

Diagnostic reference levels and complexity indices in interventional radiology: a national programme

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Abstract

Objectives To propose national diagnostic reference levels (DRLs) for interventional radiology and to evaluate the impact of the procedural complexity on patient doses.

Methods Eight interventional radiology units from Spanish hospitals were involved in this project. The participants agreed to undergo common quality control procedures for X-ray systems. Kerma area product (KAP) was collected from a sample of 1,649 procedures. A consensus document established the criteria to evaluate the complexity of seven types of procedures. DRLs were set as the 3rd quartile of KAP values.

Results The KAP (3rd quartile) in Gy cm² for the procedures included in the survey were: lower extremity arteriography (n=784) 78; renal arteriography (n=37) 107; transjugular hepatic biopsies (THB) (n=30) 45; biliary drainage (BD)

(n=314) 30; uterine fibroid embolization (UFE) (n=56) 214; colon endoprostheses (CE) (n=31) 169; hepatic chemoembolization (HC) (n=269) 303; femoropopliteal revascularization (FR) (n=62) 119; and iliac stent (n=66) 170. The complexity involved the increases in the following KAP factors from simple to complex procedures: THB x4; BD x13; UFE x3; CE x3; HC x5; FR x5 and IS x4.

Conclusions The evaluation of the procedure complexity in patient doses will allow the proper use of DRLs for the optimization of interventional radiology.

Key Points

- National DRLs for interventional procedures have been proposed given level of complexity
- For clinical audits, the level of complexity should be taken into account.
- An evaluation of the complexity levels of the procedure should be made.

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Keywords Interventional radiology · Diagnostic reference levels · Patient doses · Optimization · Clinical audit

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Introduction

According to the International Commission on Radiological Protection (ICRP), diagnostic reference levels (DRLs) help optimize radiological protection in imaging procedures and can facilitate the management of patient doses in diagnostic and interventional radiology (IR) procedures as they offer a method of discrimination for unusually high or unusually low patient doses for a particular medical imaging procedure [1–6].

For fluoroscopically guided interventional procedures, DRLs could also be used to promote the management of patient doses. However, because the duration and complexity of fluoroscopic exposures for each procedure are strongly dependent on the individual clinical circumstances, the observed distribution of patient doses is very wide, even for a specified protocol [3, 5, 7, 8].

The Council Directive 2013/59/EURATOM considers IR to be a special practice involving high doses and requiring strict monitoring to ensure the best quality assurance programs as well as quality control measures. The Directive also states that member states of the European Union should promote the establishment, regular review and use of DRLs for radiodiagnostic procedures [9]. The legal definition in the Directive for “radiodiagnostic” is: “pertaining to radiodiagnostic and radiotherapeutic procedures, and interventional radiology or other medical uses of ionizing radiation for planning, guiding, and verification purposes”.

The European Society of Radiology plans to have an electronic “Clinical Decision Support” (CDS) system as well as dose recording and dose management procedures using DRLs [10]. The proper use of DRLs for IR requires that the dose recording systems be complemented by information on the complexity of the procedure.

The radiation dose values for similar IR procedures may be very different. This could be due to problems with the classification and proper identification of the intervention procedures and their complexities, which make comparisons difficult [11–15].

Very few papers have reported the impact of the complexity of the interventional procedures on the dosimetric quantities used to set DRLs, to perform the clinical audit of local patient doses that are compared with DRLs and to decide if optimization actions are necessary. Efforts to improve radiation protection by the implementation of DRLs were made for interventional cardiology during the DIMOND and SENTINEL European research programmes [16, 17] and the International Atomic Energy Agency (IAEA) [18], but a similar approach is missing for peripheral vascular and non-vascular interventional procedures.

Currently, there is no classification for IR procedures according to their complexity for radiation protection purposes. The Spanish Society of Interventional Radiology and the results of this national project may be used in the future as part of the strategies for optimization and for the proper use of DRLs in IR.

In addition, this study could allow, as it has been suggested for cardiology [16], for the refinement of workload quantifications or the payment system for IR units that are currently based only on the number and type of procedures carried out per month, but not on their complexities.

The purpose of this paper is to develop national diagnostic reference levels for IR, to propose complexity criteria for

seven common therapeutic IR procedures, and to evaluate their impact on patient doses.

Materials and methods

A group of eight representative university Spanish hospitals in cooperation with the national Society of Vascular and Interventional Radiology agreed to launch a research project (called “ERRAPRI”, Evaluation of Radiological Risk for patients in Interventional Radiology) to investigate the complexity indices and their impact on patient doses, to derive a new set of national DRLs for interventional radiology, to set complexity criteria for other Spanish hospitals and the medical IR society and to facilitate local clinical audits and the proper use of DRLs as recommended by the ICRP [3, 5] and the new European Directive [9].

Each hospital nominated a senior interventionist and a senior medical physicist to be part of the team who proposed the complexity criteria and the dosimetric parameters to be collected and validated before being sent to a central database to complete and refine the existing preliminary national DRLs [11]. During the period of the survey very few automatic systems to collect and process patient dose values were available. Also, very few systems were able to produce DICOM dose structured report. Thus, data for the national survey were collected and processed manually.

The X-ray systems used were the ones available at the hospitals involved in the survey and are detailed in Table 1. Imaging systems were representative of the technology used in interventional radiology in Spain during the years 2010–2013. Most of them had the dose reduction techniques available in these years. Common basic quality control procedures for the X-ray and imaging systems, including the calibration of patient dosimetry systems, were developed among the participants before starting the project. The quality control methodology was based on the European DIMOND and SENTINEL research programmes and was applied to the dosimetric characterization of the X-ray and imaging systems and the primary evaluation of image quality parameters using test objects [11, 19].

Based on the clinical experience of the senior intervention radiologists involved in the project, the levels of complexity were suggested based on different criteria (described later), and their impact on the different patient dose-related quantities was evaluated, including the kerma area product (KAP), fluoroscopy time, and number of DSA (digital subtraction angiography) images, depending on the anatomical details and the outcome of the intervention (e.g., stent placement). For simplicity, we only present the main KAP results in this paper to report the impact of complexity on this dosimetric parameter, which is also used as the primary quantity for setting national DRLs.

Table 1 Equipment information

Hospital	Trademark	Model	DICOM
Madrid (San Carlos)	Philips	Allura	Yes
Huelva	Siemens	Artis Zee	Yes
Córdoba	Philips	Allura	Yes
Canarias	Siemens	Artis Zee	Yes
Bilbao	Siemens	Angio Star Plus	Yes
Málaga (C. Haya)	Toshiba	Infinix VCI	Yes
Málaga (V. Victoria)	Siemens	Artis Zee	Yes

KAP is defined as the integral of the air kerma over the area of the beam in a plane, perpendicular to the central axis of the X-ray beam [20].

Diagnostic reference level updates

The DRLs for the IR procedures were calculated using the distribution of the KAP values collected during the 3 years of the project (2010 to 2013) in a sample of 1,649 procedures (nine different types).

A consensus document was used to agree upon the criteria to include in the survey and to archive in the central database. This consensus document also included the criteria used to evaluate the complexity of the seven types of therapeutic procedures. National DRLs were set as the 3rd quartile of KAP values. These values, before being included in the database, were corrected by each hospital (by the medical physicist nominated for the project) using the calibration factors of the different X-ray systems.

For each of the procedures, a short description was made in the consensus document (including some quality criteria) to ensure that the dosimetric data introduced in the database corresponded to the same procedure defined by the research team. For therapeutic procedures, the scoring complexities (as described later) were also included. Interventional procedures have been considered diagnostic when used to identify a particular pathologic process and therapeutic when used to treat a pathologic process.

The selected procedures and collected samples were:

- Lower extremity arteriography (n = 784)
- Renal arteriography (n = 37)
- Transjugular hepatic biopsies (THB) (n = 30)
- Biliary drainage (BD) (n = 314)
- Uterine fibroid embolization (UFE) (n = 56)
- Colon endoprostheses (CE) (n = 31)
- Hepatic chemoembolization (HC) (n = 269)
- Femoropopliteal revascularization (FR) (n = 62)
- Iliac stent (IS) (n = 66)

Complexity indices and scoring

The complexity level was evaluated for the seven therapeutic types of procedures. The main criteria to select these procedures were having several participant hospitals performing a relevant number of these procedures per year, as well as the opinion of the interventionists regarding the feasibility of reaching a consensus on the definition and application of complexity criteria.

Consensus on the complexity indices scoring was reached after several meetings of the senior interventionists, also taking into account the possibility of practical evaluations during routine clinical practice. The complexity scoring used different values for the different procedures as suggested by the senior radiologist and the hospital leading the proposal. This scoring was later normalized (and simplified) into three levels: simple, medium, and complex procedures. Simple procedures had the lowest scores, and complex procedures had the highest scores. This method allowed the derivation of multiplicative factors for the KAP to be used to estimate the impact of complexity on patient doses and to compare with DRLs. A short description of the complexity scoring is presented in the next sections. Scores ranging from 1 to 3 are used by the complexity index for the different items proposed for each of the procedures.

1. Transjugular hepatic biopsy.

CI 1	By the anatomical characteristics
1	Liver of normal size
2	Lift diaphragmatic
3	Liver of small size
CI 2	By the angulation of the suprahepatic vein regarding the inferior vena cava.
1	Easy obtuse angle (>120°)
2	Medium difficulty (90° to 120°)
3	Very difficult (<90°)

2. Biliary drainage.

CI 1	By the anatomical characteristics
1	Liver of normal size
2	Lift diaphragmatic
3	Liver of small size
CI 2	By the degree of intrahepatic biliary ductal dilatation (IBD)
1	IBD very long
2	IBD moderately dilated
3	IBD not dilated
CI 3	By the location of the obstruction
1	In medial/distal extrahepatic biliary ductal (EBD)
2	In proximal bile/EBD confluence
3	In IBD

CI 4 By passage through the obstacle

- 1 Easy step of the obstacle
- 2 Medium difficulty
- 3 Very difficult

3. Uterine fibroid embolization.**CI 1 By the arterial access:**

- 1 Unilateral femoral puncture
- 2 Bilateral femoral puncture
- 3 Puncture radial, brachial, or axillary

CI 2 By the anatomy:

- 1 Uterine arteries with origin in previous and dilated trunk
- 2 Uterine arteries with origin in trunk earlier and not dilated
- 3 Uterine artery with abnormal origin and/or decreased caliber

CI 3 By the technique:

- 1 Supraselective catheterization of uterine arteries with diagnostic catheter (4F)
- 2 Supraselective catheterization with microcatheter uterine arteries
- 3 More than four exchanges of catheters or appearance of spasms.

4. Colon endoprostheses.**CI 1 By the location:**

- 1 Recto
- 2 Sigma
- 3 Descending colon

CI 2 By the type of injury:

- 1 Stenosis
- 2 Simple obstruction
- 3 Complex obstruction

CI 3 The anatomical shape of the distal colon injury:

- 1 Little/small elongation and haustration
- 2 Moderate elongation and haustration
- 3 Lot/Large elongation and haustration

5. Hepatic chemoembolization.**CI 1 By the anatomical characteristics (tortuosity, angulation of the origin of the vessel, atheromatosis) of the aorta and its branches:**

- 1 Easy
- 2 Medium difficulty
- 3 Very high difficulty

CI 2 According to the configuration of the hepatic arteries or other branches:

- 1 Standard
- 2 Accessory artery to a lobe
- 3 Accessory artery for both lobes

CI 3 By the type of embolization:

- 1 Lobar unilateral

2 Lobar bilateral or one supraselective

3 Two or more supraselective

6. Femoropopliteal revascularization.**CI 1**

- 1 Contralateral
- 2 Ipsilateral
- 3 Axillary, brachial or popliteal

CI 2

- 1 **By the type of injury:**
Stenosis
- 2 Short obstruction (≤ 3 cm.)
- 3 Long/large obstruction (> 3 cm.)

CI 3

- 1 **By the type of treatment:**
Pre- or postdilatation
- 2 Pre- and postdilatation
- 3 Distal protection filter

7. Iliac stent placement.**CI 1**

- 1 Ipsilateral
- 2 Contralateral
- 3 Bilateral, axillary, or brachial

CI 2

- 1 **By the type of injury:**
Stenosis
- 2 Short obstruction (≤ 3 cm.)
- 3 Long/large obstruction (> 3 cm.)

CI 3

- 1 **By the type of treatment:**
Stent directly
- 2 Stent, predilatation, or postdilatation
- 3 Stent, predilatation, and postdilatation

Results**Diagnostic reference levels**

The Spanish DRLs (set as the 3rd quartile of the KAP value distribution) were obtained as a result of this project and are summarized in Table 2. The complexity indices have been analysed for the seven therapeutic procedures, and as described in the following section, the samples for the different types of procedures resulted in a medium level of complexity.

The complexity index analyses and their impact on patient doses

The kerma area product (the mean and 3rd quartile values in Gy cm²) values for the seven procedures included in the

Table 2 National Diagnostic Reference Levels derived from this study

Procedure	N	DRLs for KAP (Gy cm ²)	FT (min)	Images
Lower extremity arteriography	784	78	4	137
Renal arteriography	37	107	5.6	128
Transjugular hepatic biopsies (THB)	30	45	13.2	56
Biliary drainage (BD)	314	30	17.3	7
Uterine fibroid embolization (UFE)	56	214	31	138
Colon endoprotheses (CE)	31	169	46.5	11
Hepatic chemoembolization (HC)	269	303	26.3	245
Femoropopliteal revascularization (FR)	62	119	30	350
Iliac stent (IS)	66	170	21.4	309

N, Sample size. FT, Fluoroscopy time. Images, number of DSA images.

Table 3 Kerma area product (Gy cm²) and complexity indices (CI) for the subsample of procedures for which complexity criteria were analyzed

Procedure	N	KAP (mean)	KAP (3 rd Q)	CI (range)	CI (mean)	CI (% of max)
THB	30	30.8	44.9	2 to 6	2.9	48
BD	129	30.4	36.3	4 to 12	5.5	46
UFE	37	189.6	256.5	2 to 6	3.7	62
CE	25	120.2	174.1	3 to 9	6.1	68
HC	138	216.1	338.7	3 to 9	4.7	52
FR	57	83.9	114.1	3 to 9	4.9	54
IS	48	105.7	170.1	3 to 9	5.2	58

complexity analysis are presented in Table 3, with the complexity index (CI) (range and mean values) for the different procedures. Note that for all of the procedures analysed by complexity, the mean value was approximately 50 % (range 48-62 %) and the full sample may be considered to have medium complexity.

The increase in complexity for the different procedures also implies, as expected, an increase in the mean KAP values. The resulting increasing factors (from simple to complex procedures) were:

THB x 4; BD x 13; UFE x 3; CE x 3; HC x 5; FR x 5; and IS x 4

Figures 1, 2, 3, 4, and 5 present the global results of the complexity index grouped in three levels: simple, medium, and complex procedures, for the most relevant therapeutic procedures. The vertical bars in these figures represent standard deviations of the mean KAP values. Note that the quantitative differences in the KAP percentage between simple, medium, and complex procedures vary.

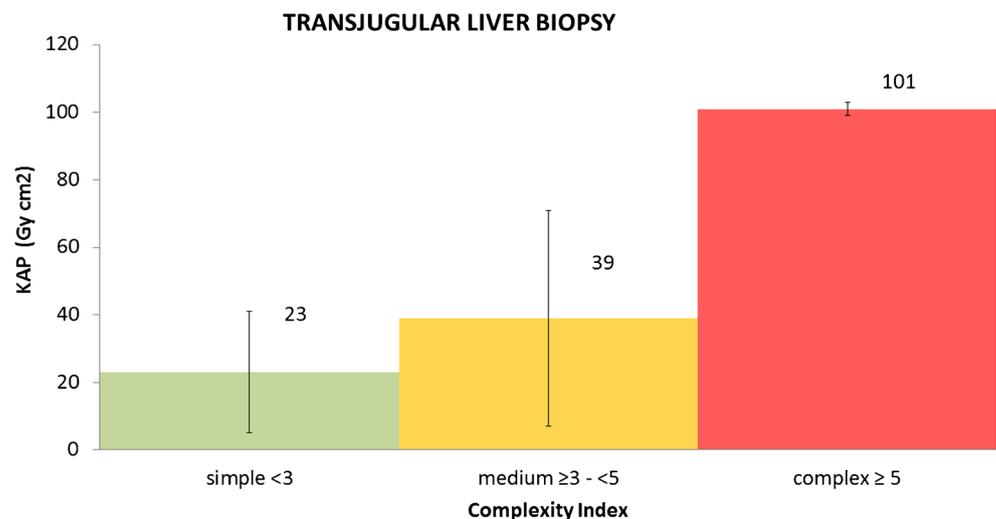
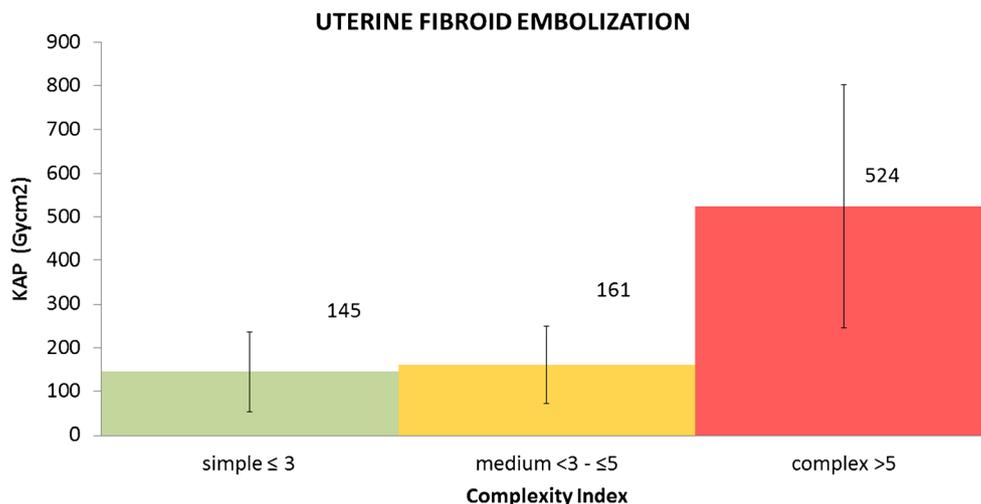
Fig. 1 Complexity index levels versus KAP values for transjugular liver biopsy

Fig. 2 Complexity index levels versus KAP values in uterine fibroid embolization



The full scoring range used to identify the complexity of the different procedures was normalized to these three levels in all cases to facilitate an easier comparison of the complexity impact on patient doses similar to the already published results for interventional cardiology procedures [16–18, 21].

Statistical analyses (r Pearson and ANOVA test) identified significant correlations between the complexity score and patient dose (KAP) for all of the procedures ($F < 0.05$).

Discussion

A relevant aspect of the quality assurance programme of any interventional radiology unit should be the regular audit of patient doses and the comparison of the mean or median values with existing diagnostic reference levels (DRLs) to decide if correction action is necessary to refine and improve the X-ray system settings or the employed protocols and procedures. However, for interventional radiology, an assessment of the different levels of complexity for the audited procedures

is necessary due to the impact of the complexity indices on the values of patient dose parameters. In our case, multiplicative factors for the KAP between 3 and 5 (with the exception of biliary drainage with a factor of 13) were found. Bernardi et al. [16] defined complexity indexes for interventional cardiology procedures in 402 random percutaneous transluminal coronary angioplasties and divided into three groups. KAP and fluoroscopy time were well correlated with the three complexity levels: simple, medium, and complex. Obtained multiplicative factors for KAP were 1.4 from simple to medium and 1.8 from simple to complex. Balter et al. [18] based on Hospitals from five countries also explored the impact of complexity of cardiology therapeutic interventional procedures (not related to operator skill or technique) and concluded that appropriate scaling of DRLs by complexity provides an additional tool for refining a facility's quality assurance and optimization processes. In this survey, the multiplying factors for KAP resulted in 1.3 from simple to medium and 2.0 from simple to complex. The recent European Report (PR-180) on DRLs [22] has data on interventional cardiology, but few values for other interventional radiology procedures.

Fig. 3 Complexity index levels versus KAP values in colon endoprostheses

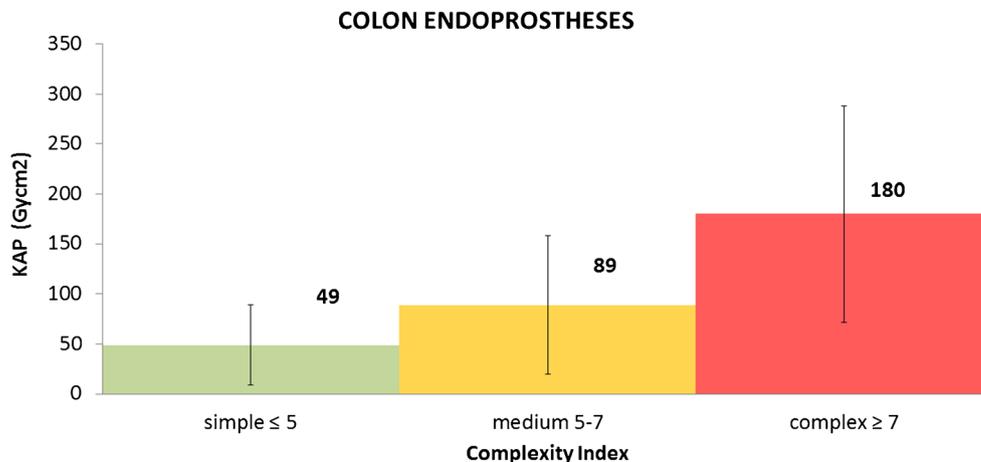
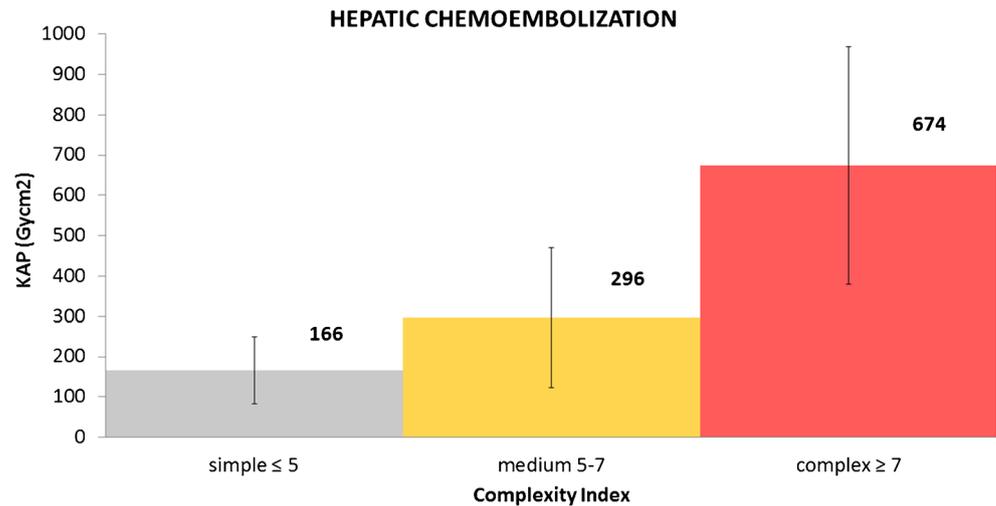


Fig. 4 Complexity index levels versus KAP values in hepatic chemoembolization



The impact of the complexity indices for biliary drainage requires re-evaluation in the future. A multiplicative factor of 13 in the KAP from the simple to the more complex procedures has been obtained and seems too high, although the sample used in our case was quite large (314 procedures) and the correlation between the KAP and the complexity index was very good ($F = 1 * 10^{-13}$).

Wide scale surveys to obtain or to update national DRLs in interventional radiology are not, in general, taken into account by complexity indices. However, with large samples, the adopted DRL values (the 3rd quartile of the patient dose related quantities) should correspond to the “standard” or medium complexity, which was the situation in our survey.

The importance of evaluating the impact of the complexity indices in interventional radiology is to decide if optimization actions are necessary after comparisons of the local median or mean values with the national DRLs.

During the clinical audit process, the local mean or median KAP values should be compared with the national DRLs,

although a degree of “tolerance” derived from the multiplicative factors reported in this paper and derived by the analysed complexity indices should also be incorporated.

Table 4 presents the values of the national DRL estimates for the three levels of complexity (simple, medium, and complex) to facilitate the comparison of groups of local procedures with different complexity levels with the national DRLs derived from this project. The values in Table 4 have been obtained from the complexity indices derived from this project (some of them are shown in Figs. 1, 2, 3, 4, and 5) and are applied to Table 2 (the national DRLs) to obtain the corresponding reduction factors for simple procedures (compared with medium complexity procedures) and the multiplying factors for complex procedures (compared with medium complexity procedures).

The results of this national survey allow for the consideration of the impact of the complexity factors on patient doses and, subsequently, on the national DRLs for the seven interventional therapeutic procedures included in this survey. Our methodology is consistent with the recommendations of the

Fig. 5 Complexity index levels versus KAP values in iliac stent placement

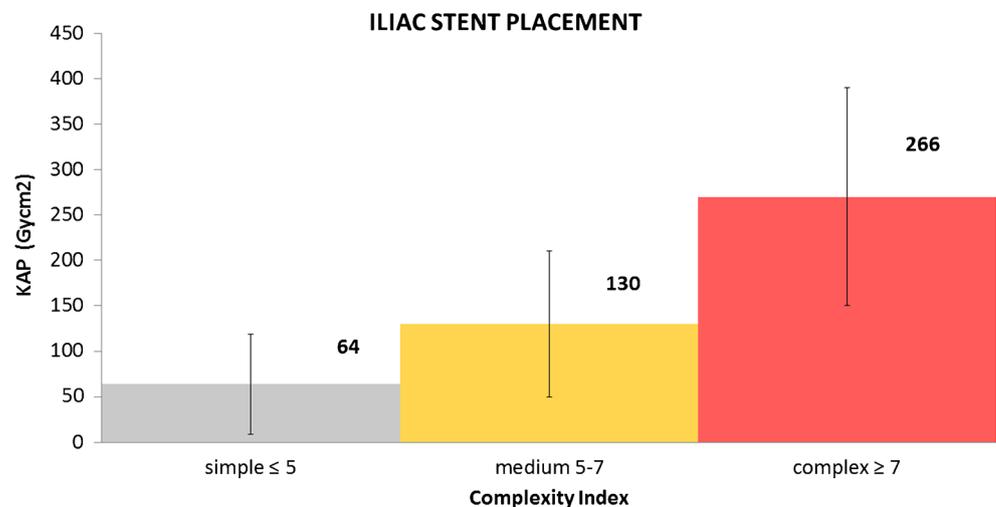


Table 4 The Diagnostic Reference Levels for the three levels of complexity

Procedure	DRLs (Gy cm ²) for simple procedures	DRLs (Gy cm ²) for medium procedures	DRLs (Gy cm ²) for complex procedures
Lower extremity arteriography	n.a.	78	n.a.
Renal arteriography	n.a.	107	n.a.
Transjugular hepatic biopsies (THB)	30 (15)	45 (14)	110 (1)
Biliary drainage (BD)	10 (85)	30 (32)	141 (12)
Uterine fibroid embolization (UFE)	167 (24)	214 (9)	613 (4)
Colon endoprosthesis (CE)	93 (5)	169 (15)	342 (5)
Hepatic chemoembolization (HC)	170 (50)	303 (77)	881 (11)
Femoropopliteal revascularization (FR)	50 (32)	119 (21)	255 (4)
Iliac stent (IS)	84 (22)	170 (20)	348 (4)

Numbers in parentheses indicate the size of the sample classified as simple, medium, and complex procedures.

ICRP and can be used by other countries as an initial approach to refine DRLs for interventional procedures.

Comparisons with the published results from previous papers may be difficult because some authors report the mean values instead of the median or 3rd quartile values. Table 5 presents a comparison of the mean values obtained in the present national survey with other published papers [11, 23–25]. The mean values presented in the table have been selected for comparison purposes with other authors, but note that the DRLs are set as the 3rd quartile of the patient dose distribution.

The large difference in the DRL for biliary drainage with the previous Spanish national survey published in 2009 [11] could be in part due to the large multiplying factor (x13) resulting from the complexity of these procedures. The proposed national DRL for biliary drainage in 2009 was 80 Gy cm², and in the current survey, the 3rd quartile was 30 Gy cm² for medium complexity procedures, but 141 Gy cm² for complex procedures (see Table 4). This discrepancy could be indicative of the fact that the sample in 2009 may have contained more complex cases than the current sample. The mean complexity index in this last survey was 46 % of the maximum (see Table 3). A similar comment could be made for the discrepancies between our mean value

(216 Gy cm²) for hepatic chemoembolization and the higher values reported by Aroura et al. (620 Gy cm²) [24] and Miller et al. (353 Gy cm²) [25].

These differences support the value of evaluating the level of complexity of the local samples when comparing DRLs for interventional radiology procedures before deciding on optimization actions.

Conclusions

The complexity criteria for seven therapeutic interventional procedures were developed among eight representative hospitals and were applied in a national survey over three years. A similar approach should also be explored for interventional diagnostic procedures.

These criteria facilitate evaluations of the impact of procedural complexity on patient doses and propose a new set of diagnostic reference levels for these procedures with the possibility of differentiating between low, medium and complex procedures.

These three complexity levels facilitate clinical audits and the proper use of DRLs for patient dose optimization in interventional radiology.

Table 5 The mean KAP (Gy cm²) values reported in the literature for interventional procedures

Procedure	This work	Zotova [22]	Vano [11]	Aroura [23]	Miller [24]
Transjugular hepatic biopsies (THB)	45				
Biliary drainage (BD)	30	31	61		
Uterine fibroid embolization (UFE)	214		170		
Colon endoprosthesis (CE)	169				
Hepatic chemoembolization (HC)	303		216	620	353
Femoropopliteal revascularization (FR)	119				
Iliac stent (IS)	170		91		

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