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Occupational radiation exposure of radiopharmacy-, nuclear medicine-, and surgical personnel during use of [^{99m}Tc]Tc-PSMA-I&S for prostate cancer surgery

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ABSTRACT

Aim: The aim of this study was to estimate and subsequently measure the occupational radiation exposure for all personnel involved in the production, administration, imaging, or surgery with [^{99m}Tc]Tc-PSMA-I&S, which has been introduced for identification of tumor-positive lymph nodes during salvage prostate cancer surgery

Materials and Methods: The effective dose was estimated and subsequently measured with electronic personal dosimeters for the following procedures and personnel: labeling and quality control by the radiopharmacy technician, syringe preparation by the nuclear medicine laboratory technician, patient administration by the nuclear medicine physician, patient imaging by the nuclear medicine imaging technician, and robot-assisted laparoscopic salvage lymph node dissection attended by an anesthesiology technician, scrub nurse, surgical nurse, and surgeon. The dose rate of the patient was measured immediately after administration of [^{99m}Tc]Tc-PSMA-I&S, after imaging, and after surgery.

Results: The estimated dose per procedure ranged from 1.59×10^{-10} µSv (imaging technician) to 9.74 µSv (scrub nurse). The measured effective dose ranged from 0 to 5 µSv for all personnel during one procedure with [^{99m}Tc]Tc-PSMA-I&S. The highest effective dose was received by the scrub nurse (3.2±1.3 µSv), whilst the lowest dose was measured for the surgical nurse (0.2±0.5 µSv). If a single scrub nurse would perform as much as 100 procedures with [^{99m}Tc]Tc-PSMA-I&S in a year, the total effective dose would be 320 µSv/year. Immediately after administration, the dose rate at 50 cm from the patient was 18.5±1.6 µSv/h, which dropped to 1.8±0.3 µSv/h after imaging the following day and reducing even further to 0.56±0.33 µSv/h after surgery.

Conclusion: The effective dose for personnel involved in handling [^{99m}Tc]Tc-PSMA-I&S is comparable to that of other ^{99m}Tc-radiopharmaceuticals and therefore safe for imaging and radioguided surgery.

INTRODUCTION

Prostate cancer (PCa) is the most common malignancy in men of ≥50-years and the second cause of cancer-death among men after lung cancer (*1*). Local therapy, such as a radical prostatectomy and extended pelvic lymph node dissection (ePLND), can be used to cure patients with intermediate- or high-risk (localized) PCa (*2*). However, up to 25% of the prostate-draining pelvic lymph nodes are outside the standard ePLND template and remain *in vivo* after ePLND (*3*). Improvements in pre-operative and intra-operative techniques for detection and removal of loco-regional lymph node metastases may result in a shift towards increased cure rates in patients with prostate cancer.

Conventional pre-operative lymph node imaging techniques, such as magnetic resonance imaging (MRI) and computed tomography (CT), are neither sensitive nor specific enough for accurate lymph node staging (*4*). In recent years multiple PET tracers have been clinically introduced, targeting the Prostate-Specific Membrane Antigen (PSMA), a transmembrane glycoprotein that is overexpressed on most prostate cancer cells. Today, PSMA PET/CT has significantly improved the specificity and sensitivity for the detection of PCa compared to conventional imaging (*5*).

PSMA-based image guided surgery has been proposed as a technique to prevent incomplete resections and to improve intra-operative detection and clearance of nodal metastases. However, intra-operative use of positron-emitting PSMA PET tracers is challenging due to the relatively short half-life, radiation dose to personnel, and the lack of suitable positron detecting surgical probes. To tackle this problem, [^{111}In]In-PSMA radioguided surgery (RGS) was developed and proven feasible in localized and limited recurrent PCa (*6*). Hereafter, [^{99m}Tc]Tc-PSMA-Imaging&Surgery ([^{99m}Tc]Tc-PSMA-I&S) RGS was introduced (*7*). The good commercial availability and favorable radiation properties with gamma-emission and a half-life of 6.01 hours of ^{99m}Tc make this isotope ideal for this application, allowing ample time for pre-operative imaging followed by RGS with a gamma probe.

Imaging and RGS with [^{99m}Tc]Tc-PSMA-I&S involves personnel at different departments in the hospital: production takes place at the radiopharmacy department, patient syringes are prepared by the nuclear medicine laboratory, patient administration and imaging takes place at the out-patient nuclear medicine department, and radioguided surgery is performed in the operating room. In order to ensure the radiation protection of all staff members, the radiation burden of the entire procedure with [^{99m}Tc]Tc-PSMA-I&S must be known. Therefore the aim of this study is to estimate and subsequently measure the occupational radiation exposure for all personnel involved in the production, administration, imaging, or surgery with [^{99m}Tc]Tc-PSMA-I&S.

MATERIALS AND METHODS

Workflow of [^{99m}Tc]Tc-PSMA RGS and personnel

Production of [^{99m}Tc]Tc-PSMA is performed with an automated module by two radiopharmacy technicians as previously described (*8*). In short, the steps are (1) placement of a cassette on the automated labeling module without the presence of radioactivity, (2) attaching a syringe of 2000 MBq [^{99m}Tc]pertechnetate immediately followed by closing the lead shielding surrounding the labeling module, (3) automated synthesis of [^{99m}Tc]Tc-PSMA without personnel present, (4) opening the lead shielding and removal of the final product in shielding, and (5) removal and disposal of the cassette.

Subsequently, in a laminar flow hood with lead glass, the final vial is calibrated in a dose calibrator and a quality control syringe and a patient syringe are prepared by a nuclear medicine laboratory technician. Quality control is then performed by the radiopharmacy technician with instant thin layer chromatography (iTLC) and high performance liquid chromatograph (HPLC) as previously described (*8*). After approval by the pharmacist, the nuclear medicine physician administers 550 MBq [^{99m}Tc]Tc-PSMA-I&S to the patient through an intravenous cannula.

The following day the patient returns to the nuclear medicine department for total body planar imaging followed by a 1 bed-position SPECT/CT scan of the pelvis and abdomen performed by a nuclear medicine technician 16 hours after intravenous injection of the [^{99m}Tc]Tc-PSMA-I&S. The SPECT/CT scan serves as quality control for tracer injection and distribution. Afterwards, a robot-assisted laparoscopic salvage lymph node dissection is performed using the *da Vinci* (Intuitive Surgical Inc., Sunnyvale, CA, USA). An intraoperative DROP-IN probe prototype (Eurorad S.A. Ecbolsheim, France) is inserted through a trocar next to or through the Alexis® port (Alexis laparoscopic system, Applied Medical Corp., Rancho Santa Margarita, CA, USA) and is used to detect lymph node metastases with gamma tracing (*9*). After surgical removal of lymph nodes, *ex vivo* measurements are performed to confirm [^{99m}Tc]Tc-PSMA-I&S uptake. During this procedure, an anesthesiology is seated at the patient's head, a scrub nurse stands next to the patient, a surgeon is seated in the console several feet from the patient, and a surgical nurse is present in the room.

Estimated effective dose

Prior to the first prepared patient dose, the estimated effective dose was calculated for all the steps described in the workflow according to equation 1. This assumes a worst-case in which there is no biological elimination but physical decay only.

Equation 1 $$E = A \times e^{-\ln 2 \times {}^{t}/_{t1/2}} \times \Gamma \times t_s \times {}^{1}/_{l^2} \times e^{-\ln 2 \times {}^{d}/_{d1/2}}$$

In which E = effective dose (μSv), A = activity (MBq) at start, t = time between starting activity and procedure (h), $t_{1/2}$ = half-life (h), Γ = effective dose rate constant (μSv m^2 Mbq^{-1} h^{-1}), t_s= time (duration) of step based on prior measurements and experience (h), l = distance to radioactive source (m), d = lead thickness (mm), $d_{1/2}$ = half-value layer of lead (mm). For all steps $t_{1/2}$ of ^{99m}Tc = 6.01 h, and $d_{1/2}$ of lead for ^{99m}Tc = 0.3 mm. All other values vary per step and are estimated in Table 1.

Effective dose measurements

Actual dose measurements were performed with electronic personal dosimeters (EPD) (DMC 2000 XB, MGP Instruments). The EPDs were worn at chest height by the following personnel: radiopharmacy technician during labeling and quality control of [^{99m}Tc]Tc-PSMA-I&S, nuclear medicine laboratory technician during syringe preparation, nuclear medicine physician during administration to a patient, nuclear medicine imaging technician during patient positioning and imaging, and during surgery by the anesthesiology technician, scrub nurse, surgical nurse, and surgeon. The total dose received during the handling of [^{99m}Tc]Tc-PSMA-I&S or of the patient and the total time was noted by the researchers. The minimum dose that can be reported by the EPDs is 1 μSv.

Dose rate measurements

Dose rate measurements (Thermo Eberline ESM FH 40 G-L, Thermo Fisher Scientific) of the patient were performed immediately after administration of [^{99m}Tc]Tc-PSMA at 30 cm, 50 cm, and 1 m, which was repeated following the SPECT/CT imaging. Immediately after surgery, whilst still in the operating room, dose rate measurements were performed at 30 cm and 50 cm. After administration and imaging, these measurements were done standing in front of the patient at the height of the liver, whilst the patient was in an up-right position. Following surgery, these measurements were performed standing by the side of the patient, while the patient was lying down with his arms at his side. The minimum measurable dose rate is 0.1 μSv/h.

Data analysis

Data was analyzed in SPSS Statistics (v25, IBM) and is represented as mean ± standard deviation (mean±SD).

RESULTS

Patients

For the evaluation of personnel dose, the first five consecutive [^{99m}Tc]Tc-PSMA-I&S RGS procedures which were performed in the context of the prospective '^{99m}Technetium based PSMA-Radioguided Assisted surgery for prostate Cancer (TRACE) feasibility Study' (NL68290.031.18), were measured to audit the estimated effective dose. The five patients involved in these procedures had provided informed consent for the TRACE trial. The labeling started with 2123±854 MBq, which resulted in 1284±473 MBq of the final product, and 567±26 MBq was administered to the patients.

Estimated effective dose

The estimated effective dose for each step is shown in Table 1. According to these calculations, the effective dose for one procedure with [^{99m}Tc]Tc-PSMA-I&S for the radiopharmacy technician is 2.93 x 10^{-1} µSv, the nuclear medicine laboratory technician receives 1.59 x 10^{-10} µSv, the nuclear medicine physician receives 3.75 x 10^{-1} µSv, the nuclear medicine imaging technician receives 1.24 x 10^{-1} µSv, the anesthesiology technician receives 3.51 µSv, the scrub nurse receives 9.74 µSv, the surgical nurse receives 2.19 x 10^{-1} µSv, and the surgeon receives 2.19 x 10^{-1} µSv. For all staff members the estimated effective dose from [^{99m}Tc]Tc-PSMA-I&S on a yearly basis (100 procedures) is below 1 mSv if that same staff member would perform all procedures, well below the limit of 6 mSv/year for classified radiation workers category B as set by Dutch legislation (*10*).

Measured effective dose

The measured effective dose ranged from 0-5 µSv for all personnel during one procedure with [^{99m}Tc]Tc-PSMA-I&S. All results are shown in Table 2. The highest effective dose is received by the scrub nurse (3.2±1.3 µSv), followed by the radiopharmacy technician (1.6±0.5 µSv). The lowest dose was measured for the surgical nurse (0.2±0.5 µSv) and the nuclear medicine imaging technician (0.8±0.4 µSv). If a single scrub nurse would perform all procedures with [^{99m}Tc]Tc-PSMA-I&S in a year (100 procedures), the total effective dose would be 320 µSv/year.

Dose rate measurements

Immediately after administration, the dose rate at 50 cm was 18.5±1.6 µSv/h, which dropped to 1.8±0.3 µSv/h after imaging the following day and reducing even further to 0.56±0.33 µSv/h after surgery. All results for the dose rate measurements are shown in Table 3.

DISCUSSION

Radioguided surgery using [^{99m}Tc]Tc-PSMA-I&S is designed to aid in the intra-operative detection of PSMA positive lesions that contain prostate cancer metastases. The aim of this present analysis was to estimate and subsequently measure the occupational radiation dose of all personnel involved in the production, administration, imaging, and surgery with [^{99m}Tc]Tc-PSMA-I&S.

Differences between estimated and measured effective dose

The largest differences between the estimated and measured effective dose were seen for the radiopharmacy and nuclear medicine laboratory technicians on one hand, and for all surgical staff on the other hand. For radiopharmacy and nuclear medicine laboratory personnel the measured effective dose is higher than the estimated effective dose. This is most probably due to the conditions in which the production is done. In both cases, multiple radioactive sources (e.g. ^{68}Ga-generator, ^{18}F-labeled tracers, etc.) are in close proximity. These sources do contribute to the measured effective dose but are not taken into account when the effective dose from [^{99m}Tc]Tc-PSMA-I&S alone is estimated. For most surgical personnel, the measured dose is lower than the estimated dose. The largest contributor to this is the fact that biological excretion of [^{99m}Tc]Tc-PSMA-I&S is not taken into account. For [^{177}Lu]Lu-PSMA it is known that 56% is excreted within 24 hours (*11*) and it is expected that [^{99m}Tc]Tc-PSMA-I&S follows a similar excretion pattern (*12*). For the surgeon the measured dose was higher than the estimated dose. Since a robotic approach was used, the surgeon was estimated to be at a distance of 2 meters from the patient. In practice however, the surgeon was much closer to the patient during both the time-out-procedure prior to surgery and whilst making incisions, placing trocars, and installation of the robot.

Hand dose

In this study the hand dose (or extremity dose) was not taken into account, which would have been the highest for the radiopharmacy technician and nuclear medicine laboratory technician. This was not performed for two main reasons. Firstly, for the nuclear medicine laboratory technician the preparation of a patient syringe containing ^{99m}Tc is daily practice. The effect of ^{99m}Tc-syringe preparation has been well-studied worldwide and reported. In a study with 32 European centers, the mean hand dose for preparation of a ^{99m}Tc syringe was found to be 320 µSv/GBq (*13*). For a [^{99m}Tc]Tc-PSMA syringe with 550MBq this would lead to an extremity dose of 176 µSv. Secondly, hand (or finger) dosimeters that can be read out after each procedure are not available at our institute. The additional radiation dose of the prepared five syringes over several months with ^{99m}Tc is negligible compared to the total number of syringes that have been prepared with various isotopes during this period and could therefore not be determined from the monthly extremity dose reports.

Comparison with other ^{99m}Tc- and PSMA-procedures

Technetium-99m is the most common isotope in nuclear medicine procedures worldwide. Dose to personnel at nuclear medicine departments is therefore well-known. Although the preparation of [^{99m}Tc]Tc-PSMA-I&S is different from most ^{99m}Tc-radiopharmaceuticals (labeling instead of kit preparation), the dose to radiopharmacy and nuclear medicine laboratory personnel for preparation lies well within that of other ^{99m}Tc-radiopharmaceuticals (*13,14*).

For the surgical staff a comparison is made with a sentinel node biopsy procedure (common procedure with ^{99m}Tc but different pharmaceutical) and with [^{68}Ga]Ga-PSMA (other isotope but comparable peptide and distribution). For a sentinel lymph node biopsy procedure, the injected activity is much lower than that of [^{99m}Tc]Tc-PSMA, ranging from ~20-240 MBq depending on the time between injection and surgery. Furthermore, the activity is injected locally instead of intravenously. The dose to the surgeon in this procedure is reported to be 2-10 µSv (*15,16*). The values found for surgical staff during [^{99m}Tc]Tc-PSMA-I&S RGS fell well within this range. Another comparison can be made with [^{68}Ga]Ga-PSMA for Cerenkov luminescence imaging. In this case patient administration is always on the same day as surgery due to the shorter half-life of ^{68}Ga (68 minutes). Additionally, less activity is injected (~100 MBq) and the energy emitted by the isotope is much higher. In this case the scrub nurse standing next to the patient receives 16 µSv/procedure, while other staff members present obtain 1-5 µSv/procedure (*17*). In this study, all surgeries were performed with a robotic approach. Although no data was collected during an open- or laparoscopic approach, it is assumed that the dose of the surgeon would be comparable to that of the scrub nurse in this study. In summary, the radiation burden to surgical staff from [^{99m}Tc]Tc-PSMA-I&S is comparable to that of other surgical procedures with ^{99m}Tc, and lower than intraoperative Cerenkov luminescence imaging procedures with [^{68}Ga]Ga-PSMA.

CONCLUSION

[^{99m}Tc]Tc-PSMA-I&S has been introduced for identification of tumor-positive lymph nodes during salvage prostate cancer surgery. The effective dose for all involved personnel (radiopharmacy technician, nuclear medicine laboratory technician, nuclear medicine physician, nuclear medicine imaging technician, scrub nurse, surgical nurse, anesthesiology technician, and surgeon) is comparable to that of other ^{99m}Tc-radiopharmaceuticals. [^{99m}Tc]Tc-PSMA-I&S RGS can therefore be performed safely by all staff members.

FINANCIAL DISCLOSURES

The authors have nothing to disclose.

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TABLE 1: Estimated variables and effected dose for personnel during different steps of [^{99m}Tc]Tc-PSMA-I&S radioguided surgery procedure

Location	Procedure	Step	Personnel	A (MBq)	l (m)	t_s	t_s (h)	t (h)	d (mm)	Γ (µSv m^2 Mbq^{-1} h^{-1})	E (µSv)
Radiopharmacy	Labeling	Attaching [^{99m}Tc]pertechnetate	Technician RP	2000	0.3	10 s	0.003	0	3	0.023	1.50×10^{-3}
		Labeling	Technician RP	2000	2.0	30 min	0.500	0	55	0.023	3.72×10^{-55}
		Removal final product	Technician RP	2000	0.3	10 s	0.003	0	50	0.023	1.03×10^{-50}
	Quality control	iTLC	Technician RP	100	0.3	1 min	0.017	0	2	0.023	4.28×10^{-3}
		HPLC	Technician RP	100	2.0	30 min	0.500	0	0	0.023	2.88×10^{-1}
Nuclear Medicine	Syringe preparation	Calibration of vial	Technician NML	2000	0.4	10 s	0.003	0	50	0.023	5.81×10^{-51}
		Preparing syringes	Technician NML	2000	0.4	2 min	0.006	0	10	0.023	1.59×10^{-10}
	Patient administration	Patient administration	Physician NM	550	0.4	1 min	0.003	0	3	0.023	2.32×10^{-4}
		Care after administration	Physician NM	550	1.0	5 min	0.083	0	0	0.008	3.65×10^{-1}
	Imaging	Patient positioning	Technician NM	550	0.5	3 min	0.050	17	0	0.008	1.24×10^{-1}
		Patient imaging	Technician NM	550	3.0	30 min	0.500	17	2	0.008	3.39×10^{-4}
Operating room	Surgery	Surgery	Anesthesiology technician	550	0.5	120 min	2.000	20	0	0.008	3.51×10^{0}
			Scrub nurse	550	0.3	120 min	2.000	20	0	0.008	9.74×10^{0}
			Surgical nurse	550	2.0	120 min	2.000	20	0	0.008	2.19×10^{-1}
			Surgeon	550	2.0	120 min	2.000	20	0	0.008	2.19×10^{-1}

Abbreviations: RP = radiopharmacy, NM = nuclear medicine, A = Activity in megabecquerel, l (m) = distance in meters, t (h) = time between starting activity and step in hours, , t_s = time (duration) of this step, t_s (h) = t_s converted to hours, d (mm) = amount of lead shielding in millimeters, Γ = effective dose rate constant, and E (µSv) = effective dose.

TABLE 2: Estimated, measured, and mean effective dose for personnel during different steps of [^{99m}Tc]Tc-PSMA-I&S radioguided surgery procedure

Procedure	Personnel	E (μSv)						
		Estimated	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Mean±SD
Labeling	Technician RP	1.50×10^{-3}	2	2	1	2	1	1.6±0.5
Quality control	Technician RP	2.91×10^{-1}	1	0	0	0	0	0.2±0.4
Syringe preparation	Technician NML	1.59×10^{-10}	0	0	0	0	1	0.2±0.4
Patient administration	Physician NM	3.75×10^{-1}	1	1	1	0	1	0.8±0.4
Patient imaging	Technician NM	1.24×10^{-1}	0	0	0	0	0	0
Surgery	Anesthesiology technician	3.51×10^{0}	1	0	0	0	1	0.6±0.5
	Scrub nurse	9.74×10^{0}	2	5	4	3	2	3.2±1.3
	Surgical nurse	2.19×10^{-1}	0	0	0	1	0	0.2±0.4
	Surgeon	2.19×10^{-1}	1	1	1	1	1	1.0±0.0

Abbreviations: RP=radiopharmacy, NML=nuclear medicine laboratory, NM=nuclear medicine, E=effective dose, SD=standard deviation.

TABLE 3: Measured and mean dose rate of the patient during different steps of [^{99m}Tc]Tc-PSMA-I&S radioguided surgery procedure

		Dose rate (µSv/h)					
	Distance (cm)	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Mean ± SD
Administration	30	32.8	34.2	29.9	30.0	38.5	33.1 ± 3.5
	50	17.3	18.8	16.6	19.3	20.5	18.5 ± 1.6
	100	7.6	7.7	6.2	5.6	7.3	6.9 ± 0.9
Imaging	30	3.4	3.1	3.2	3.9	4.5	3.6 ± 0.6
	50	1.8	2.1	1.4	1.5	2.1	1.8 ± 0.3
	100	1.2	0.74	0.41	0.31	1.1	0.74 ± 0.39
Surgery	30	0.50	0.58	0.80	0.21	1.4	0.69 ± 0.43
	50	0.28	0.39	0.30	0.08	0.98	0.56 ± 0.33

GRAPHICAL ABSTRACT