Journal of Associated Medical Sciences 2023; 56 (1): 167-175

JAMS
Journal of Associated Medical Sciences

Scopus indexed & Thai-Journal Citation Index Centre (TCI)

Journal of Associated Medical Sciences

Journal homepage: https://www.tci-thaijo.org/index.php/bulletinAMS/index

Patient radiation dose from fluoroscopic-guided transcatheter cardiac aortic valve implantation procedure: A single-center study in Thailand

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ARTICLE INFO

Article history:
Received 25 August 2022
Accepted as revised 14 November 2022
Available online 28 November 2022

Keywords:
Patient radiation dose, TAVI, median dose, diagnostic reference levels

ABSTRACT

Background: The trend in the use of fluoroscopic-guided transcatheter aortic valve implantation (TAVI) is increasing because the procedure is less invasive than surgical procedure. However, high radiation doses have been reported with the procedure. Moreover, the amount of radiation received by patients undergoing TAVI has never before been registered in Thailand.

Objectives: This study aimed to investigate the radiation dose and the effects of sex and body mass index (BMI) on the radiation dose received by patients undergoing TAVI at Chulabhorn Hospital.

Materials and methods: Data were collected on the radiation dose received by patients undergoing the TAVI procedure during the first 26 months after the operation at the Cardiology Center, Chulabhorn Hospital. We recorded patient demographic data including age, sex, and BMI and the following measures of radiation dose from the procedure: the number of exposure images, air kerma-area product (P_{KA}), cumulative air kerma at the patient entrance reference point ($K_{a,r}$), and total fluoroscopy time.

Results: In total, 68 patients (35 male and 33 female) underwent TAVI, with median exposure images, P_{KA}, $K_{a,r}$, and total fluoroscopy time of 1,067 images, 166.14 Gy/cm^2, 1,171.50 mGy, and 31.90 minutes, respectively. The patient's sex did not affect total fluoroscopy time or the radiation dose received. Patients with BMI ≥30.0 kg/m^2 had the highest median values of P_{KA}, $K_{a,r}$, and total fluoroscopy time. Moreover, patients with BMI ≥18.5-24.9 kg/m^2 received higher doses of radiation than patients with BMI ≥25.0-29.9 kg/m^2; the result corresponded with longer total fluoroscopy time in the lower BMI category.

Conclusion: The amount of radiation that patients received during TAVI was appropriate for diagnosis and treatment. However, to ensure patient safety, operators should consider reducing the duration of radiation during the procedure. Data from this study are a starting point for the recording of radiation doses received by patients undergoing TAVI and can be used as a future dose reference.

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doi: 10.12982/JAMS.2023.032
E-ISSN: 2539-6056

Introduction

Aortic stenosis is the most prevalent form of valvular heart disease worldwide and its prevalence continues to increase.[1] As a treatment approach for aortic stenosis, transcatheter aortic valve implantation (TAVI) plays an important role in patients at high risk for surgical aortic valve replacement.[2] Because this procedure is minimally invasive and allows patients to recover more quickly than with surgery, the number of patients receiving treatment with such procedures has increased.[3,4] In the TAVI procedure, X-ray fluoroscopy produces real-time radiographs that guide the catheter through blood vessels into the target treatment location in the heart, where ionizing radiation is used for a long period to create medical images, thus exposing patients to high doses of radiation. According to Koenig *et al.*, patients diagnosed and treated with X-ray fluoroscopy suffer from cutaneous radiation injury, which causes erythema within 2-24 hours of exposure to radiation doses higher than 2 Gy, a level within the range that causes skin abnormalities.[5,6] Generally, the dose rate for X-ray fluoroscopy in radiological interventions is in the range of 0.02-0.05 Gy/minute. In cardiac catheterization, the average radiation dose received by patients is 2.5 Gy and, in some cases, as high as 6.4 Gy-considerably above the threshold for skin abnormalities-potentially causing adverse events because of the deterministic effects of ionizing radiation.7 In addition, low-threshold radiation can induce biological changes in cells, leading to cancer with stochastic effects and side effects directly proportional to the amount of radiation received by the body. This is because ionizing radiation reacts with the patient's cells or tissues, causing cell death and abnormalities in cell function and various systems within the body.[8] Nonetheless, delivering the appropriate radiation dose for TAVI is necessary in the diagnosis and treatment of disease given the benefits of medical radiation to patients' quality of life. Therefore, establishing guidelines to monitor the dose of radiation received by patients undergoing TAVI is important.[9] The radiation dose received by the patient can be assessed using the air kerma-area product (P_{KA}), a parameter obtained by measuring the amount of radiation (Gy) released from the X-ray tube in area units (cm^2), the cumulative air-kerma value ($K_{a,r}$) at the patient entrance reference point, the dose at a defined reference point, and total fluoroscopy time.[10-12]

Information on the radiation dose from the procedure is important for determining whether the dose is suitable for the examination. The data are important for optimizing the patient's protection against medical exposure to radiation during cardiovascular catheterization. The diagnostic reference level (DRL) indicates the appropriate value of the radiation dose for the same type of radiological diagnosis from different sites at which the TAVI procedure is performed. Currently, DRL data for diagnostic and interventional radiology and cardiovascular catheterization in Thailand are being collected and compiled into a national DRL database through collaboration between the Department of Medical Sciences of the Thai Ministry of Public Health and hospitals across the country. However, given that TAVI is a new procedure that has only been implemented in Thailand in the past ten years by a small number of treating hospitals and for a limited number of patients, data on radiation doses during treatment with TAVI are insufficient.[13] Therefore, this study aimed to collect data on radiation doses received by patients undergoing TAVI at Chulabhorn Hospital, determine the median dose received from the procedure, and study the correlation between sex, body mass index (BMI), and radiation dose.

Materials and methods

Study design and sample selection

This study was approved by the Human Research Ethics Committee of Chulabhorn Research Institute (Project code 005/2563) as a retrospective and prospective study on patients undergoing TAVI fluoroscopy. The retrospective and prospective study was a preliminary investigation conducted at the Cardiology Center of the Chulabhorn Hospital between August 2019 and September 2021. The inclusion criterion was all patients who consented to undergo a TAVI procedure; the exclusion criterion was patients with incomplete radiation dose data in the data storage system.

Equipment performance and techniques

All procedures were performed in the same catheterization laboratory using a Philips Azurion 7 C20 with FlexMove (Philips Healthcare, Best, Netherlands) angiography system. A beam filtration control of 1 mm of aluminum with 0.1 mm copper filtration was used with fluoroscopy (7.5 frames per second) and cine-angiography (15 frames per second) X-ray imaging modes. The automatic control of X-ray exposure parameters was selected as the technical setting to ensure high image quality and a minimal dose for all patients undergoing the procedure. The radiation dose was registered using integrated dosimetry instrumentation. The equipment was subjected to annual quality assurance testing by the local medical physics services of the Department of Medical Sciences (Nonthaburi, Thailand).

Patients were consulted and treatments were planned before TAVI by a team of medical professionals in the TAVI conference committee. During the TAVI procedure, vascular access was gained by a multidisciplinary heart team using a percutaneous transfemoral approach and a physician who operated the fluoroscopy during the procedure, for a total of three operators. Clinical follow-up was performed 30 days after the procedure.

Data collection

The following data of patients undergoing TAVI procedures were recorded: demographics including age, sex, and BMI; dosimetry measurement (number of exposure images); air kerma-area product value (P_{KA}, in Gy/cm^2); cumulative air kerma at the patient entrance reference point ($K_{a,r}$, in Gy); and total fluoroscopy time (in min) obtained from the examination dose report in the structured radiation report, which is saved in the equipment upon process completion.[14]

Statistical analysis

Data were analyzed with descriptive statistics using the Stata/SE 12.1 (StataCorp, College Station, TX, USA) program and data were expressed as average, maximum, minimum, median, interquartile range, 1st quartile, and 3rd quartile values.

Results

Patient demographic data

Among the 68 patients undergoing TAVI in the department, 35 were male (51.47 %) and 33 were female (48.53 %), with a mean age of 80.25±5.51 years (range, 69-91 years) and mean BMI of 22.78±4.20 kg/m^2 (range, 14.34-37.50 kg/m^2). Overall, male and female patients had a similar mean age and BMI, as listed in Table 1.

Table 1 Patient demographic data.

Parameters	Mean±SD (range)
Age (years), N=68	80.25±5.51 (69-91)
BMI (kg/m2), N=68	22.7±4.20 (14.34-37.50)
Male, N=35 (51.47%)	
Age (years)	81.03±5.85 (69-91)
BMI (kg/m^2)	22.12±3.99 (14.53-37.50)
Female, N=33 (48.53%)	
Age (years)	79.42±5.00 (69-89)
BMI (kg/m^2)	23.48±4.03 (14.34-32.72)

Note: BMI: body mass index

Dosimetry measurement in patients undergoing TAVI

Table 2 Radiation dose received by patients undergoing transcatheter aortic valve implantation (TAVI).

Parameters (N=68, Female=33 and Male=35)	Dosimetry measurements			
	Number of exposure images	P_{KA} (Gy.cm^2)	$K_{a,r}$ (mGy)	Total fluoroscopy time (minutes)
Mean±SD	1,181.07±573.81	204.79±137.70	1,492.87±952.42	35.89±15.19
Median	1,067.00	166.14	1,171.50	31.90
1st Quartile (Q1)	789.75	113.50	874.50	26.58
3rd Quartile (Q3)	1,522.75	242.84	1,673.75	41.70
IQR	789.75-1,522.75	113.50-242.84	874.50-1,673.75	26.58-41.70

Note: IQR: interquartile range, P_{KA}: air kerma area product, $K_{a,r}$: cumulative air kerma at patient entrance reference point.

Table 3 Comparison of radiation dose received by patients undergoing TAVI between this study and international DRL.

National DRLs	P_{KA} (Gy.cm²)		$K_{a,r}$ (mGy)	
	Median	3rd Quartile (Q3)	Median	3rd Quartile (Q3)
Chulabhorn Hospital	166.14	242.84	1,171.50	1,673.75
Europe[11]	-	130.00	-	1,200.00
Finland[15]	-	90.00	-	-
Germany[15]	-	80.00	-	-
Australia[16]	47.86	78.38	721.00	1,124.00
Switzerland[17]	-	141.00	-	1,189.00
United States (US)[18]	188.00	321.00	1,639.00	2,420.00

DRLs, Diagnostic reference levels; P_{KA}, Air kerma area product; $K_{a,r}$, Cumulative air kerma at patient entrance reference point.

Table 4 Radiation dose for patients within genders.

Parameters	Male (N=35)	Female (N=33)
P_{KA} (Gy.cm²)		
Mean±SD	220.29±154.01	188.36±115.73
Median	166.84	162.56
1st Quartile (Q1)	128.62	109.15
3rd quartile (Q3)	237.66	246.87
IQR	128.62-237.66	109.15-246.87
$K_{a,r}$ (mGy)		
Mean±SD	1,644.09±1,046.00	1,332.48±811.66
Median	1,172.00	1,171.00
1st Quartile (Q1)	941.00	756.50
3rd quartile (Q3)	1,899.00	1,629.00
IQR	941.00-1,899.00	756.50-1,629.00
Total fluoroscopy time (minutes)		
Mean±SD	35.07±12.19	36.76±17.78
Median	32.40	30.70
1st Quartile (Q1)	26.50	26.40
3rd quartile (Q3)	42.60	41.40
IQR	26.50-42.60	26.40-41.40

IQR, Interquartile range; P_{KA}, Air kerma area product; $K_{a,r}$, Cumulative air kerma at patient entrance reference point.

Table 5 Radiation dose for patients according to different BMI categories.

	BMI categories (N=68)			
Parameters	**BMI <18.5 kg/m² (N=8, 11.76%)**	**BMI ≥18.5-24.9 kg/m² (N=42, 61.76%)**	**BMI ≥25.0-29.9 kg/m² (N=15, 22.06%)**	**BMI ≥30.0 kg/m² (N=3, 4.41%)**
P_{KA} (Gy.cm²)				
Mean±SD	134.81±51.67	197.19±118.04	212.39±157.48	459.81±156.31
Median	129.13	168.85	162.56	514.85
1st Quartile (Q1)	96.51	118.75	110.99	246.89
3rd quartile (Q3)	156.53	233.08	244.25	617.71
IQR	96.51-156.53	118.75-233.08	110.99-244.25	246.89-617.71

Table 5 Radiation dose for patients according to different BMI categories. (continued)

Parameters	BMI categories (N=68)			
	BMI <18.5 kg/m² (N=8, 11.76%)	BMI ≥18.5-24.9 kg/m² (N=42, 61.76%)	BMI ≥25.0-29.9 kg/m² (N=15, 22.06%)	BMI ≥30.0 kg/m² (N=3, 4.41%)
$K_{a,r}$ (mGy)				
Mean±SD	1,080.50±454.45	1,474.93±873.12	1,433.73±996.88	3,139.33±1087.44
Median	1,054.00	1,196.50	1,152.00	3,848.00
1st Quartile (Q1)	681.50	903.50	725.00	1603.00
3rd quartile (Q3)	1,289.50	1,669.25	1,899.00	3,967.00
IQR	681.50-1,289.50	903.50-1,669.25	725.00-1,899.00	1,603.00-3,967.00
Total fluoroscopy time (minutes)				
Mean±SD	31.69±11.63	35.50±15.76	35.55±11.17	54.33±19.39
Median	28.40	32.40	30.20	54.10
1st Quartile (Q1)	20.33	26.90	26.50	30.70
3rd quartile (Q3)	40.20	41.70	45.30	78.20
IQR	20.33-40.20	26.90-41.70	26.50-45.30	30.70-78.20

BMI, Body mass index; IQR, Interquartile range; P_{KA}, Air kerma area product; $K_{a,r}$, Cumulative air kerma at patient entrance reference point.

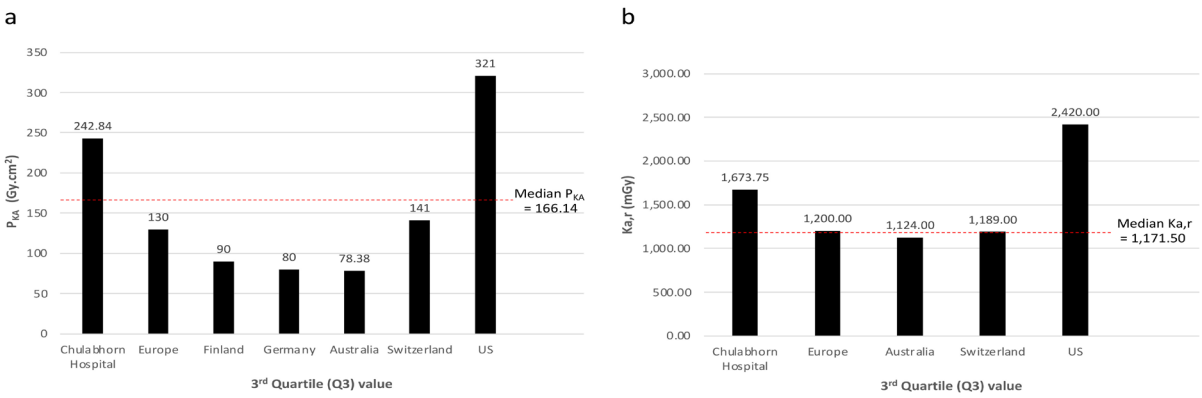

Figure 1 *Comparison of the third quartile (Q3) value of P_{KA} (a) and $K_{a,r}$ (b) undergoing TAVI between this study and international DRL. Dashed line: median value of this study, P_{KA}: air kerma area product, $K_{a,r}$: cumulative air kerma at patient, US: United States.*

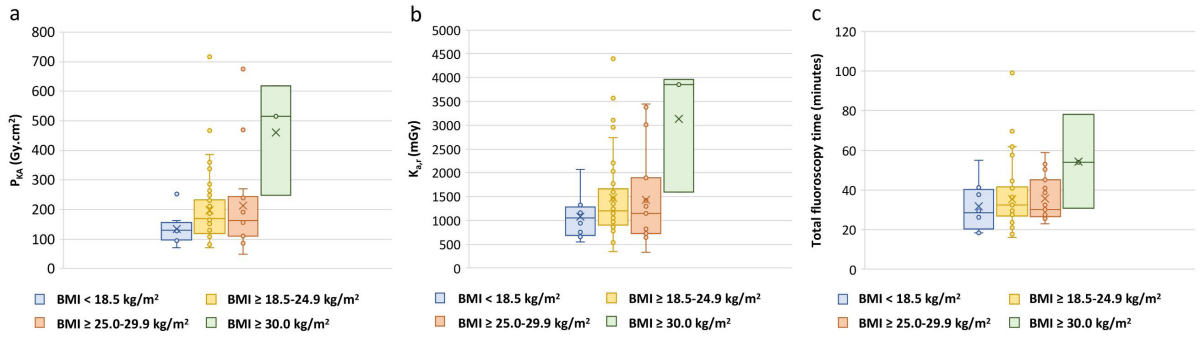

Figure 2 *Distribution of patient's radiation dose for TAVI procedure in the different BMI categories. The data are for P_{KA} (a), $K_{a,r}$ (b), and total fluoroscopy time (c). Box: the first and third quartiles, Line between box: median value.*

Discussion

This is the first Thai study of radiation doses in TAVI in which patient BMI and not patient sex affected the radiation dose received from the procedure. The number of patients undergoing radiological diagnosis increased in the US during the 2006-2016 period; the top four radiological diagnosis techniques included computed tomography, radiography and fluoroscopy, cardiac interventional fluoroscopy, and noncardiac interventional fluoroscopy.[19] Although cardiac interventional fluoroscopy is an important noninvasive procedure for the diagnosis and treatment of cardiovascular disease (with up to 1 million operations performed annually), TAVI is an important procedure in the treatment of aortic stenosis in high-risk patients who cannot undergo surgical procedures.[20] However, TAVI requires that X-ray fluoroscopy produce radiation that creates images during a prolonged and continuous process. Given that the process involves complicated procedures, the patient is exposed to high doses of radiation that may cause deterministic and stochastic side effects. The risk assessment of radiation exposure from X-ray fluoroscopic medical procedures is performed by measuring the values of cumulative air kerma at the patient entrance reference point ($K_{a,r}$)-which correlates with deterministic tissue effects such as skin erythema and epilation-and air kerma-area product (P_{KA}), which is used to estimate stochastic risks.[21, 22] This assessment is similar to the establishment of a DRL for cardiovascular catheterization.[12] The DRL values for cardiac interventional fluoroscopy were obtained by surveying radiation doses from similar X-ray fluoroscopy procedures in various departments. These values were used to compare the radiation dose received by patients from in-house X-ray machines to optimally protect patients against medical exposure to radiation. Guidance dose levels for diagnostic radiology were used in the US, Europe, and the United Kingdom until the current international recommendations for DRLs were established.[12,23] In addition, a US study of radiation doses received by patients undergoing cardiac interventional fluoroscopy between 2006 and 2016 found that the TAVI procedure was promising and the amount of radiation received by patients was reduced from the level originally observed during the 1960-2006 period.[19] Results may be attributable to the monitoring and evaluation of the patient's radiation doses in each instrument or in each standardized examination. As a result, several organizations worldwide are now aware of the importance of radiation dose assessment in patients and medical radiation users have become more knowledgeable in controlling, optimizing, and monitoring radiation doses. Moreover, technology has been developed and techniques have been modified to reduce the amount of radiation used in the TAVI procedure.

In this study, all patients undergoing TAVI were older adults and males and females were similarly represented. Correspondingly, the incidence of aortic stenosis among the population is considerably higher in older adults than in younger individuals and male and female patients are treated equally with TAVI.[1,24] Notably, the radiation doses received by patients as measured by median P_{KA}, $K_{a,r}$, and total fluoroscopy time were similar between males and females, indicating that sex does not affect the duration of the procedure or the radiation dose received from the procedure. However, previous studies report the effect of patient size or BMI on the radiation dose received by the patient. Patients who were obese or had a BMI higher than 30.0 kg/m^2 had higher radiation exposure from cardiac catheterization and statistically significant increases in P_{KA} and $K_{a,r}$ compared with patients with lower BMI values.[2,5] In this study, male and female participants had similar BMI values; therefore, the median values of P_{KA} and $K_{a,r}$ were similar. Notably, when patients were grouped according to BMI into four categories regardless of sex, patients with a BMI higher than 30.0 kg/m^2 received the highest radiation dose. As previously reported, higher BMI is associated with higher P_{KA} (dose area product) and $K_{a,r}$ values, likely because the potential and current of the X-ray machine tube are altered by higher BMI levels to maintain radiographic image quality, hence increasing the radiation dose received by patients.[23,25-27] Therefore, fluoroscopy procedures in larger patients may increase the risk of radiation exposure, which may result in deterministic and stochastic effects in patients. However, patients with the highest BMI values in this study were subjected to the longest total fluoroscopy time. This may be a limitation of a study with a small sample size because a correlation between increased BMI and the procedure's total fluoroscopy time has not been reported.[21] Furthermore, we observed that patients with BMI ≥18.5-24.9 kg/m^2 had higher P_{KA} and $K_{a,r}$ values than those with BMI ≥25.0-29.9 kg/m^2 because of longer total fluoroscopy time. Consequently, the duration of radiation during the procedure is an important element in determining the radiation dose received by patients. Therefore, in cases for which the duration of the procedure cannot be shortened, appropriate adjustments should be made to techniques, the rate of radiation use, and visualization modes.

The TAVI procedure involves a higher variety of radiation doses than other interventional cardiology procedures and reporting of the procedure in the national DRL database is still lacking in Thailand.[11,28] Additionally, this dataset is from only the first 2 years of the department's use of the procedure and a learning curve remains for the operator. The result of this study revealed that the radiation dose as measured by the relevant parameters -P_{KA}, $K_{a,r}$ and total fluoroscopy time -was different for each patient; this may be caused by factors such as operator technique and procedure complexity.[29] The study results provided a typical value or a median P_{KA} of 166.14 Gy/cm^2 whereas international DRLs of previous studies were in the range of 78.38-140 Gy/cm^2.[11, 15-17] The higher P_{KA} value in this study compared with the DRL of other countries could be attributed to procedure performance during femoral access (which widely opens the radiation field size and requires a longer time during the procedure), beginners' experience, the complexity of lesions in each case, and differences in patient anatomy that may have increased procedure duration.[18, 30-32] However, the other typical value-the median $K_{a,r}$ of 1,171.50 mGy was in the

range of 1,124-1,200 mGy of the international DRLs of previous studies.[11, 26-28] This value from our study is similar to DRLs of other countries. When comparing the radiation dose received by patients undergoing TAVI in a single-center study in a US hospital that used the same methods as in our study, the typical median values of P_{KA} and $K_{a,r}$ were approximately two times lower than US DRL values (P_{KA} and $K_{a,r}$ of 321 Gy/cm^2 and 2,420 mGy, respectively).[29] Admittedly, this could be attributable to the smaller body size of Thai patients, and therefore lower BMI and body surface area, and to different sets of image creation techniques or modes across various facilities. Overall, the median values of radiation dose received by TAVI patients in this study were below the threshold defined in the Society of Interventional Radiology guidelines for patient radiation dose management; these included P_{KA} (<500 Gy/cm^2), $K_{a,r}$ (<5,000 mGy), and total fluoroscopy time (<60 minutes).[18] However, in-house surveillance of the medical radiation dose is still a critically important concern.

The limitations of this study include its small sample size and data collection from a single piece of equipment in a single organization. However, the data from this study can be used to report radiation doses received by patients undergoing TAVI-a dataset that is currently underwhelming and insufficient. Furthermore, the median dose results of this study were compared with international DRLs, but do not account for different patient body habitus. Therefore, a national or Asian DRL database must be established in the future to allow the comparison of median dose values of radiation received by patients of similar body sizes undergoing TAVI. Furthermore, as recommended by the International Commission on Radiological Protection, continuous data collection and analysis must be performed to review DRL values every 3-5 years to determine the appropriate radiation doses for fluoroscopically guided TAVI procedures.

Conclusion

The amount of radiation that patients received from TAVI was appropriate for diagnosis and treatment. However, to ensure patient safety, operators should consider adjusting technique settings or reducing the duration of radiation during the procedure because patients in both the lowest and highest BMI categories in our study were subjected to long total fluoroscopy time leading to an increase in the radiation dose received. Data from this study are a starting point for recording radiation doses received by patients undergoing the TAVI procedure; data can be used as a future dose reference and compiled into a national DRL database.

Acknowledgements

This study was supported by a research grant from Thailand Science Research and Innovation (FRB640039/0240 Project code 106226). The authors would like to thank the staff of the Cardiology Center, Chulabhorn Hospital and Chulabhorn Royal Academy for supporting this project. Furthermore, the authors wish to express their sincere thanks to Woranan Kirisattayakul, Ph.D, Department of Radiology, Faculty of Medicine, Khon Kaen University for guidance and suggestions.

Conflicting interests

The authors declare that they have no conflicts of interest.

Ethics approval

This study was granted ethics approval by the Human Research Ethics Committee of Chulabhorn Research Institute (Project code 005/2563).

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