Original Article

Analysis of radiation risk to patients from intra-operative use of the mobile X-ray system (C-arm)

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Background: The aim of this study was to investigate clinical applications of mobile C-arms and consequent radiation risk, to increase medical attention on radiation protection, and to provide basic data for safe radiation use in the operating room. **Materials and Methods:** In this study, a total of 374 surgical operations, conducted using a portable fluoroscopic X-ray system from January to March of 2013, were analyzed. Dose summaries produced by the General Electric C-arm and data elements in digital imaging and communications in the medicine header of Ziehm C-arm, fluoroscopy time were used to obtain dose-area product (DAP) and effective dose. Corresponding mean and maximum values were calculated, and the resulting data on the frequency of application, fluoroscopy time, DAP, and effective dose were compared and analyzed in terms of surgical specialty and operation types. **Results:** Orthopedic surgery was the most frequent with 165 cases (44.1%). The highest DAP value and effective dose were found in liver transplant among surgical specialty fields, with mean values of 2.90 ± 3.76 mGy·m^2 and 58 ± 75.2 mSv, respectively (P = 0.0001). The highest DAP value and effective dose were observed in intra-operative mesenteric portography among types of surgery, showing mean values of 2.90 ± 3.81 mGy·m^2 and 58.03 ± 76.24 mSv, respectively (P = 0.0001). **Conclusion:** Because DAP varies significantly across surgical specialties and types of operation, aggressive efforts to understand the effects of radiation dose is critical for radiation protection from intra-operative use of mobile C-arms.

Key words: Dose-area product, effective dose, mobile C-arm

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INTRODUCTION

The mobile image intensifier system (C-arm) is widely used in surgical operations, particularly in orthopedic surgery, because it provides real-time visualization and accurate guidance during the surgical process and because it shortens operating time. Especially, C-arm systems offer benefits of early recovery by minimizing postoperative wounds and pain.[1] This imaging system is also developed to perform a wide variety of surgical requirements, making it necessity for various surgeries. As the use of mobile C-arm had also expanded to intravascular surgery, it performs a substantial part of vascular dissection. It becomes a treatment option as important as surgical treatment in terms of long-term results. Among surgeons, the tendency of performing surgical procedures for the kind of patients whom they used to send to radiologists is also increasing as clinical doctors becomes more experienced with interventional procedures.[2,3] Image guidance is essential for interventional procedures, and fluoroscopy is used. Fluoroscopy is easy to operate and provides high temporal and spatial resolution and more importantly images and records, at various angles. The system is therefore seen as an essential tool in vascular surgery. However, fluoroscopy procedures involve unavoidable exposure to radiation. High exposure to radiation may result in skin damage and cancer risk. Given that fluoroscopy is conducted for the sole purpose of achieving best possible surgical outcomes, radiation protection may not be optimized. In such cases, the risk of high radiation exposure increases for patients and surgeons alike.[4] According to the International Commission on Radiological Protection, the fundamental principles of radiological protection include the justification that benefit is larger than damage by radiation, optimization of protection to apply diagnostic reference levels (DRL) and the application of dose limits. DRL is a dose reference level, which is established for frequent use and periodic test to recommend for diagnosis in diagnosis filming tests for patients.[4]

In a study of intra-operative radiation exposure in vascular patients, effective dose to patients was estimated to be 4.6-18.8 mSv in the case of endovascular aneurysm

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repair in which fluoroscopy time is long.[5,6] Another study also estimated that 29% of patients were exposed to radiation of 2 Gy, the threshold dose for skin injuries, suggesting a significant impact of radiation exposure during fluoroscopy.[7] In a study of radiation exposure to medical personnel in vascular surgery using endovascular repair, annual effective dose to surgeons was estimated at 0.20 mSv (0.13-0.27 mSv). Effective dose to around their eyes and hands were estimated to be 0.19 mSv (0.10-0.33 mSv) and 0.99 mSv (0.29-1.84 mSv), respectively.[8] A study by Lipsitz *et al*. revealed that annual effective dose to vascular surgeons was 1.52 mSv, while effective dose was 7.77 mSv around eyes and 18.69 mSv in hands, revealing significantly higher dose levels.[9] The possible cancer risk associated with radiation exposure during fluoroscopic procedures cannot be ruled out. The European Commission on Radiological Protection suggested one of 1000 people is prone to solid cancer or leukemia during their lifetime when exposed to radiation of 10 mSv.[10] In the evaluation of the risk of fatal cancer among operation types, EAR was associated with risks over 1%, followed by abdominal arterial treatment (nearly 1%) and atherectomy (nearly 0.5%).[11] The present study was aimed to measure radiation dose to surgical members from mobile C-arm during surgery and assess cancer risk associated with radiation exposure.

MATERIALS AND METHODS

Study subjects

A total of 522 surgical procedures, conducted using a mobile C-arm from January to March of 2013, were reviewed in this study. To improve reliability, 148 cases were excluded as each type of operation was conducted <5 times during the period. The remaining 374 cases were analyzed. A total of 87 patients were eligible, regardless of gender, with an average age of 48.2 (0-84) years.

Study methods

The mobile C-arms used were OEC 9900 Elite (General Electric: GE, USA), OEC 9800 Plus (GE, USA), OEC 9800 (GE, USA), and Ziehm Vision (Ziehm, Germany). All image intensifiers were of 12 inches (21 cm) in diameter. The distance between the X-tube and patient was about 50 cm, while source-to-image intensifier distance was 100 cm [Figure 1]. Fluoroscopy was conducted in a continuous mode while exposure parameters such as tube voltage, current, and exposure times were controlled by an auto exposure control (AEC). KV range was 40-120 kV_P and mA range was 0.44-20.0 mA. Auto brightness controller was also used. Magnification and collimator functions were explored if necessary, depending on the type of surgery. Roadmap and digital subtraction functions were used for angiography and interventional procedures. Patient dose was measured by dose-area product (DAP) value [Figure 2],

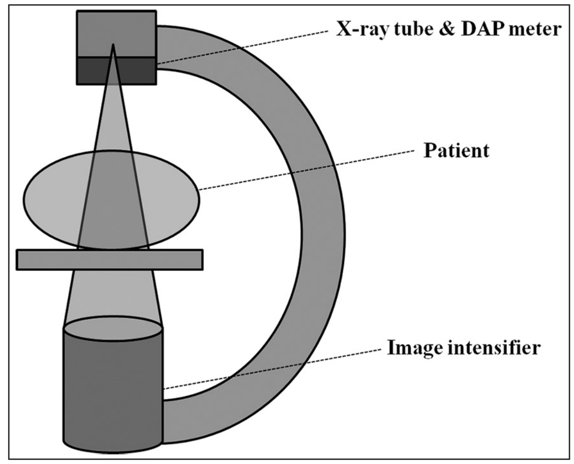

Figure 1: Structure of C-arm fluoroscopy apparatus

which is automatically measured by DAP meter (Diamentor PTW, Freiburg, Germany) mounted on the collimator, and the value is displayed on monitor. DAP represents the amount of radiation absorbed to air in the area of X-ray as described in equation 1.

$$\text{DAP (Gy.m}^2) = \text{Dose (Gy)} \times \text{Area (m}^2) \quad (1)$$

In general, DAP can be calculated by multiplying the X-ray beam cross-sectional area field by the absorbed dose in air (air kerma) at a point based on the assumption that the X-ray is equally distributed in terms of absorbed dose, regardless of the location, in a triangle-shaped distribution. In other words, when the area of X-ray beam is placed by a collimator, DAP is independent of the distance between the collimator and X-ray tube [Figure 3]. Once DAP values were obtained, mean, and maximum values were calculated. National Radiological Protection Board Report 262 addressed conversion factors used to convert DAP value into effective dose.[12] In this study, effective dose was calculated by multiplying DAP value with a conversion factor, 0.20 mSv/Gy.cm².[12-15] That is, effective dose can be presented as follows:

$$\text{E (mSv)} = \text{DAP (Gy.cm}^2) \times CC_{dap} \text{ (mSv/Gy.cm}^2) \quad (2)$$

CC_{dap}: Effective dose conversion factor (0.2 mSv/Gy.cm²).

Based on statistical data analysis, the frequency of application, fluoroscopy time, DAP and effective dose were compared and analyzed in terms of surgical specialty and surgery type. ANOVA was performed to determine the difference between mean values using SPSS software (win 18.0, USA, Chicago). The frequency of applications was analyzed for surgical specialty and operation types. The Chi-square test was performed to determine the association of effective dose with surgical specialty and operation types.

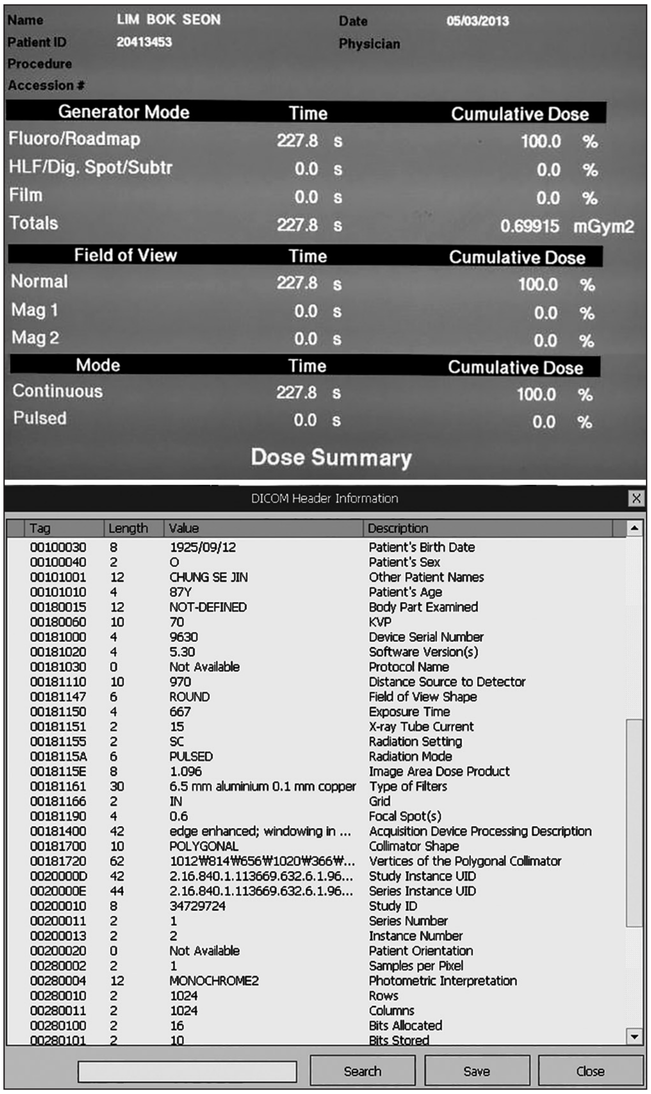

Figure 2: Acquisition of fluoroscopy times and dose-area product

RESULTS

Fluoroscopy time, dose-area product and effective dose by surgical specialty

Of the 374 cases, 165 were orthopedic procedures (44.1%), followed by 77 anesthesiology procedures (20.6%), and 43 neurosurgical operations (11.5%). Mean fluoroscopy time was higher in vascular surgery recording 771.68 s, which was followed by 416.99 s in liver transplant and 172.50 s in urological procedures. Mean values of DAP and effective dose were higher in liver transplantation at 2.90 ± 3.76 mGy·m^2 and 58 ± 75.2 mSv, respectively. Live transplant was followed by vascular surgery and urology surgery ($P < 0.05$). Maximum values of DAP and effective dose were higher for the liver transplant at 18.24 ± 3.76 mGy·m^2 and 364.8 ± 75.2 mSv, respectively, ($P < 0.05$). In conclusion, orthopedic surgery demonstrated short fluoroscopy time and low DAP and effective dose although it was the most frequently performed surgery in this study. Liver transplant and urology surgery exhibited long fluoroscopy time and high DAP and effective dose although surgical application of C-arm was low. There were no associations of surgical specialty with DAP and effective dose ($P > 0.05$) [Table 1].

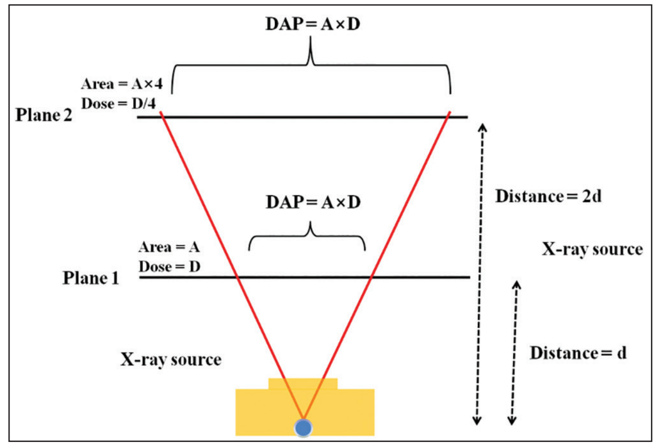

Figure 3: Illustration of the dose-area product principle

Fluoroscopy time, dose-area product and effective dose by surgical type

A total of 26 different surgical procedures were performed in this study. Of those, 77 cases were facet nerve injection (20.6%), followed by 36 (intra-operative mesenteric portography) (9.6%), 33 kyphoplasty (8.8%), 23 percutaneous nephrolithotomy (6.1%) and 19 open reduction and internal fixation — Leg (5.1%). The surgery type performed over 30 times accounted for 39.0% of total surgeries, followed by the type with below 10 times (28.3%), the type with 10-19 times (26.5%) and the type with 20-29 times (6.1%). Mean fluoroscopy time of all surgeries was 229.96 s. Lower extremity angiography had the highest fluoroscopy time with 771.68 s, followed by intra-operative mesenteric portography with 416.99 s, percutaneous nephrolithotomy with 259.03 s, proximal femoral nail antirotation with 249.07 s, and femoral nail surgery with 219.21 s. Top five operation types in terms of fluoroscopy time accounted for 56.6% of total surgeries, where only a few operations explored long fluoroscopy time while most surgeries required short fluoroscopy time. Among orthopedic surgeries, the highest DAP value and effective dose were found in posterior lumbar fusion with *P* 1.20 ± 0.82 mGy·m^2 and 24.2 ± 16.40 mSv, respectively. Proximal femur nail antirotation and nail-femur followed with second and third ($P < 0.05$) highest. Maximum values of DAP and effective dose were higher in proximal femur nail antirotation at 2.92 ± 3.76 mGy·m^2 and 58.4 ± 75.2 mSv, respectively, ($P < 0.05$). In neurosurgery, the highest DAP value and effective dose were found in kyphoplasty at *P*1.94 ± 0.70 mGy·m^2 and 38.80 ± 14.01 mSv, respectively. Posterior lumbar fusion and nerve root block followed as second and third ($P < 0.05$). Maximum values of DAP and effective dose were higher in posterior lumbar fusion

Table 1: Fluoroscopy time, dose-area product and effective dose by surgical specialty

Departments	Number of patients (%)	Fluoroscopy Times mean (s)	DAP Mean (mGy·m²)	Effective dose (mSv)	DAP Maximum (mGy·m²)	Effective dose (mSv)	*P*	χ^2	*P*
Orthopedic surgery	165 (44.1)	78.53	0.27±0.54	5.40±10.80	2.92	58.4	0.000	2195.07	0.643
Neuro surgery	43 (11.5)	82.43	0.95±0.94	19.0±18.8	3.63	72.6			
Anesthesiology	77 (20.6)	70.25	0.64±0.94	12.8±18.8	4.09	81.8			
Urology	41 (11.0)	172.5	1.06±0.97	19.6±19.4	3.8	76			
Pediatric surgery	7 (1.9)	17.33	0.05±0.03	1.00±0.20	0.11	2.2			
Vascular surgery	5 (1.3)	771.68	1.10±0.60	22±12.0	1.58	31.6			
Liver transplantation surgery	36 (9.6)	416.99	2.90±3.76	58±75.2	18.24	364.8			

DAP = Dose-area product

at 3.63 ± 3.76 mGy·m² and 72.60 ± 75.2 mSv, respectively, (P < 0.05). In anesthesiology, mean values of DAP and effective dose were higher for pain control management 0.64 ± 0.50 mGy·m² and 12.81 ± 10.21 mSv, respectively (P < 0.05). In urology, mean values of DAP and effective dose were higher in percutaneous nephrolithotomy at 1.63 ± 1.20 mGy·m² and 32.61 ± 24.11 mSv, respectively (P < 0.05). In vascular surgery, mean values of DAP and effective dose were higher in angiography-extremity at 1.63 ± 1.20 mGy·m² and 32.61 ± 24.11 mSv, respectively (P < 0.05). In liver transplantation surgery, mean values of DAP and effective dose were higher for intra-operative mesenteric portography at 2.9 ± 3.81 mGy·m² and 58.03 ± 76.24 mSv (P < 0.05). Thus, intra-operative mesenteric portography exhibited the highest mean DAP, followed by kyphoplasty, percutaneous nephrolithotomy, neurological posterior lumbar fusion, and posterior lumbar fusion. Maximum value of DAP was higher in intra-operative mesenteric portography, followed by facet nerve injection, percutaneous nephrolithotomy, posterior lumbar fusion, and kyphoplasty. There was no associations between surgical type and either DAP or effective dose (P > 0.05) [Table 2].

DISCUSSION

Surgical operations and procedures represent a source of high-dose radiation because the involved process is complicated and lengthy. Thus, fluoroscopic imaging lasted a long time. As mobile C-arm fluoroscopic systems are designed to automatically control radiation, radiation dose to the patient is not easy to measure. In addition, a part of the body exposed to primary radiation is changed with fluoroscopic conditions, making dose measurement difficult. Therefore, DAP is used as an alternative to estimating the doses of radiation exposure. Validity of DAP as an indicator of radiation risk is justified by the theory that possible effects of radiation on patients are correlated with radiation dose and exposure area.[16] In this study, effective dose was calculated by multiplying DAP values displayed on mobile C-arm monitor with effective dose conversion factor to ensure validity. In general, radiation doses should be measured on exposed skin or tissues. The use of the dosimeter is not realistic for the patient and surgical members in the operating room. Radiation dose from fluoroscopy depends on a variety of factors, including fluoroscopy time, the distance between patient and the source, angle, size and shape of collimator, patient-receptor distance, magnification, and AEC. In addition, surgical procedures, position of surgical members and radiation protection methods affect radiation exposure. Accurate dose measurement is very difficult.[17]

In this study, orthopedic surgery used mobile C-arm systems most frequently, but mean recorded fluoroscopy time was 78.53 s, which was one-third that of the overall mean of 229.96 s with DAP was as low as 0.38 mGy·m² and 2.92 mGy·m². Among operation types, proximal femoral nail antirotation and femoral nail antirotation exhibited high DAP. Bae *et al*.[18] claimed that the radiation dose was high in tibia and femor fracture nail antirotation but still was relatively safe, as dose limit was not exceeded. Crawley and Rogers[19] reported mean DAP value of 0.39 Gy·cm² for open reduction and internal fixation, 1.62 Gy·cm² for femoral nail antirotation, 2.58 Gy·cm² for dynamic hip screw 10.17 Gy·cm² for L spine fusion, 1.29 Gy·cm² for C spine injection facets, and 2.08 Gy·cm² for L spine injection facets. The findings of this study are consistent with these previous reports, although DAP value for GK nail and dynamic hip screw were 2-10 times higher in that study. The DAP values in these two procedures were nearly 10 times higher than those reported in Botchu and Ravikumar study.[20] The differences in radiation dose are likely associated with surgical experience and competence and condition of surgical sites.

The highest DAP value was found in intra-operative mesenteric portography performed during liver transplant in this study. As reported in a study by Vano *et al*.,[6] high dose of radiation likely resulted from the nature of liver transplantation, in which fluoroscopy times are long and serial angiograms are needed. The second highest DAP was observed for kyphoplasty showing mean and maximum

Table 2: Fluoroscopy time, dose-area product and effective dose by surgical type

	Number (%)	Fluoroscopy Times mean (s)	DAP Mean (mGy·m²)	Effective dose (mSv)	DAP Maximum (mGy·m²)	Effective dose (mSv)	*P*	χ^2	*P*
Orthopedic surgery									
ACDF[a]	15 (4.0)	9.89	0.02±0.01	0.40±0.20	0.04	0.8	0.000	7078.35	0.340
Deformity correction	33 (8.8)	17.18	0.05±0.05	1.20±6.40	0.32	6.4			
Posterior lumbar fusion	5 (1.3)	107.9	1.20±0.82	24.2±16.40	2.39	47.8			
Kyphoplasty	5 (1.3)	109.54	1.09±0.56	21.8±11.20	1.71	34.2			
Proximal femur nail anti-rotation	12 (3.2)	249.07	1.12±0.84	22.4±16.80	2.92	58.4			
Nail-femur	9 (2.4)	219.21	1.11±0.72	22.20±14.40	2.23	44.6			
Dynamization	5 (1.3)	94.96	0.32±0.49	6.40±9.80	1.2	24			
Dynamic hip screw	6 (1.6)	109.13	0.42±0.35	8.42±7.02	0.78	15.6			
LM allograft	7 (1.9)	20.76	0.03±0.02	0.61±0.42	0.04	0.8			
ORIF[b]-leg	19 (5.1)	67.11	0.07±0.05	1.40±+1.02	0.15	3			
ORIF[b]-ankle	17 (4.5)	35.14	0.04±0.02	0.80±0.41	0.12	2.4			
ORIF[b]-humerus	7 (1.9)	62.11	0.07±0.05	1.42±1.00	0.23	4.6			
ORIF[b]-distal radius	8 (2.1)	77.35	0.04±0.02	0.81±0.41	0.12	2.4			
ORIF[b]-wrist	9 (2.4)	59.39	0.03±0.02	0.61±0.41	0.07	1.4			
RI[c]-ankle	8 (2.1)	21.15	0.02±0.01	0.401±0.21	0.05	1			
Neuro surgery									
Deep brain stimulation	7 (1.9)	29	0.15±0.12	3.01±2.40	0.36	7.2			
ACDF[a]	8 (2.1)	58.13	0.40±0.21	8.10±4.21	0.78	15.6			
Posterior lumbar fusion	18 (4.8)	85.11	1.35±0.90	27.02±18.01	3.63	72.6			
Kyphoplasty	5 (1.3)	186.2	1.94±0.70	38.80±14.01	3.6	72			
Nerve root block	5 (1.3)	82.72	0.81±0.50	16.2	1.2	24			
Anesthesiology									
Ingection	77 (20.6)	70.25	0.64±0.50	12.81±10.21	4.09	81.8			
Urology				0					
Percutaneous nephro lithotomy	23 (6.1)	259.03	1.63±1.20	32.61±24.11	3.8	76			
Retrograde pyelography	18 (4.8)	61.94	0.34±0.20	6.8	1.44	28.8			
Pediatric surgery									
Chemoport insertion	7 (1.9)	17.33	0.05±0.02	1.02±0.47	0.11	2.2			
Vascular surgery						31.6			
Angiography-extremity	5 (1.3)	771.68	1.10±0.08	22.02±1.61	1.58				
Livertransplantation surgery									
Intra-operative portography	36 (9.6)	416.99	2.9±3.81	58.03±76.24	18.24	364.8			

[a]ACDF = Anterior cervical discectomy and fusion; [b]ORIF = Open reduction and internal fixation; [c]RI = Removal implant; DAP = Dose-area product; LM = Lateral meniscus

values of 1.94 ± 0.70 mGy·m² and 3.6 mGy·m², respectively. The results are higher than corresponding values of 2.73 Gy·cm² and 6.366 Gy·cm², respectively, as reported in Boszczyk *et al*. study.[21] Theocharopoulos *et al*.[22] estimated the effects of kyphoplasty, spine surgery, and hip joint surgery on surgeon at 90%, 8% and 2%, respectively. The possible cause of cancer as a result of radiation exposure during fluoroscopic procedures cannot be ruled out. The European Commission on Radiological Protection reported one per 1000 patients is prone to solid cancer or leukemia during the lifetime upon exposure to a radiation dose of 10 mSv.[12] Caution should be taken in dealing with high radiation dose during surgery, and aggressive protection is necessary.

The findings of this study magnify the importance of assessing frequency of radiation usage and radiation dose with the use of intra-operative mobile C-arm, as part of an effort to protect against radiation exposure. Understanding that DAP values vary with surgical specialty and operation types on the part of surgical personnel is crucial for effective dose management.

The limitations of this study are as follows. First, data of one hospital were used only without other devices of various hospitals. Second, the study has a DAP related limit. It was not possible to measure accurate exposure doses as there was no unique feature of patients and DAP calculates the estimated level in the test of each patient. Third, dose could not be added as there was no supply of Exam information of the C-arm device.

The findings of this study can serve as basic data for effective radiation protection and safe radiation management.

CONCLUSIONS

Surgical members need to understand effects of intra-operative radiation and make efforts to prevent any risks stemmed from radiation. Staff members are recommended to wear a dosimeter for effective dose management, and surgeons need to ensure radiation protection for patients and surgical staff.

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Yang-Sub Lee and Hae-Kag Lee equally contributed to this work.

AUTHOR'S CONTRIBUTION

All authors have contributed in designing and conducting the study. YSL and HKL collected the data, YSL and JHC did the analysis. All authors have assisted in preparation of the first draft of the manuscript or revising it critically for important intellectual content. All authors have read and approved the content of the manuscript and are accountable for all aspects of the work.

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