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Radiation Dose to Medical Staff in ^{177}Lu-PSMA-DKFZ-617 therapy And Estimation of Annual Dose

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Abbreviated title: External dose

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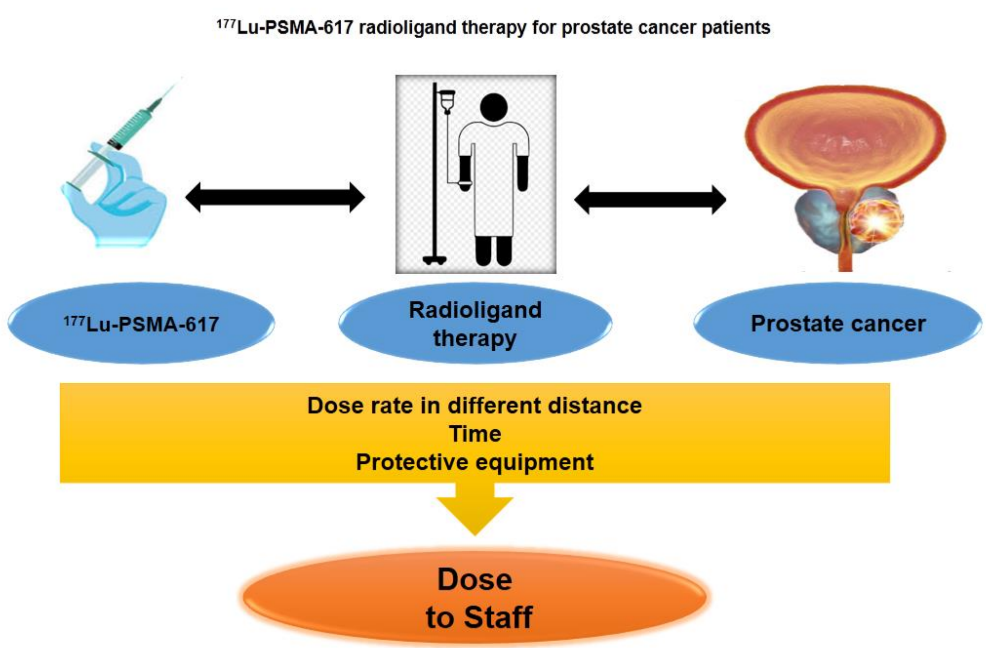
Abstract

Radioligand therapy applications for metastatic castration-resistant prostate cancer have been continuously rising in most nuclear medicine departments in Iran, but to our knowledge, no one has studied the doses of staff who perform treatment procedures. The current study aimed to determine the external radiation dose received by the staff of patients treated with ^{177}Lu- prostate-specific membrane antigen therapy with and without a lead shield. This study used a dose ionization chamber to measure dose rates to the staff at various distances from patients and determined the average time spent by staff at these distances using an ionization chamber. Deep-dose equivalent to staff was obtained. The measured deep-dose equivalent to staff per patient was whitening the range of 1.8 to 5.2 mSv using a lead shield and 3.3 to 8.1 mSv without a lead shield. This study showed that a 2-mm lead shield markedly reduced the external dose to staff.It was indicated that the skill, accuracy, and speed of action of staff can directly affect their received dose.

Keywords: Nuclear medicine, ^{177}Lu-PSMA-DKFZ-617, dose rate, prostate cancer, mean doses



Introduction

Recently, prostate-specific membrane antigen (PSMA) target radioligand therapy has been introduced for targeted therapy. Regarding the increased mortality rate caused by prostate cancer, radioligand therapy (RLT) with ^{177}Lu-PSMA-DKFZ-617 is known as a promising treatment for castration-resistant prostate cancer patients. Notably, the physical half-life of ^{177}Lu was estimated as 6.73 days. The ^{177}Lu emits two types of radiations, named beta (has a maximum energy of 0.498 MeV) and gamma rays (the energies of 113 Kev with 6% abundance and 208 KeV with 11% abundance) (*1*-*3*). These gamma rays allow scintigraphy and subsequent dosimetry with the same therapeutic compounds. Because of the gamma rays of ^{177}Lu, the radiation protection issue can become a problem (*4*). The golden aim of radionuclide therapy is to deliver an effective absorbed dose to tumor cells, while protecting critical organs from excessive radiation dose. Meanwhile, unnecessary radiation doses to family members, the medical team, and the general public must be avoided. Particularly, the nuclear medicine technologists come into nearby proximity with radiation sources, receiving radiation doses while performing procedures such as preparing and administering the ^{177}Lu-PSMA-DKFZ-617, positioning the patient treated with ^{177}Lu-PSMA-DKFZ-617on the scanner bed, controlling the patient during data acquisition, transferring the patient from the bed, and escorting the patient to the department (*5*). Thus, nuclear medicine societies have introduced several protective recommendations for the procedures of targeted therapy. However, various reports on methods used for reducing the dose received by patients and staff in various tests have been published in some national and international journals (*6*). Many investigators have measured the average external dose rates to staff by used pocket electronic and Thermo luminescent (TLD) dosimeters to record the total dose per study (*7*-*8*). Direct experimental determination of the external radiation dose to the nuclear medicine staff per procedure may follow different tactics:

a) The first one is based on accurate measurements of the dose rate at set distances from the patient and less accurate evaluations of the time spent by the operator at those distances.

b) The second one can consist of the direct reading of an electronic dosimeter used by the staff while the procedure.

The first tactic produces a rough approximation of measurements of dose rate but is more general and provides a direct comparison of dose rates between different published data (*9*) .The present study aimed to describe the mean external dose to staff in a different position from patients related to radioligand therapy with ^{177}Lu-PSMA-DKFZ-617 with and without a lead shield using measured dose rates. The second aim was to determine the annual dose to staff performing a single type of procedure throughout the year.

Materials and Methods

The study was authorized by the hospital ethics committee, all patients gave their informed consent, and it was carried out in accordance with the Declaration of Helsinki. The inclusion criteria were as follows: age over 55 years old with metastatic castration-resistant prostate cancer being treated with ^{177}Lu-PSMA-DKFZ-617. The mean age of the included patients was 66.2 years old (range 55-80 years). In total, 45 patients were enrolled in the current study from March 2019 to March 2020. The patients were then admitted to The Nuclear Medicine Department, Shohada-e Tajrish Hospital in Tehran, Iran. Four patients were treated sequentially on each therapy day in a four-bedroom in the hospital's day procedure unit. Accordingly, each one of these rooms included 4 beds, which were located in 4 corners of the room with an area of about 30 m^2. Patients must be isolated in lead-shielded rooms (lead thickness 1.6 cm, height 2 m door lead width 0.8 cm) after the administration. The distance between the beds is 2-m. A mobile shield (2-mm Pb) was placed between two beds. The injection was treated in a separate single room. All the patients were measured separately in a completely safe and protected room with the lead walls at the specified intervals. The current study was performed using an ionization chamber (Thermo, FH 40G-L10 (made in Germany), which was calibrated by the secondary standards dosimetry laboratory. The feature of the dosimeter was considered as its capability for photons in the range of 10 nSv/h-100 mSv/h. In addition, the range of energy response of the dosimeter was considered from 30 keV to 4.4 MeV. The dose rate was then measured on the chest position at distances of 0, 0.25, 0.5, 1, and 2 m from the patients (*10*) who were treated with the mean 5.5 ± 1.1 (a range of: 3.7-7.4) GBq of ^{177}Lu-PSMA-DKFZ-617, once with and once without 2-mm lead shield after the mentioned times (0, 1 h, 2 h, 3 h, 4 h, 5 h, 6h, 18 h, 24h and, 36h). Radiation doses to staff were estimated by recording the time interval and dose rate at various distances from the patient. In some cases, patients after receiving instructions, are in their position. Operators carefully measured the mean time spent and dose rate by staff at these distances. The measurements were obtained as µSv/h using the ionization detector and were converted to µSv/GBq.h according to the amount of radiopharmaceutical injection. Time (seconds) and relative dose rates were multiplied by each other. Finally, mean external doses to staff and their SDs were calculated. Personal TLD dosimeters were dedicated to the ^{177}Lu-PSMA-DKFZ-617 therapy procedures. The demographic information of the staff included in the current study are presented in Table 1. We routinely administer ^{177}Lu-PSMA-DKFZ-617 treatment on an outpatient basis. The dose limit recommended by European guidelines for the discharge of patients after iodine-131 therapy and by Africa guidelines ^{177}Lu-PSMA-DKFZ-617 was set as the basis for discharge (20 µSv/h within 1 meter) (*11-15*). From equation No.1 the cumulative dose can be estimated, *E*, to a caregiver standing from the patient for an unlimited time, assuming that only physical decay occurs. The authors assumed a distance of 1 m and set initial dose rate reading at this distance, D_0, = 20 μSv/h. The half-life of ^{177}Lu, 6.7 days, is represented by $t_{1/2}$. Following the calculation it can be found that E=4.6 mSv (*16*).

$$E = \int_0^\infty D_0 \times e^{-\ln(2)\times\frac{t}{t1/2}}\,\mathrm{dt} \qquad (1)$$

Statistical analysis

Data processing and fitting were performed using Microsoft Excel (Microsoft office professional plus 2013) and SPSS (ver. 16.0, IBM Corp.) was used for the statistical analysis. For this purpose the K-S (Kolmogorov-Smirnov) method was used to investigate the normal distribution of data. A value of $p <= 0.05$ was assumed to indicate statistical significance. Data are presented as the mean and standard deviation unless stated otherwise.

Results

The mean external dose rates based on μSv/(h.GBq) at various distances and time intervals from the patients treated with ^{177}Lu-PSMA-DKFZ-617, are presented in Table 2. Based on the results presented in Table 2, the dose rate gradually decreased due to the excretion of activity from the body. Initial conditions such as different injectable activity, tumor's uptake, and different renal functions were found to have great impacts on the clearance of radiopharmaceuticals from the patient. Since most of the patients started to urinate approximately after the first hour of infusion, the initial observed dose rate readings were at the highest level at different distances (47.5±2.0 (40.0-58.0) μSv/(h.GBq) at 0.25 m, 21.5±1.2 (18.5-24.5) μSv/(h.GBq) at 0.5 m and 7.1±0.3 (5.5-8.3) μSv/(h.GBq) at 1 m taking into account the similar geometry of measurement after ^{177}Lu-PSMA-DKFZ-617 infusion. The dose rate at 1 m distance from the patient decreases exponentially with the proceeding time. The average radiation dose rate at 1 m distance from the patient, 4–5 h after the infusion is considered to be safe, as the dose rate falls below the release limit in our department (20 μSv /h). The main results are summarized in Table 3, which shows the mean, minimum, and maximum doses to the staff in charge of the treatment by ^{177}Lu-PSMA-DKFZ-617, which were measured according to the time of exposure and the distance from the patients with and without the lead shield. The annual mean dose for staff in all the treatment cycles has been calculated for the patients who were selected to be studied as well as for the patients who were excluded. Table 4 shows the estimated total annual doses to staff who work with and without a lead shield. The annual total dose to staff in table 4 responsible for only a particular procedure throughout the year was determined using the values in Table 3 and the annual numbers of cases in the nuclear medicine laboratory. Table 5 shows the annual doses to staff, as measured using personal thermo luminescence dosimeters. Personal TLD dosimeters were dedicated to the ^{177}Lu-PSMA-DKFZ-617 therapy procedures. The calculations have been done based on the number of treatment sessions performed during a year, by assuming that nuclear medicine staff participated in all these treatment sessions. The annual doses to staff responsible for the same procedure throughout the year were different from one another. The annual mean dose received by the nurse was higher than all the staff as approximately 3.8 mSv. In the case of using the lead shield, the value was estimated to be 2.3 mSv. The annual mean dose received by the technologist who was in charge of radiopharmaceutical injection and the technologist responsible for imaging in case of using the lead shield was also estimated to be 2.2 mSv and 1.5 mSv, respectively. Moreover, in case of lack of any lead shield, these were estimated as 3.4 mSv and 2.6 mSv, respectively. Physician and physicist had the lowest received annual dose as 1.0 mSv and 1.2 mSv, respectively. Physician and physicist had the lowest received annual dose as 1.8 mSv and 2.1 mSv in case of lack of any lead shield, respectively.

Discussion:

^{177}Lu-PSMA-DKFZ- 617 therapy of castration-resistant prostate cancer has been practiced in a few specialized centers in the world. The essential criteria for incorporating any new cancer therapy into the going of targeted therapy is: a) ensure the privileges of safety b) efficacy C) regularity D) practicality E) affordability (*7*-*8*). The patients should bear extra costs and expenses if they have to stay for a long period of time at the hospital. Also, isolation may cause potential emotional disturbances and patients could be threatened by possible hospital infections during an extended stay. Our findings demonstrate that ^{177}Lu-PSMA-DKFZ-617 is a safe treatment modality to be applied as an outpatient protocol, since the dose rate decreases below the determined threshold of <20 μSv/h after approximately 4-5 h. Different studies have been done. In a study by Demir and et al., (*7*) patients can be discharged from the hospital when the dose rate decreases below the determined threshold of <30 μSv/h after approximately 4-5 h. A similar study was performed by Calais et al., (*17*). In this study, Patients attained the radiation exposure release limit of 25 μSv/h at 1 m at a mean of 2.3 h after infusion, and all were released within 6 h. The differences among the results of various studies may also be due differences in the injected activity, biological uptake, and radiopharmaceutical clearance of patients. In our study, the highest dose was received by the nurse (8.1 μSv per patient) who routinely entered the patients' rooms at the beginning of infusion to meet the needs of the patients and for medical observation. The scheduled time of radioligand therapy with ^{177}Lu-PSMA-DKFZ-617 in the nuclear medicine department was appointed regularly the same nurse on duty generally contributed to the therapy of all patients. Our department carries out around 300 sessions of ^{177}Lu-PSMA-DKFZ- 617 therapy per year (45 patients who are treated 3-6 times with an interval of 12-8 weeks during a year). Nurses have the highest contribution of their annual dose. In comparison to the physicist, the physician and technologists, technologist in charge of injection received a higher radiation dose (7.6 μSv per patient) as predicted, because of spending long hours during the preparation of the demanded activity and also staying close to the patients' bedsides during infusion ^{177}Lu-PSMA-DKFZ-617, resulting in a relatively high radiation dose. Furthermore, the nuclear medicine technologist (in charge of imaging), who was responsible accompanied patients to the scintigraphy room and guided them for positioning on the bed, significant time spent near the patients, resulting in receiving a considerably total dose. (4 mSv per patient). According to this result, the technologist who is responsible for injection received more than who is responsible for imaging; so rotation shifts for technologists are recommended. Unlike the nurse and technologists, the physician, who had a confined role during the therapy concourse represented by medical supervision with sporadical attendance in the treatment room, recorded a total dose of 3.3 μSv per patient. Lastly, the physicist showed a relatively low dose of 3.5 μSv per patient resulting from frequently entering the isolation room for dose rate measurement. Generally, our results were close to those of Demir and et al., (*7*). Demir and et al., (*7*) showed that the mean radiation doses of the nurse and radio pharmacist were 6.0 and 4.0 μSv/patient, respectively, whereas the mean radiation dose of the physicist and physician was calculated as 2.0μSv/patient. This work analyzed the dose rate of 23 patients treated with 7400 MBq^{177}Lu-PSMA-DKFZ-617 and the total dose of the medical team was estimated by an electronic personnel dosimeter. The estimated values of international studies for comparison are presented in Table 6. Differences were observed between the values presented in the current study and study Demir and et al., (*7*). These values can be seen in Table 6. The differences among the results of various studies may also be due to the experience, skills, time between examinations and injection, and promptness of the staff. Some treatment centers may choose to hospitalize patients to monitor the condition of their patients or to facilitate further medical examinations. If four patients were treated sequentially on each therapy day in a four-bedroom in the hospital's day procedure unit, the nurse, who spent up to 4 h attending the four patients post-infusion, received a mean radiation dose range of 26–53 μSv. The wide variety reflects the differences between nursing requirements, tumor burden in each patient group, and the behavior of the individual nurse. Whilst in this situation, patient privacy may be somewhat compromised, the ability of both patients, and their careers (usually a family member or friend), to talk to fellow sufferers and share their individual experiences and gain mutual support for what is regarded as a rare disease, for which authoritative and firsthand patient information is relatively scarce, is a valuable therapeutic supplement. Although no measured radiation dose to medical staff exceeded the allowed limits (20mSv/year), it is recommended to propose a protocol for good practice, in order to decrease the exposure to staff as minimum as possible in each nuclear medicine center. Accordingly, this includes improving the work procedures, minimizing the close contact with the patients, and having equipment and shield helping in lowering the radiation doses when it is not possible to avoid having any contact. The values in Table 3 indicate that the use of a lead shield while performing radioligand therapy procedures significantly decreased the dose to staff. For the medical team including the physicist, physician, nurse, and nuclear medicine technologist, a 2-mm lead barrier reduced the dose by approximately 2 times for the therapeutic procedures performed in this study. The values in Tables 3 and 4 show that even without a rotation of the workforce, and even with a significant increase in the number of patients, the annual dose to individual staff would not reach the annual limit (20 mSv/year) defined by the International Commission on Radiological Protection (ICRP). Annual doses as indicated by thermo luminescence dosimeters agreed with the estimated mean annual doses but not for technologists responsible in charge of injection. With regard to external dose to technologists, the lack of agreement may have occurred because technologists administered ^{177}Lu-PSMA-DKFZ-617 in radioligand therapy and administered radiopharmaceuticals to patients in diagnostic procedures at the same shift. The doses may therefore have appeared lower than they really were. Dose reduction to the staff in nuclear medicine is recorded after wearing the lead shield and aprons (*18*-*20*). He, (*21*) in his study reported the effects of the lead apron on ^{57}Co, ^{33}Ba, ^{137}Cs, ^{99m}Tc, and ^{131}I radionuclides. Accordingly, it was found to have the greatest effect on reducing radiation by wearing a lead apron when using radiopharmaceuticals that emit gamma rays less than 140 keV. Furthermore, Bayram and et al., (*10*) in another study showed that a 2- mm lead shield could reduce the external radiation dose for staff in various diagnostic tests. If a lead shield thicker than 2- mm were to be used, the dose could be lowered even further. The authors emphasize that staff should consider the use of protective equipment in each position. Additionally, of course, reducing the exposure time and increasing the distance from the radiation source are advisable measures when facing the positron nuclides and other high energy gamma-ray sources. The limitation of this study was the low number of patients included in this study. In addition, the absence of lead with varying thicknesses (less and more than 2-mm) for a general overview of the impact of protective equipment on the received dose can be considered as another limitation. The sensitivity of measuring and imaging devices is reduced with the use and over time, and this means that more radioactive materials are administered to the patient in order to obtain a suitable count to produce a quality image. With increasing radioactivity, more radiation is given to patients and as a result, radiation exposure of radiotherapists increases, so in order to reduce it, a regular quality control program of nuclear medicine devices of the centers is necessary. Finally, our measured data during this research shows that radionuclide therapy of prostate cancer with ^{177}Lu-PSMA-DKFZ-617 is a considerably safe and tolerable therapy modality provided that the safety precautions are well undertaken. Furthermore, this study found that external radiation doses to medical staff were within the allowable limits.

Conclusion

The results of the present study show that the 2-mm lead barrier reduced the dose to staff for the therapeutic procedures performed in this study. Due to the known effects of the lead shield on reducing staff mean radiation dose, it is recommended to use the protective device at all treatment stages. In summary, it was indicated that no measured radiation doses to medical staff exceed the annual dose limits (20 mSv/year).

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Key points:

Radioligand therapy applications for metastatic castration-resistant prostate cancer. The amount of radiation dose to staff, related to patients treated with ^{177}Lu-PSMA-DKFZ-617 is within the allowable range. Results are statistically significant. Lead protection can reduce radiation dose to staff. This finding underscores the need of staff considering the use of shielding

Conflict of interest:

The authors confirm there is no conflict of interest

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Table 1. The demographic information of staffs who are included in current study**.**

Staff	No.		
	Female	**Male**	**Distance**
Technologist (in charge of injection)	4	4	0 m (injecting radiopharmaceutical)
Technologist (in charge of imaging)	4	4	0.25 m (positioning the patient) -1 m (presentation information for the patient)
Nurse	2	2	2 m (check out the treatment process)
Physicist	2	2	2 m (providing protection guidelines)
Physician	3	1	0.25 m (check patient vital signs)

Table 2. The mean dose rate (µSv/(h.GBq)) and related standard deviation at various distance and time for patients underwent treatment with ^{177}Lu-PSMA-DKFZ-617.

Time	**Distance(m)**				
(h)	**0**	**0.25**	**0.5**	**1**	**2**
0	78.6±5.0 (72.7-87.5)	47.5±2.0 (40.0-58.0)	21.5±1.2 (18.5-24.5)	7.1±0.3 (5.5-8.3)	5.4±0.5 (4.4-7.2)
1	70.3±3.0 (63.6-78.1)	36.3±3.1 (32.0-44.6)	19.1±1.5 (16.8-21.3)	6.0±0.5 (4.4-6.6)	3.6±0.4(2.8-4.5)
2	53.0±3.4 (55.0-44.9)	32.3±1.1 (24.3-34.4)	16.5±1.1 (12.4-18.4)	5.1±0.6 (3.4-5.5)	2.6±0.3(2.0-3.1)
3	44.5±3.0 (35.7-47.3)	24.3±1.2 (18.8-27.9)	12.6±1.3 (7.7-14.4)	4.2±0.2 (2.7-4.7)	2.3±0.2 (1.6-2.7)
4	34.4±1.5 (29.9-39.5)	17.2±1.6 (14.6-19.7)	8.5±1.7 (6.5-10.8)	3.2±0.3 (2.4-3.9)	1.8±0.2 (1.4-2.4)
5	24.2±1.5 (19.0-27.3)	13.3±0.9 (10.9-14.9)	6.1±0.3 (5.5-7.6)	2.8±0.2 (1.9-3.2)	1.3±0.3(0.8-1.8)
6	22.2±1.3 (17.0-25.5)	11.5±0.5 (8.8-14.0)	5.5±0.2 (5.0-7.0)	2.2±0.3 (1.2-3.0)	1.0±0.5(0.5-1.5)
18	17.5±1.1(15.2-20.4)	10.5±0.7 (7.9-11.9)	5.0±0.4 (3.7-5.9)	1.4 ±0.3 (0.9-1.7)	0.8±0.2(0.3-1.0)
24	13.5±1.3 (12.4-16.2)	6.5±1.1 (5.9-8.0)	3.1±0.2(2.9-3.5)	1.0±0.04(0.5-1.4)	0.5±0.02(0.3-0.8)
36	10.0±1.1 (8.4-13.3)	4.5±1.0 (3.8-6.0)	2.3±0.3(1.8-3.0)	0.6±0.03(0.3-1.0)	0.3±0.03(0.1-0.8)

Data are Mean±SD

Table 3. Mean, minimum and maximum dose to the staff (μSv per patient) in different job position

	Total dose without lead shield			Total dose using lead shield			
Staff	**Minimum dose per patient (μSv)**	**Maximum dose per patient (μsv)**	**Mean ± SD**	**Minimum dose per patient (μSv)**	**Maximum dose per patient (μsv)**	**Mean ± SD**	
Technologist (in charge of injection)	6.5	8.6	7.6±1.1	4.0	5.2	4.8±0.9	p<= 0.05
Technologist (in charge of imaging)	3.7	5.0	4.0 ±0.5	2.1	3.0	2.4±0.3	p<= 0.05
Physician	3.0	3.6	3.3±0.3	1.6	2.1	1.8±0.4	p< 0.05
Physicist	3.2	4.2	3.5±0.5	1.7	2.5	2.2±0.3	p< 0.05
Nurse	7.4	9.2	8.1±0.8	4.2	5.7	5.2±0.3	p<= 0.05

Data are mean ± SD (μSv per patient)

Table 4.Estimated annual doses to staff

Staff	Mean annual dose using lead shield (mSv)	Mean annual dose without lead shield (mSv)
Technologist in charge of injection	2.2	3.4
Technologist in charge of imaging	1.5	2.6
Physician	1.0	1.8
Physicist	1.2	2.1
Nurse	2.3	3.8

Data are mean (mSv)

Table 5. Annual doses to staff as measured with Thermo luminescence dosimeters

Staff	Maximum annual dose (mSv)	Minimum annual dose (mSv)	Mean annual dose without lead shield (mSv)
Technologist in charge of injection	4.9	3.6	4.6
Technologist in charge of imaging	3.5	2.4	3.1
Physician	1.8	1.3	1.6
Physicist	2.2	1.6	1.9
Nurse	4.8	3.8	4.3

Data are mean (mSv)

Table 6. Comparison of the results obtained in current study with other international studies

Staff	Demire and et al (7)	Current study (without lead shield)	Current study (with lead shield)
Radio pharmacist	4.0	7.6±1.1	4.8±0.9
Physicist	2.0	4.0 ±0.5	2.4±0.3
Physician	2.0	3.3±0.3	1.8±0.4
Technologist	3.0	3.5±0.5	2.2±0.3
Nurse	6.0	8.1±0.8	5.2±0.3

Data are mean ±SD (µSv per patient)