15% according to an international study [38].

The Swiss Circular R-06-05 [22] regarding ablation procedures (using electro anatomical mapping systems) gave the following values: 30 $Gy\cdot cm^2$ for KAP, 9 min for FT and 0.623 Gy for $K_{a,r}$. The 110 $Gy\cdot cm^2$ and 40 min values of the ISTISAN report refer to procedures performed entirely under fluoroscopic guidance [15].

The remarkable fluoroscopy time variability let us suppose that, within the sample, different complexity procedures were grouped (e.g. the inclusion of lung veins ablation in the radiofrequency ablation

group has an enormous impact on fluoroscopy time and hence on exposition doses).

4.7. Pacemaker implantation

It is important to underline that centres D and L use mobile arc units with image intensification for this procedure (the diameter is 23 cm in centre L and 31 cm in centre D).

Furthermore, in this study all procedures were grouped without distinguishing between various typologies (single or dual chamber cardiac pacemakers) which, as highlighted in literature, require different procedure time [39,40].

In particular, Siiskonen et al. [26] divided the pacemaker implantations into single (SCH) and dual chamber (DCH) procedures and implantations of cardiac resynchronization therapy (CRT) pacemaker, proposing at European level different DRL.

In several centres, the dosimetric indicators median values suggest that these are lower dose procedures ($K_{a,r}$ median values were below 0.2 Gy); nevertheless in a centre high doses ($K_{a,r}$ median values higher than 2 Gy) were recorded.

For this type of procedure, KAP_{tot} coincides with the fluoroscopy KAP because the acquisition mode is not used.

Centre T was the only centre that exceeded the DRL of the ISTISAN report both with regards to FT (Fig. 7a) and to total KAP (Fig. 7b).

In centre T, the procedures performed on a FPD fixed angiographic system are single, dual or triple chamber implantations; whether we

evaluate only the single and dual chambers procedures, the median fluoroscopy time and KAPtot decrease respectively to 9 min and 30 Gy cm^2 values, comparable to the reference ones [15,22].

The analysis of the acquisition methods revealed that centre T uses normal mode with 15 pps and FOV of 42 cm in fluoroscopy; other centres use normal or low fluoroscopy modalities with 7.5 pps.

Centre L uses a mobile arc unit with an image intensifier (diameter 23 cm): the median values of the total KAP were very low (two orders of magnitude smaller than those of centre T and an order of magnitude smaller than that of centre D which uses a C arm) probably because of the good manual skills of the operator and the small size of the detector.

4.8. Hepatic chemoembolization (TACE)

As shown in Table 2, ISTISAN DRL are comparable to those proposed in literature (20 min vs 28 min [24] and 20 min vs 20 min [22], and 400 Gy cm^2 vs 300 Gy cm^2 [22,25] and 400 Gy cm^2 vs 250 Gy cm^2 [24]).

The comparison not only with DRL values but also with the median values of the single centres shows an excessive use of the acquisition modality in centres A and C. Fig. 12d illustrates the comparison between the fluoroscopy KAP and the acquisition KAP: KAP acquisition values are comparable in centres A and C even though the median value in centre C is 457 images against the 267 of centre A. Ruiz-Cruces et al. [41], reported DRL values for KAP, FT and number of images as 303 Gy cm^2 , 26.3 min and 245, respectively confirming the excessive use of acquisitions in centre C. In the work by Ruiz-Cruces et al., the DRL values for hepatic chemoembolization were obtained taking into account the complexity of the procedure, with the KAP values being 170 Gy cm^2 for simple procedures, 303 Gy cm^2 for procedures of medium complexity and 881 Gy cm^2 for complex procedures. In this case, it might be useful to evaluate the complexity of these procedures.

The fluoroscopy KAP in centre C was higher than that in centre A: this finding is related to the fact that the fluoroscopy mode used in centre C was Normal, at 15 pps, whereas centre A, like almost all the other centres, used the 15 pps Low fluoroscopy mode; in centre N the Normal mode was used at 7.5–10 pps. Furthermore, in centre C a FOV of 27/32 was used, compared to the FOV of 31/32 in the other centres.

In flat panel detection systems, the relationship between skin entrance exposure and FOV is complicated. In fact, radiation dose levels could potentially be the same for all FOV because the radiation dose captured by each digital detector element is the same with decreasing FOV. This is one of the key advantages of flat panel detection systems; however, manufacturers often increase the skin entrance exposure by the order of 1/FOV to maintain similar image noise [42].

4.9. Angioplasty and stenting for peripheral arterial disease of the lower limbs

The data related to percutaneous transluminal angioplasty of the lower limbs were compared with Swiss DRL [22] because the ISTISAN report [15] does not provide reference levels for this type of procedure.

The FT of centre L exceeds literature reference level [22], while that of centres C and U are borderline (Fig. 9a). As far as regards the KAP, no Italian hospital of this study exceeded the values from Switzerland (Fig. 9b). All centres use Digital flat-panel detectors (FPD); only centre

C uses mobile C-arm with FPD.

R. Ruiz-Cruces et al. [41] proposed as iliac stent LDR, the values of 170 Gy cm^2 and 21.4 min for KAP and fluoroscopy time respectively.

The subdivision as a function of the treated region, was performed in four centres: all centres median values are lower than the DRL recommended at national level in Spain.

4.10. Endovascular aortic repair

Only four centres provided data on the procedure and there was a difference between the types of radiological equipment used (C-arm (centre C) and fixed appliances) all with FPD. The ISTISAN report does not provide reference levels but it was possible to compare the median values with those reported in the study by Tuthill et al. [21] which provides reference values for KAP and FT for standard non-fenestrated EVAR procedures.

The comparison between the median values of the centres highlights the need for an optimization process in centres D and T (Fig. 10): it may, however, be useful to evaluate complexity also for this type of procedure and exclude fenestrated EVAR procedures, since these tend to take much longer and be more complex [21].

4.11. Endoscopic retrograde cholangiopancreatography

The radiology instruments used for ERCP procedures in the various centres are C-arm units with under-couch x-ray tubes. For this type of procedure, the ISTISAN report only provides DRL. It is possible to make a comparison with the European Commission publication [25] and the DRL value proposed by Switzerland [22].

The only centres that had KAP values (Fig. 11b) that were borderline both with respect to the Austria DRL [25] were D1 and O, which need to optimize radiological practice while working with two different systems from a technological point of view (image intensifier vs flat panel).

As regard FT, all centres are below the DRL proposed by Switzerland [22]. For KAP values D1 and O are confirmed higher and C Borderline.

Tsapanaki V. et al. [43] proposed, for Greece, as preliminary DRLs (deriving them from the third quartiles of the total sample) the following values: KAP = 19 Gy cm^2 and FT = 8 min. All centres median fluoroscopy time values are lower than the one proposed (8 min), while for the 50% of them, KAP is higher than the recommended DRL.

Digital flat-panel detectors (FPD) were used at two (A and O) of the sites studied, whilst six sites used an image intensifier (II). As to how the radiation dose exposure of FPD systems compares to II systems, this remains uncertain. At present few studies have compared radiation dose between FPD and II images devices for non cardiac procedures [21,44,45].

In this study, in the centres where FPD are used, no significant dose decreases were observed.

4.12. Comparison between local DRLs established in this study and DRL published in the ISTISAN report

For cerebral angiography procedures the same DRL value for FT was found in both studies. On the other side, KAP DRL value in this study was higher of about 38% than the ISTISAN value.

Table 3
Differences in N, ND, FT DRL, KAP DRL between ISTISAN and this study for CA, PTCA and Cerebral Angiography procedures.

| PROCEDURE | N | | ND | | FT (min) | | KAP Gy cm^2 | |
|--|------------|---------|------------|---------|-----------|-------------|----------------------|-------------|
| | This study | ISTISAN | This study | ISTISAN | Local DRL | DRL ISTISAN | Local DRL | DRL ISTISAN |
| Coronary angiography (CA) | 6143 | 550 | 15 | 9 | 4 | 7 | 33 | 70 |
| Percutaneous transluminal coronary angioplasty (PTCA) or CA + PTCA | 3747 | 634 | 15 | 9 | 14 | 19 | 94 | 160 |
| Cerebral angiography | 981 | 319 | 10 | 6 | 10 | 10 | 159 | 115 |

For CA procedures as well as PTCA, both DRLs (for FT and KAP) have been shown much lower than the once published in the ISTISAN report.

In this study, which included a higher number of centres and data collected (Table 3), also $K_{a,r}$ values have been investigated.

For the purpose of optimizing radiological practice, the European Directive 2013/59/EURATOM [14] reinforces requirements regarding the adoption of DRL, which have proven to be an essential tool in the processes of optimizing exposure, identifying radiological practices that require methodological and/or technical interventions to reduce the average dose to patients. It is, therefore, necessary to evaluate local or national reference levels in order to estimate doses also for procedures that are difficult to standardize.

The rapid development of technology used in interventional procedures has led to appreciable variations in working modalities with consequent reductions of the doses delivered: periodic updates of reference levels are, therefore, necessary. One method to facilitate updating is proposed in the work by Simeonov et al. [46]. This is clear, for example, by looking at Table 2 in which our local reference levels are in general lower than the ISTISAN DRL.

This study reports the data from a sample of procedures performed in several Italian centres (in a wide geographical area of northern and central Italy) in the period between January 2015 and January 2019.

The median FT, KAP, and $K_{a,r}$ values of the centres were compared to each other, with the ISTISAN DRL [15] and/or with the local reference levels calculated as the 75th percentile of the total distribution of the median values per procedure per centre and/or literature results (Table 2).

This study has some limitations. Our data do not include information on the patients' body mass index or the factors that determine the complexity of various procedures. However, the dose given to a patient during fluoroscopically-guided operations is influenced much more by the complexity of the procedure than by the patient's weight [47,48]. Another parameter that should be taken into account is the use of electronic magnification, which is related to the type of procedure performed [49].

Furthermore, image quality was not evaluated and the required dosimetric data were not always fully available. In addition, in EVAR and pacemaker procedures, data from both mobile (C-arm) and fixed equipment were compared; this methodology was also used in other studies for the evaluation of preliminary DRL for complementary activities [31].

A further imprecision was introduced during the evaluation of the total $K_{a,r}$ for biplane systems because the $K_{a,r}$ was calculated by summing the frontal and lateral contributions; although summing Kerma values for different projections is not correct from a theoretical point of view, in this study, this strategy was accepted to represent the total Kerma delivered in the air. However, this value cannot be used to calculate the risk of deterministic effects (such as alopecia).

The sample size is another limitation: in a few centres data were collected with the aid of automatic DACS (Dose Archiving and Communication System). For others, the data were collected and processed manually using structured reports or paper records (the latter mainly for complementary activities such as ERCP, EVAR, and pacemaker procedures).

In this study DRLs were obtained following the method proposed by ICRP 135, based on 75 percentile of median values. This method was also used by Siiskonen [26] and Etard [24]. Other values of DRL reported in Table 2 were derived from 75 percentile of the total distribution of the data, or as a third quartile of the average values of the distribution.

The report SFPM: Niveaux de Reference en Radiologie Interventionnelle [50] has derived local DRL starting from 75th percentile of the median value (ICRP method) for six procedure: specifically, of our interest, cerebral angiography (three or more arteries), embolization of the head aneurysm and hepatic chemoembolization

(without radionuclides). DRL of KAP and FT per centres calculated by ICRP method for these procedures were compared with the values obtained with the 75th percentile of the total values distribution. The range between the two methods is within $\pm 20\%$ (except for FT in cerebral aneurysm embolization $\sim 27\%$).

Instead, Vassileva J et al. [51] find that difference between DRL calculated starting from mean and median values not being very significant, this can result in up to 20–25% difference in set DRL.

5. Conclusions

Our KAPTot Local DRL in neuroradiology (cerebral angiography procedures) is superior to the ISTISAN DRL even though this study included some angiographic systems with innovative technology. The ISTISAN DRL for neuroradiology procedures were obtained starting from a very small sample of centres: for cerebral angiography procedures, six centres were involved for a total of 319 procedures (vs ten centres and 981 procedures in this study).

This first data collection serves to take stock of the situation on dosimetry of patients in different sectors and is the starting point for obtaining DRL recalling that the levels depend on the experience and technology available at a given time. Radiological practice can be optimized not only by technological improvements, but also by modifying working modalities such using the low-dose fluoroscopy mode and reducing fps and pps.

This study represents a first attempt to obtain reference levels that could help to optimize working modalities and has made it possible to compare the median values of the centres with the DRL values proposed at a national level in Italy in the ISTISAN 17/33 report.

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References

- [1] Mooney RB, McKinstry CS, Kamel HA. Absorbed dose and deterministic effect to patients from interventional neuroradiology. *Br J Radiol* 2000;87:1:745–51.
- [2] Wagner LK, McNeese MD, Marx MV, Siegel EL. Severe skin reactions from interventional fluoroscopy: case report and review of the literature. *Radiology* 1999;213:773–6.
- [3] Balter S, Hopewell JW, Miller DL, Wagner LK, Zelefsky MJ. Fluoroscopically guided interventional procedures: a review of radiation effects on patients' skin and hair. *Radiology* 2010;232:326–41.
- [4] Spiker A, Zinn Z, Carter WH, Powers R, Kovach R. Fluoroscopy-induced chronic radiation dermatitis. *Am J Cardiol* 2012;110:1861–3.
- [5] Mettler Jr. FA, Koenig TR, Wagner LK, Kelsey CA. Radiation injuries after fluoroscopic procedures. *Semin Ultrasound, CT MRI* 2002;23(5):428–42. [https://doi.org/10.1016/S0887-2171\(02\)90014-4](https://doi.org/10.1016/S0887-2171(02)90014-4).
- [6] Giordano C, D'Ercole L, Gobbi R, Bocchiola M, Passerini F. Coronary angiography and percutaneous transluminal coronary angioplasty procedures: evaluation of patients' maximum skin dose using Gafchromic films and a comparison of local levels with reference levels proposed in the literature. *Phys Med* 2010;26:224–32.
- [7] Wagner LK, Archer BR. Minimizing risks for fluoroscopic X-rays—bioeffects, instrumentation and examination. A credentialing program. *Med Phys* 1998;25(2).
- [8] Stewart FA, Akleyev AV, Hauer-Jensen M, Hendry JH, Kleiman NJ, MacVittie TJ, et al. ICRP Publication 118: ICRP statement on tissue reactions and early and late effects of radiation in normal tissues and organs—threshold doses for tissue reactions in a radiation protection context. *Ann ICRP* 2012;41:1–322.
- [9] Moritake T, Matsumaru Y, Takigawa T, Nishizawa K, Matsumura A, Tsuboi K. Dose measurement on both patients and operators during neurointerventional procedures using photoluminescence glass dosimeters. *AJNR Am J Neuroradiol* 2008;29:1910–7.
- [10] Sandborg M, Rossitti S, Pettersson H. Local skin and eye lens equivalent in interventional neuroradiology. *Eur Radiol* 2010;20:725–33.
- [11] Safari MJ, Wong JHD, Kadir KA, Thorpe NK, Cutajar DL, Petasecca M, et al. Real-time eye lens dose monitoring during cerebral angiography procedures. *Eur Radiol* 2016;26:79–86.
- [12] Pearce MS, Salotti JA, Little MP, McHugh K, Lee C, Kim KP, et al. Radiation exposure from CT scans in childhood and subsequent risk of leukaemia and brain tumours: a retrospective cohort study. *Lancet* 2012;380(9840):499–505. [https://doi.org/10.1016/S0140-6736\(12\)60815-0](https://doi.org/10.1016/S0140-6736(12)60815-0).
- [13] International Commission on Radiological Protection. The 2007 recommendations

- of the international commission on radiological protection. ICRP publication 103. Ann ICRP 2007;37:1–332.
- [14] European Society of Radiology (ESR) Summary of the European Directive 2013/59/Euratom: essentials for health professionals in radiology. 2015, pp. Insights Imaging 6:411–417. doi: 10.1007/s13244-015-0410-4.
- [15] Padovani R, Compagnone G, D'Ercole L, Orlacchio A, Bernardi G, Rosi A, et al. Livelli diagnostici di riferimento nazionali per la radiologia diagnostica e interventistica. Roma: Istituto Superiore di Sanità; 2017. Rapporti ISTISAN 17/33.
- [16] Vaño E, Miller DL, Martin CJ, Rehani MM, Kang K, Rosenstein M, et al. Diagnostic reference levels in medical imaging. ICRP Publication 135. Ann ICRP 2017;46(1).
- [17] Vano E, Gonzalez L. Approaches to establishing reference levels in interventional radiology. Radiat Prot Dosim 2001;94(1):109–12. <https://doi.org/10.1093/oxfordjournals.rpd.a006451>.
- [18] Balter S, Fletcher DW, Kuan HM, Miller D, Richter D, Seissl H, et al. Techniques to estimate radiation dose to skin during fluoroscopically guided procedures. AAPM summer school proceedings. 2002.
- [19] International Electrotechnical Commission. Particular requirements for safety of X-ray equipment for interventional procedures. Geneva: Switzerland; 2000.
- [20] Food and Drug Administration. Performance standards for ionizing radiation emitting products. Washington DC: US Government Printing Office; 2009. p. 21.
- [21] Tuthill E, O'Hara L, O'Donohoe M, Panci S, Gilligan P, Campion D, et al. Investigation of reference levels and radiation dose associated with abdominal EVAR (endovascular aneurysm repair) procedures across several European Centres. Eur Radiol 2017;27(11):4846–56. <https://doi.org/10.1007/s00330-017-4791-2>.
- [22] Ufficio Federale della Sanità Pubblica. Circolare R-06-05. Valori diagnostici di riferimento per applicazioni di radiologia interventistica. Berna: Confederazione Svizzera; 2008. N. di revisione 2 del 01/06/2016.
- [23] Sharma D, Ramsewak A, O'Conaire S, Manoharan G, Spense MS Reducing radiation exposure during transcatheter aortic valve implantation (TAVI). Catheterization Cardiovasc Interventions 2015;85:1256–61.
- [24] Etard C, Bigand E, Salvat C, Vidal V, Beregi JP, et al. Patient dose in interventional radiology: a multicentre study of the most frequent procedures in France. Eur Radiol 2017;27(10):4281–90.
- [25] European Commission. Radiation protection 180: diagnostic reference levels in thirty-six European countries: part 2 of 2. Luxembourg: Publications Office of the European Union; 2014.
- [26] Siiskonen T, Ciraj-Bjelac O, Dabin J, Diklic A, Domienik-Andrzejewska J, Farah J, et al. Establishing the European diagnostic reference levels for interventional cardiology. Phys Med 2018;54:42–8.
- [27] International Electrotechnical Commission, IEC 60601-2-43 Ed 2.0: medical electrical equipment. Part 2-43: particular requirements for basic safety and essential performance of X-ray equipment for interventional procedures. Geneva: 2010.
- [28] European Commission. Radiation protection 162: criteria for acceptability of medical radiological equipment used in diagnostic radiology, nuclear medicine and radiotherapy. Luxembourg: Publications Office of the European Union; 2012.
- [29] Soderman M, Holmin S, Anderson T, Palmgren C, Babic D, Hoornaert B. Image noise reduction algorithm for digital subtraction angiography: clinical results. Radiology 2013;269(2):553–60.
- [30] Söderman Michael, Mauti Maria, Boon Sjirk, Omar Artur, Martensdóttir María, Andersson Tommy, et al. Radiation dose in neuroangiography using image noise reduction technology: a population study based on 614 patients. Neuroradiology 2013;55:1365–72.
- [31] Kahn EN, Gemmete JJ, Chaudhary N, Thompson BG, Chen K, Christodoulou EG, et al. Radiation dose reduction during neurointerventional procedures by modification of default settings on biplane angiography equipment. J NeuroInterv Surg 2016;8:819–23.
- [32] Pearl MS, Torok C, Wang J, Wyse E, Mahesh M, Gailloud P. Practical techniques for reducing radiation exposure during cerebral angiography procedures. J NeuroInterv Surg 2015;7:141–5.
- [33] Levitt MR, Osbun JW, Ghodke BV, Kim LJ. Radiation dose reduction in neuroendovascular procedures. World Neurosurg 2013;80:681–2.
- [34] STUK's decision 15/3020/2016. Available at <http://www.stuk.fi/documents/88234/1106801/Decision-15-3020-2015+Reference+levels+for+the+patients+radiation+exposure+20122016.pdf>.
- [35] Lauterbach M, Hauptmann KE. Reducing patient radiation dose with image noise reduction technology in transcatheter aortic valve procedures. Am J Cardiol 2016;117:834–8.
- [36] Gislason-Lee AJ, Keeble C, Malkin CJ, Egleston D, Bexon J, Kengyelics SM, Blackman D, Davies AG. Impact of latest generation cardiac interventional X-ray equipment on patient image quality and radiation dose for trans-catheter aortic valve implantations. Br J Radiol November 2016;89(1067):20160269.
- [37] See J, Amora JL, Lee S, Lim P, Teo WS, Tan BY, et al. Non-fluoroscopic navigation systems for radiofrequency catheter ablation for supraventricular tachycardia reduce ionising radiation exposure. Singapore Med J 2016;57(7):390–5.
- [38] Casella M, Dello Russo A, Pelargonio G, Del Greco M, Zingarini G, Piacenti M, et al. Near zero fluoroscopic exposure during catheter ablation of supraventricular arrhythmias: the NO-PARTY multicentre randomized trial. Europace 2016;18:1565–72.
- [39] Tsalafoutas IA, Spanodimos SG, Maniatis PN, Fournarakis GM, Koulentianos ED, Tsigas DL. Radiation doses to patients and cardiologists from permanent cardiac pacemaker implantation procedures. Pacing Clin Electrophysiol 2005;28(9):910–6.
- [40] Perisinakis K, Theocharopoulos N, Damilakis J, Manios E, Vardas P, Gourtsoyiannis N. Fluoroscopically guided implantation of modern cardiac resynchronization devices: radiation burden to the patient and associated risks. J Am Coll Cardiol 2005;46(12):2335–9.
- [41] Ruiz-Cruces R, Vano E, Carrera-Magariño F, Moreno-Rodríguez F, Soler-Cantos MM, Canis-Lopez M, et al. Diagnostic reference levels and complexity indices in interventional radiology: a national programme. Eur Radiol 2016;26:4268–76. <https://doi.org/10.1007/s00330-016-4334-2>.
- [42] Nickoloff EL. AAPM/RSNA physics tutorial for residents: physics of flat-panel fluoroscopy systems: survey of modern fluoroscopy imaging: flat-panel detectors versus image intensifiers and more. Radiographics 2011;31:591–602.
- [43] Tsapaki V, Delinikolas P, Paraskeva KD, Paspatis IA, Scotiniotis H, et al. Preliminary diagnostic reference levels for endoscopic retrograde cholangio-pancreatography in Greece. Phys Med 2016 Apr;32(4):607–11.
- [44] Spira D, Kirchner S, Blumenstock G, Herz K, Ketelsen D, Wiskirchen J, et al. Therapeutic angiographic procedures: differences in dose area product between analog image intensifier and digital flat panel detector. Acta Radiol 2016;57:587–94.
- [45] Miraglia R, Maruzzelli L, Tuzzolino F, Indovina PL, Luca A. Radiation exposure in biliary procedures performed to manage anastomotic strictures in pediatric liver transplant recipients: comparison between radiation exposure levels using an image intensifier and a flat-panel detector-based system. Cardiovasc Intervent Radiol 2013;36:1670–6.
- [46] Simeonov F, Palov N, Ivanova D, Kostova-Lefterova D, Georgiev E, Zagorska A, et al. Web-based platform for patient dose surveys in diagnostic and interventional radiology in Bulgaria: functionality testing and optimization. Phys Med 2017;41:87–92.
- [47] IAEA, Establishing Guidance Levels in X Ray Guided Medical Interventional Procedures: A Pilot Study. 2009 Safety Report Series No. 59.
- [48] Miller DL, Kwon D, Bonavia GH. Reference levels for patient radiation doses in interventional radiology: proposed initial values for U.S. practice. Radiology 2009;253:753–64.
- [49] Safari Mohammad Javad, Wong Jeannie Hsiu Ding, Jong Wei Loong, Thorpe Nathan, Cutajar Dean, Rosenfeld Anatoly, et al. Influence of exposure and geometric parameters on absorbed doses associated with common neuro-interventional procedures. Phys Med: Eur J Med Phys 2017;35:66–72.
- [50] Greffier J, Bigand E, Etard C, Hornbeck A, Salvat C. Niveaux de Reference en Radiologie Interventionnelle. Paris: Société Française de Physique Médicale; 2017. (Rapport SFPM 32).
- [51] Vassileva J, Rehani M, et al. A study to establish international diagnostic reference levels for paediatric computed tomography. Radiat Prot Dosim 2015;165(1–4):70–80.