



# Patient dose reference levels in surgery: a multicenter study

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## Abstract

**Objective** To assess diagnostic reference levels (DRLs) in surgery for the most frequent procedures as required by the European Directive 2013/59/Euratom.

**Methods** A survey was conducted in six centers. Eight orthopedic, urology and gastrointestinal surgical procedures were analyzed. Kerma area product (KAP) and fluoroscopy time (FT) were recorded for 50 patients (except for elbow: 30 patients) per procedure and per center from September 2016 to September 2017. DRLs were calculated as the 3rd quartiles of the distributions. For shoulder surgery, DRLs were defined according to the complexity of the procedure. For hand/wrist and foot/ankle surgery, DRLs were defined according to the technology (conventional C-arm vs. mini-C-arm).

**Results** Results of 1870 procedures were retrieved. DRLs were calculated for the two dosimetric indicators and the eight procedures. DRLs were 2130 mGy.cm<sup>2</sup> and 1.4 min for proximal femoral intramedullary nail, 1185 mGy.cm<sup>2</sup> and 0.9 min for laparoscopic cholecystectomy and 2195 mGy.cm<sup>2</sup> and 1.0 min for double-J (pigtail) ureteral catheter insertion. For shoulder surgery, KAP and FT were significantly higher ( $p < 0.05$ ) for intramedullary procedures compared to extramedullary procedures. For hand/wrist and foot/ankle surgery, the KAPs were significantly higher ( $p < 0.05$ ) with conventional C-arm compared to mini-C-arm, but FTs were not significantly different ( $p$ : not significant).

**Conclusion** This study reports DRLs in surgery based on a multicentric survey.

## Key Points

- *Delivered dose in surgery depends on procedure, practice and patient.*
- *Diagnostic reference levels (DRLs) are proposed for eight surgical procedures.*
- *DRLs are useful to benchmark practices and optimize protocols.*

**Keywords** Surgery · Radiation exposure · Radiation protection · Dosimetry · Fluoroscopy

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## Abbreviations

DRL	Diagnostic reference level
FT	Fluoroscopic time
KAP	Kerma area product
DMS	Dose management system

## Introduction

The systematic use of a C-arm during surgical procedures varies depending on surgical specialty. These systems are particularly applied in orthopedic, urology or gastrointestinal surgery [1]. X-ray allows surgeons access images that improve the patient's surgical management; nevertheless, the risk of x-rays should also be considered. Except for vascular procedures, x-ray exposure is lower in surgery than in other interventional radiology fields, such as cardiology or neuroradiology.

Therefore, the appearance of deterministic effects (e.g. radiodermatitis or alopecia) is not expected under normal conditions. However, the risk of long-term stochastic effects (induced cancer) remains an issue, even for relatively low doses delivered. Therefore, all practices using x-rays must be justified and optimized to reduce this risk.

The optimization principle, one of the main radiation protection principles, consists in reducing the dose as low as reasonably achievable (ALARA) while maintaining image quality consistent with the diagnostic or therapeutic goal. The implementation of this principle in surgery first requires training of surgeons in the proper use of C-arm (using pulsed fluoroscopy, reducing field size, etc.) and to optimize their practices (reducing fluoroscopy time (FT), limiting the use of fluorography, etc.) [1, 2]. Second, it requires collection and recording dose indicators to monitor the doses delivered to patients. Finally, it requires setting up local reference levels to monitor dose variations over time and comparison against national reference levels or literature.

To provide an optimization tool to medical professionals, the International Commission on Radiological Protection (ICRP) introduced in 1997 the concept of diagnostic reference levels (DRLs) [3] for diagnostic procedures and extended this concept to interventional radiology [4–9]. The new European Council Directive 2013/59/Euratom requires all member states to establish regular review and use reference levels for interventional radiology procedures [9]. According to the 2017 ICRP publication [10], DRLs in this field should be established in terms of fluoroscopy time (FT), kerma area product (KAP) and air kerma at the patient entrance reference point (AK) when available.

Few recent local or national reference levels in interventional radiology or in surgery are available in the literature [11]. The purpose of this study was to establish local DRLs for frequent procedures in surgery using C-arm in adults that could be used as a starting point to assist the optimization process in surgery and to establish national DRLs [10].

## Materials and methods

This study was approved by our institutional review board and written informed consents were waived.

A retrospective survey was conducted on consecutive adult patients from September 2016 to September 2017 in six French centers: three public hospitals (two academic and one non-academic) and three private clinics.

The eight most frequent surgical procedures, in the participating centers were selected. For gastrointestinal and urologic surgery, three procedures were studied: laparoscopic cholecystectomy without choledochotomy (gallbladder removal);

double-J (pigtail) ureteral catheter insertion (to prevent or circumvent ureteral obstacle and to allow free passage of urine from the kidney to the bladder); and implantable venous access port insertion (performed in urologic and gastrointestinal surgery). For orthopedic surgery, five procedures were assessed: hand and wrist surgery; ankle and foot surgery; elbow surgery; hip surgery and shoulder surgery. Hand and wrist surgery included wrist fractures and metal removal procedures. Foot and ankle surgery included bimalleolar fracture and metal removal procedures. Elbow surgery included olecranon fractures and metal removal procedures. Hip surgery included the proximal femoral intramedullary nail. In shoulder surgery, intra- and extra-medullary procedures were assessed separately to determine the influence of complexity of the procedure on the dose delivered to the patient. For this surgery, there is no gold standard and surgeons are free to use a nail or plate according to their preference. The placement of a nail requires a radiographic evaluation in real time to visualize intramedullary progression into the bone and to ascertain the reduction of the invisible fracture. Whilst for extramedullary surgery, the reduction and placement of the material is directly visible; radiography is still required at the end of the intervention to ensure the correct positioning of the equipment.

Adult patients ( $\geq 18$  years old) that benefitted from one out those eight surgical procedures were included without any selection criteria regarding height, weight or clinical context. This study was restricted to procedures performed with a fluoroscopy-guided C-arm. Procedures performed with interventional radiology equipment or with a CT scan were excluded.

An invitation was e-mailed to the six centers, asking for the participation of their surgery departments in the survey. The center participants could choose to collect data for all or part of the list of procedures, depending on the types of procedure performed in their department of surgery.

A questionnaire divided into two parts was sent to the participating centers. The first part recorded radiological equipment: manufacturer, model, commissioning year, field size diameter, type of detector (flat panel or image intensifier) and type of C-arm (conventional or mini). A mandatory annual quality control was carried out on each C-arm in all centers and the ratio between the KAP measured and displayed for fluoroscopy was checked. All C-arms had a ratio lower than the regulatory tolerance ( $\pm 25\%$ ). The second part of the questionnaire reviewed x-ray exposure: total KAP and total FT (if available). These data were retrospectively retrieved from the Excel (Microsoft, Redmond, WA, USA) database of each center, built as follows: for every patient in the six participating centers, total KAP and total FT (if available on the C-arm used) are systematically collected and recorded in the Excel database at the end of the procedure, either by printing and archiving the C-arm dose report or directly from a homemade dose management system (DMS) connected to the

C-arm server with Matlab ((MathWorks, Natick, MA, USA) routine that extracts digital imaging and communications in medicine (DICOM) information from the dose reports) only in center 2. These databases also include patient information (name, surname, date of birth), the procedure type and the surgeon who carried out the procedure; all information was retrieved from the operating theatre management solution (such as Centricity™ Opera, SIGEMS, TimeWise). C-arm characteristics (manufacturer, model) are available in the dose report or from the DMS information and also recorded in the databases. All Excel databases in each center contained all this information and have the same architecture (priority standardized).

Data were anonymized before being sent to the medical physics expert responsible for the analysis (J.G.).

Each center sent a maximum number of 50 consecutive patients per procedure. This number was defined in order to avoid any center being over-represented in the sample and to obtain an acceptable statistical representation (>30 patients). However, these 50 patients may be examined on several C-arms with a detector having a similar field size diameter, rather than the same C-arm each time and not necessarily with the same surgeon. All collected data were fully documented.

If doubt existed as to the categorization of the procedure, validation with the surgeon who carried out the procedure was performed to ensure accurate classification.

Data were pooled for each procedure. Median, 1st and 3rd quartiles of the distributions of KAP and FT were calculated. DRLs were assessed as the rounded values of 3rd quartiles.

The influence of the type of the C-arm (conventional and mini) was studied for two procedures: hand or wrist; and foot

or ankle surgery. The main difference between these systems is the smaller exploration field size with the mini-C-arm than with a conventional C-arm (Table 1).

Statistical analysis was performed using BiostaTGV [12]. The comparisons according to the technology of the equipment (C-arm vs. mini-C-arm) and according to the complexity of the procedures for the two dosimetric indicators were obtained using the Wilcoxon–Mann–Whitney test. The *p* value was corrected for multiple comparisons using the Bonferroni statistical approach. All *p* values lower than 0.05 were considered as statistically significant.

## Results

A total of 1870 procedures of 8 different surgical types were collected in adults: 1220 for orthopedic procedures and 650 for gastrointestinal and urologic procedures (Table 2). For elbow surgery, some centers encountered difficulties in collecting 50 patients during the inclusion period and only 30 patients were finally recovered. For shoulder surgery, the patients were split between intramedullary (*n* = 25) and extramedullary technique (*n* = 25). No patients were excluded from this study, no data was missing and outliers were not removed.

The procedures were mostly performed with conventional C-arm (87%; Table 1). All conventional C-arms were equipped with an image intensifier from three main manufacturers: Philips Healthcare, Siemens Healthineers and GE Healthcare (Fig. 1). Among the three mini-C-arms two were equipped with flat panel from 2 manufacturers: Hologic® and Ziehm Imaging.

**Table 1** Distribution of the number of C-arms and mini-C-arms per center

	Number	Manufacturer	Model	Commissioning year	Higher field size diameter (cm)	Type of detector	Type of C-arm
Center 1	1	GE Healthcare	OEC 7900	2009	22	Image intensifier	Conventional
	1	Philips Healthcare	BV Endura	2011	23	Image intensifier	Conventional
	1	Siemens Healthineers	Siremobil Compact	2007	21	Image intensifier	Conventional
	2	Siemens Healthineers	Arcadis Varic	2015	21	Image intensifier	Conventional
	2	Siemens Healthineers	Arcadis Avantic	2010; 2012	33	Image intensifier	Conventional
	1	Ziehm Imaging	Orthoscan FD Pulse	2017	15	Flat panel	Mini
Center 2	3	Philips Healthcare	BV Endura	2015	23	Image intensifier	Conventional
	1	Hologic®	Fluoroscan Insight	2008	13	Image intensifier	Mini
	1	Hologic®	Fluoroscan Insight FD	2015	13	Flat panel	Mini
Center 3	2	Siemens Healthineers	Siremobil Compact	2006; 2014	21	Image intensifier	Conventional
	1	GE Healthcare	Flexiview 8800	2003	22	Image intensifier	Conventional
Center 4	5	GE Healthcare	OEC 7900	2004; 2005; 2007; 2008; 2012	22	Image intensifier	Conventional
Center 5	1	GE Healthcare	OEC 7900	2004	22	Image intensifier	Conventional
Center 6	1	Siemens Healthineers	Siremobil Compact	2006	21	Image intensifier	Conventional

**Table 2** Number of procedures (N), number of centers (NC) and median value of the distributions of both dosimetric estimators (kerma area product (KAP) and fluoroscopy time (FT)) for all procedures included in the survey

Surgery location	Category	N	NC	Median KAP (mGy.cm <sup>2</sup> ) (1st q.; 3rd.)	Median FT (min) (1st q.; 3rd.)
Hand/wrist*	Conventional C-arm	250	5	46 (15; 125)	0.25 (0.11; 0.55)
	Mini-C-arm	100	2	17 (11; 28)	0.20 (0.08; 0.37)
Elbow		120	4	52 (29; 182)	0.23 (0.08; 0.68)
Shoulder	Intra-medullary	100	4	541 (256; 1497)	1.13 (0.74; 2.36)
	Extra-medullary	100	4	113 (25; 417)	0.17 (0.07; 0.79)
Hip (proximal femoral intramedullary nail)		250	5	952 (376; 2128)	0.85 (0.55; 1.33)
Foot/ankle*	Conventional C-arm	200	4	71 (24; 203)	0.25 (0.09; 0.54)
	Mini-C-arm	100	2	24 (14; 54)	0.23 (0.13; 0.44)
Implantable venous access port insertion		200	4	104 (43; 338)	0.13 (0.03; 0.45)
Laparoscopic cholecystectomy		250	5	409 (145; 1185)	0.37 (0.10; 0.82)
Double-J ureteral catheter insertion		200	4	1059 (381; 2192)	0.48 (0.24; 0.90)

\*Center 1 gave data for both types of C-arm and center 2 only for the mini-C-arm

C-arm field size diameter varied from 21 to 23 cm for conventional C-arm (except for 1 C-arm: 33 cm) and from 13 to 15 cm for mini-C-arm. In all C-arms, the results of KAP meter checking were in line with the national quality criteria (< ±25% deviation). Therefore, no correction was applied to the recorded KAP values.

Table 2 presents, for each type of procedure, the number of procedures, the number of centers involved and the median value of the distributions of both dosimetric indicator (KAP and FT).

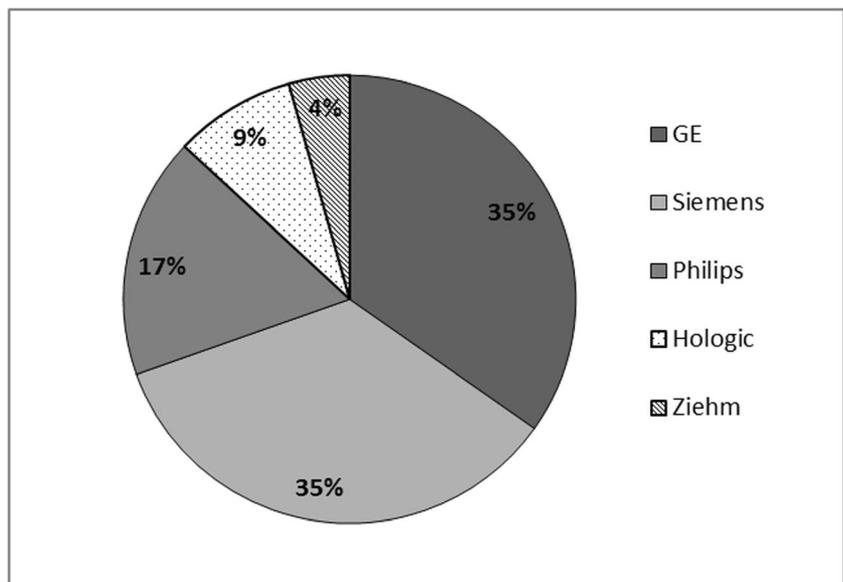
Figures 2 and 3 show the distributions of KAP values in boxplots per center for the five orthopedic procedures and the three gastrointestinal and urological procedures, respectively. Figure 2a and b also shows mini-C1 and mini-C2. These

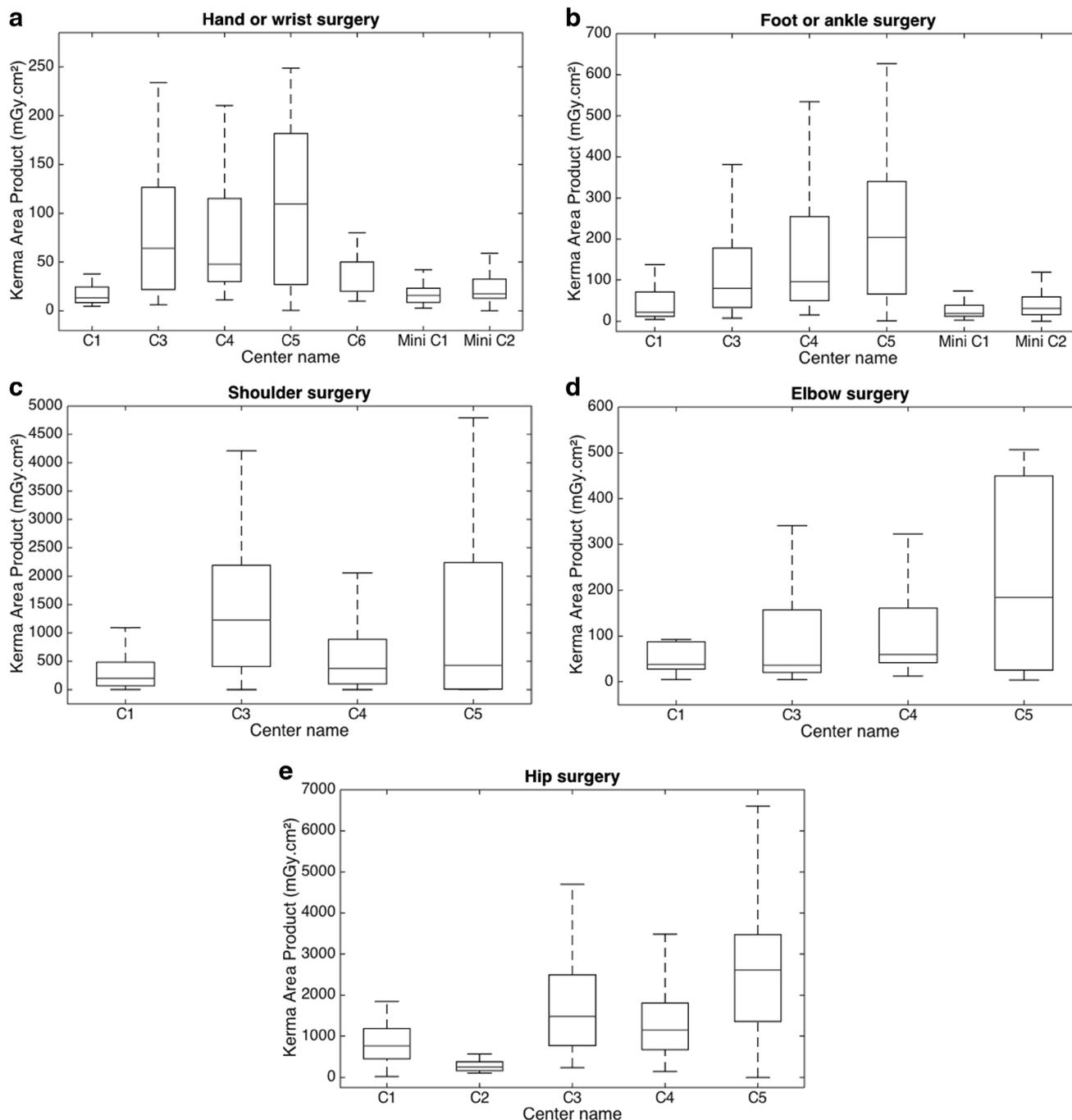
figures show a large variability of KAP between patients within and between centers.

For shoulder surgery (Table 2), dosimetric indicators were significantly higher for intra- than for extra-medullary procedures ( $p < 0.001$  for KAP and  $p < 0.001$  for FT). Median values were increased by a factor of 4.8 for KAP and 6.7 for FT.

Overall, the use of the mini-C-arm significantly decreased the KAP for hand or wrist ( $p < 0.001$ ) and for foot or ankle ( $p < 0.001$ ) surgeries (Table 2). Compared to conventional C-arm, median KAP values were decreased by 63% and 66%, respectively. FT are not statistically different for either surgery [ $p =$  not significant (NS)]. For center 1, the differences between conventional and

**Fig. 1** Percentage of C-arm according to the manufacturer. Grey segments correspond to conventional C-arm and white to mini-C-arm





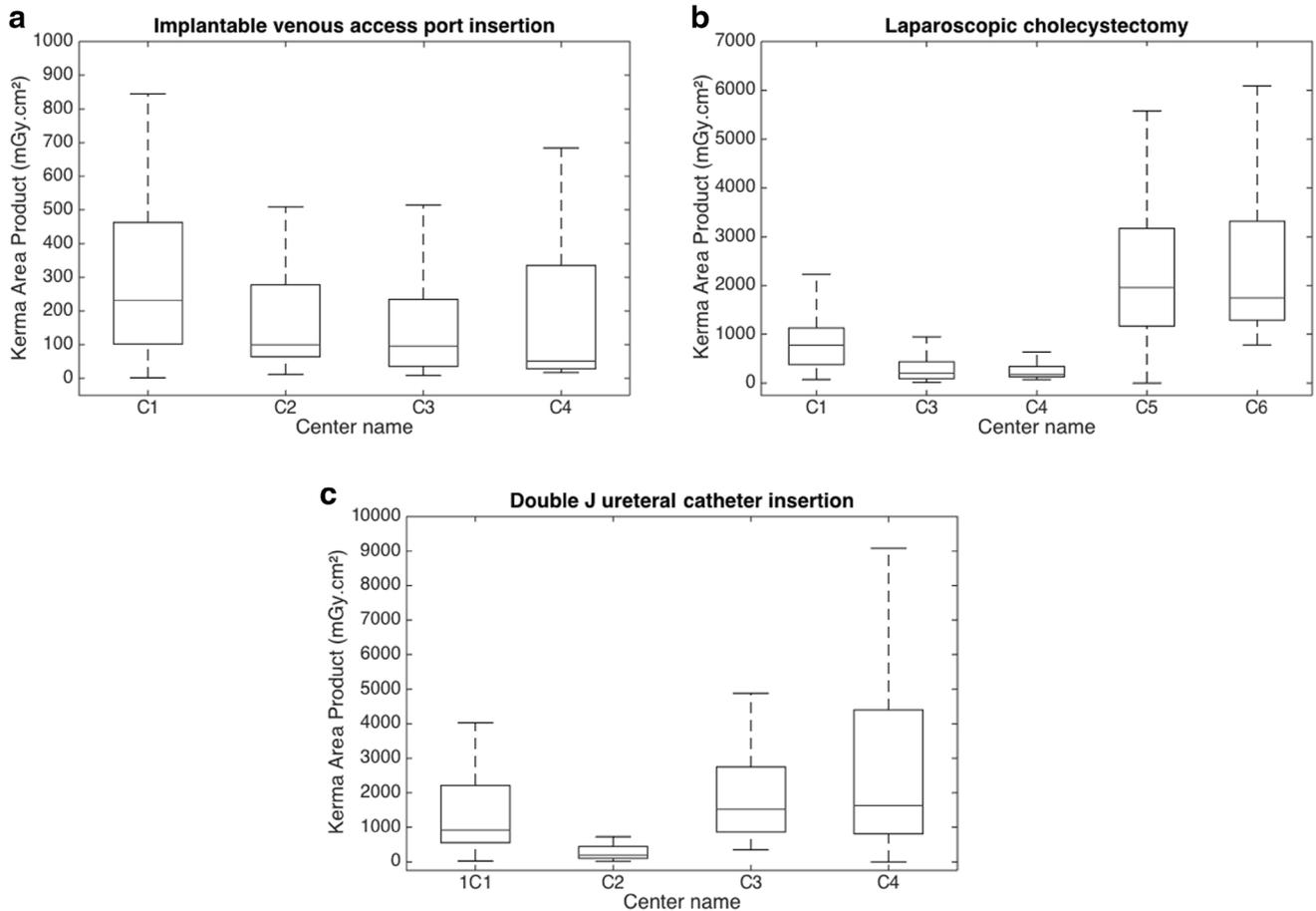
**Fig. 2** Distributions of KAP values per center for five orthopedic procedures: a. hand or wrist surgery, b. foot or ankle surgery, c. shoulder surgery, d. elbow surgery and e. hip surgery. C1 corresponds to center 1, C2 to center 2, and so on. Mini-C1 and mini-C2 correspond to mini-C-arms used in centers 1 and 2, respectively. The boxplot is defined by means of the lower bar line (minimum value except the outliers), the

lower box end (1st quartile: Q1), the margin of the lower and upper box (median), the upper box line (3rd quartile: Q3) and the top bar line (maximum value except the outliers). Outliers were defined as the values higher than  $Q3 + 1.5(Q3 - Q1)$  and lower than  $Q1 - 1.5(Q3 - Q1)$  corresponding to  $\pm 2.7\sigma$  and 99% of coverage if data were taken from a normal distribution

mini-C-arm were not significant ( $p = NS$ ) for KAP and FT values. For hand or wrist surgery, median KAP and FT values were  $13 \text{ mGy.cm}^2$  and  $0.17 \text{ min}$  for conventional C-arm and  $16 \text{ mGy.cm}^2$  and  $0.11 \text{ min}$  for mini-C-arm, respectively (Fig. 2a). For foot or ankle surgery, median

KAP and FT values were  $21 \text{ mGy.cm}^2$  and  $0.11 \text{ min}$  and  $18 \text{ mGy.cm}^2$  and  $0.13 \text{ min}$ , respectively (Fig. 2b). FT values are not depicted in Fig. 2a and b.

Table 3 provides proposed local DRLs for the two dose indicators (KAP and FT) for all eight surgical procedures,



**Fig. 3** Distributions of KAP values per center for three gastrointestinal and urologic procedures: a. implantable venous access port insertion, b. laparoscopic cholecystectomy without choledochotomy and c. double-J ureteral catheter insertion. The boxplot is defined by means of the lower bar line (minimum value except the outliers), the lower box end (1st

quartile: Q1), the margin of the lower and upper box (median), the upper box line (3rd quartile: Q3) and the top bar line (maximum value except the outliers). Outliers were defined as the values higher than  $Q3 + 1.5(Q3 - Q1)$  and lower than  $Q1 - 1.5(Q3 - Q1)$  corresponding to  $\pm 2.7\sigma$  and 99% of coverage if data were taken from a normal distribution

calculated as the rounded values of the 3<sup>rd</sup> quartiles of the whole distribution.

**Table 3** Proposed DRLs for common surgery procedures in adults

Surgery location	Category	KAP (mGy.cm <sup>2</sup> )	FT (min)
Hand/wrist	Conventional C-arm	125	0.6
	Mini-C-arm	30	0.4
Elbow		185	0.7
Shoulder	Intramedullary	1500	2.4
	Extramedullary	420	0.8
Hip (proximal femoral intramedullary nail)		2130	1.4
Foot/ankle	Conventional C-arm	205	0.6
	Mini-C-arm	55	0.5
Implantable venous access port insertion		345	0.5
Laparoscopic cholecystectomy		1185	0.9
Double-J ureteral catheter insertion		2195	1.0

KAP: kerma area product; FT: fluoroscopy time

## Discussion

Use of a C-arm during surgical procedures is becoming increasingly widespread across many surgical specialties. There is a pressing need for establishment of local and national DRLs, as tools for optimization and quality improvement of practices. This study allowed collection of dosimetric data for 1870 procedures collected in six public and private centers. Local DRLs are proposed for eight different surgical procedures. At the national level, DRLs must be based on a large dataset, representative of national practice. This survey could be used as a starting point for establishing national DRLs.

The survey was conducted according to new ICRP recommendations on DRLs [10]. Local DRLs have been calculated as the rounded values of the 3<sup>rd</sup> quartile of the distributions. This method is proposed by the ICRP to establish local DRLs, or “typical values”, when the number of facilities involved in the survey is too small to apply the advised method to establish national DRL values (set as the 3<sup>rd</sup> quartile of median values obtained in a sample of centers).

The results showed that the radiation doses delivered to the patients in the surgery procedures studied are relatively low, especially in orthopedic surgery (Table 2) compared to interventional radiology [11]. Despite these low exposures, dose optimization remains useful in this field. Indeed, staff and patient exposures in surgery are directly related and every dose decrease benefits both actors [1].

The distributions of median KAP values presented in Figs. 2 and 3 show the large variability of values between centers. These variabilities may be attributable to the individual patient (e.g. patient's pathology or morphology), to human factors (e.g. surgeon's experience or their awareness of patient radiation protection) and to C-arm used (e.g. C-arm's age or technology available). As defined by Etard et al, this variability confirms that the assumption of a "standard procedure" is not valid in surgery similarly to interventional radiology (IR) [11], and thus DRLs are more challenging to establish in surgery or IR than in diagnostic radiology [10]. Furthermore, our results for shoulder surgery show that DRLs must also be defined according to the complexity level. Therefore, local DRLs are of great interest in addition to national DRLs to assess the optimization process at the local level, taking into account the local specific features. The goal of the optimization is to reduce the dose delivered mainly by improving surgeon's training in the radiation protection, to make them aware of, for example, the use of pulsed fluoroscopy, the reduction of field size, the reduction of fluoroscopy time, etc.

The use of the mini-C-arm in orthopedics for extremities surgery appears to be an efficient way to reduce patient, and consequently staff, exposure (Table 2). For similar FT, the smaller exposure field induces a significant decrease in KAP. Nevertheless, the use of a mini-C-arm is not a magic bullet for optimization in surgery, as shown by the lack of difference in KAP at center 1 between conventional and a mini-C-arm (Figs. 2a and b). The non-significant difference between the devices might be explained by the technical protocols used in these C-

arms or the way they are being used. In this center, images were acquired with pulsed fluoroscopy for both C-arms but the frame rate was one frame per second for conventional C-arm and eight frames per second for mini-C-arm. An optimization procedure will be performed on the mini-C-arm to decrease the frame rate to minimum possible (four frames per second).

The results of this study were compared with the data available in the literature [1, 13–16] (Table 4). This comparison was challenging due to the poor number of published studies, the great varieties of procedures and the non-standardization of their designations between the different studies. For example, for the hand/wrist surgery, DRLs available in the literature correspond to the anterior osteosynthesis of the wrist [13], to the open reduction and internal fixation of the distal radius [14, 15] and for all hand/wrist surgery [1]. Furthermore, KAP and FT values were not always available.

For orthopedic procedures, KAP and FT values are within the range of literature values. For hand/wrist surgery, the study KAP value was 70 mGy.cm<sup>2</sup> and the values found in the literature range from 38 to 220 mGy.cm<sup>2</sup>; for hip, 2150 mGy.cm<sup>2</sup> and range from 794 to 11200 mGy.cm<sup>2</sup>; for foot/ankle, 140 mGy.cm<sup>2</sup> and range from 60 to 400 mGy.cm<sup>2</sup>. For hand/wrist surgery, the FT value was 0.5 min and the values found in the literature range from 0.2 to 1.3 min; for hip, 1.4 min range from 0.5 to 4.2 min for hip; for foot/ankle 0.6 min range from 0.6 to 1.5 min.

The KAP value for the double-J ureteral catheter insertion was lower than the value proposed by the ICRP publication Nr 117 [1] for the ureteric stent placement, 1059 mGy.cm<sup>2</sup> vs. 18000 mGy.cm<sup>2</sup>. This difference can be explained by older data collected (before 2005) in the ICRP publication Nr 117 [1]. Over the last decade, the technology of C-arm (detector type, field exposure size) has greatly improved, having a large impact on patient exposure, as well as the awareness of users on radiation protection issues that have greatly improved. Due to *the* lack of data in the literature, no comparison was possible for laparoscopic

**Table 4** Comparison of 3<sup>rd</sup> quartile of kerma area product (KAP; mGy.cm<sup>2</sup>) and fluoroscopy time (FT; minutes) values from this study with other international studies

KAP (mGy.cm <sup>2</sup> )	This study	ICRP	Roux et al	Pillai et al	Lee et al	Hardmann et al
Hand/wrist	70	40–220	38.4*	-	400 ±200**	130**
Elbow	185	-	-	21.8	-	-
Hip (proximal femoral intramedullary nail)	2150	-	794	981.5	11200 ±8400	-
Foot/ankle	140	-	-	60 <sup>+</sup>	400 ±200 <sup>++</sup>	322.5 <sup>++</sup>
FT (min)	This study	ICRP	Roux et al		Lee et al	Hardmann et al
Hand/wrist	0.5	0.2–0.55	0.25*		1.29**	0.93**
Hip (proximal femoral intramedullary nail)	1.4	3.2	0.53		4.15	-
Foot/ankle	0.6	1.5	-		0.59 <sup>++</sup>	0.58 <sup>++</sup>

Reference levels proposed as expressed in mean

\* Anterior osteosynthesis of the wrist; \*\*open reduction and internal fixation (ORIF) of distal radius; <sup>+</sup> ankle fracture; <sup>++</sup> ORIF ankle

cholecystectomy without choledochotomy. Concerning implantable venous access port insertion, the values of KAP and FT are 4.3 and 1.6 times lower than DRL proposed in IR by Etard et al, respectively [11]. The KAP value differences are more related to the larger detector size on the IR devices than on the C-arm.

The main limitation of our study is the non-consideration of the body habitus, although previous studies have characterized the influence of patient weight and height on the DRL values in interventional radiology [1, 17]. However, for samples of patients of normal range, no correction of body habitus needs to be applied [1, 17]. Furthermore, in orthopedics, DRLs in surgery of extremities should not be impacted by the patient weight and height. Another limitation of this study is the lack of information concerning C-arm parameters used (e.g. high voltage, tube current, fluoroscopy pulse rate). The collection and registration of this information will be facilitated with the deployment of DMS and access to the DICOM header. Finally, an additional limitation of the study is the restricted number of centers, procedures and patients. A nationwide survey should be conducted on a larger number of centers and patients and expanded to other surgical procedures to better represent the national surgical practice.

The results of this study may serve as an input for the national radiation protection authorities to implement DRLs in surgery as required by the 2017 ICRP publication [10]. These results will allow surgery departments to benchmark their practice with others and to optimize their protocols if necessary.

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## Compliance with ethical standards

**Guarantor** The scientific guarantor of this publication is Jean Paul Beregi.

**Conflict of interest** The authors of this manuscript declare no relationships with any companies, whose products or services may be related to the subject matter of the article.

**Statistics and biometry** No complex statistical methods were necessary for this paper.

**Informed consent** Written informed consent was waived by the institutional review board.

**Ethical approval** Institutional review board approval was obtained.

## Methodology

- retrospective
- multicenter study

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