

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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The aim of this study was to estimate and subsequently measure the occupational radiation exposure for all personnel involved in producing, administering, or performing 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. **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 technologist, syringe preparation by the nuclear medicine laboratory technologist, patient administration by the nuclear medicine physician, patient imaging by the nuclear medicine imaging technologist, and robot-assisted laparoscopic salvage lymph node dissection attended by an anesthesiology technologist, 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} μ Sv (imaging technologist) to 9.74 μ Sv (scrub nurse). The measured effective dose ranged from 0 to 5 μ Sv for all personnel during a single procedure with [^{99m}Tc]Tc-PSMA-I&S. The highest effective dose was received by the scrub nurse (3.2 ± 1.3 μ Sv), whereas the lowest dose was measured for the surgical nurse (0.2 ± 0.5 μ Sv). If a single scrub nurse were to perform as many as 100 procedures with [^{99m}Tc]Tc-PSMA-I&S in a year, the total effective dose would be 320 μ Sv/y. Immediately after administration, the dose rate at 50 cm from the patient was 18.5 ± 1.6 μ Sv/h, which dropped to 1.8 ± 0.3 μ Sv/h after imaging the following day, reducing even further to 0.56 ± 0.33 μ Sv/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.

Key Words: genitourinary; radiation safety; occupational radiation exposure; PSMA-I&S; radioguided surgery; technetium-99m

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Prostate cancer is the most common malignancy in men aged 50 y or older and is second only to lung cancer as the most frequent cause of cancer death among men (1). Local therapy, such as a radical prostatectomy and extended pelvic lymph node dissection, can be used to cure patients with intermediate- or high-risk (localized) prostate cancer (2). However, up to 25% of the prostate-draining pelvic lymph nodes are outside the standard extended pelvic lymph node dissection template and remain in vivo after extended pelvic lymph node dissection (3). Improvements in preoperative and intraoperative techniques for detection and removal of locoregional lymph node metastases may result in a shift toward increased cure rates in patients with prostate cancer.

Conventional preoperative lymph node imaging techniques, such as MRI and 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. Compared with conventional imaging, PSMA PET/CT has significantly improved the specificity and sensitivity of the detection of prostate cancer (5).

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

Imaging and RGS with [^{99m}Tc]Tc-PSMA-I&S involves personnel in different departments of the hospital: production

takes place at the radiopharmacy department, patient syringes are prepared by the nuclear medicine laboratory, patient administration and imaging take place at the outpatient nuclear medicine department, and RGS is performed in the operating room. 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 was to estimate and subsequently measure the occupational radiation exposure for all personnel involved in producing, administering, or performing imaging or surgery with [^{99m}Tc]Tc-PSMA-I&S.

MATERIALS AND METHODS

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

[^{99m}Tc]Tc-PSMA is produced using an automated module by 2 radiopharmacy technologists as previously described (8). In short, the steps involve placing a cassette on the automated labeling module without the presence of radioactivity, attaching a syringe containing 2,000 MBq [^{99m}Tc]pertechnetate and then immediately closing the lead shielding surrounding the labeling module, running an automated synthesis of [^{99m}Tc]Tc-PSMA without personnel present, opening the lead shielding, removing the final product in the shielding, and removing and disposing of the cassette.

Subsequently, in a laminar flow hood with lead glass, the final vial is calibrated in a dose calibrator, and then a quality control syringe and a patient syringe are prepared by a nuclear medicine laboratory technologist. Quality control is then performed by the radiopharmacy technologist with instant thin-layer chromatography and high-performance liquid chromatography as previously described (8). After approval by the pharmacist, the nuclear medicine physician administers 550 MBq of [^{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 technologist 16 h after intravenous injection of the [^{99m}Tc]Tc-PSMA-I&S. The SPECT/CT scan serves as a quality control scan for tracer injection and distribution. Afterward, a robot-assisted laparoscopic salvage lymph node dissection is performed using the da Vinci device (Intuitive Surgical Inc.). An intraoperative Drop-In probe prototype (Eurorad S.A.) is inserted through a trocar next to or through the port of the Alexis Laparoscopic System (Applied Medical Corp.) and is used to detect lymph node metastases with γ -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 technologist 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

Before the first prepared patient dose, the estimated effective dose was calculated for all the steps described in the workflow according to Equation 1. This estimation assumes a worst case in which there is no biologic elimination but physical decay only:

$$E = A \times e^{-\ln 2 \times \frac{t}{t_{1/2}}} \times \Gamma \times t_s \times \frac{1}{l^2} \times e^{-\ln 2 \times \frac{d}{d_{1/2}}}, \quad (\text{Eq. 1})$$

in which E is the effective dose (μSv), A is the activity (MBq) at the start, t is the time between the beginning of

the entire procedure and the individual step (h), $t_{1/2}$ is the half-life (h), Γ is the effective dose rate constant ($\mu\text{Sv m}^2 \text{MBq}^{-1} \text{h}^{-1}$), t_s is the duration of the step based on prior measurements and experience (h), l is the distance to the radioactive source (m), d is the lead thickness (mm), and $d_{1/2}$ is the half-value layer of lead (mm). For all steps, the $t_{1/2}$ of ^{99m}Tc is 6.01 h, and the $d_{1/2}$ of lead for ^{99m}Tc is 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 (DMC 2000 XB; MGP Instruments). The electronic personal dosimeters were worn at chest height by the following personnel: the radiopharmacy technologist during labeling and quality control of [^{99m}Tc]Tc-PSMA-I&S; the nuclear medicine laboratory technologist during syringe preparation; the nuclear medicine physician during administration to a patient; the nuclear medicine imaging technologist during patient positioning and imaging; and, during surgery, by the anesthesiology technologist, 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 were noted by the researchers. The minimum dose that can be reported by the electronic personal dosimeters is 1 μSv .

Dose Rate Measurements

Dose rate measurements (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 and were repeated after the SPECT/CT imaging. Immediately after surgery, while still in the operating room, dose rate measurements were performed at 30 and 50 cm. After administration and imaging, these measurements were done while the technologist was standing in front of the patient at the height of the liver, while the patient was upright. After surgery, these measurements were performed while the technologist was standing by the side of the patient, who lying down with the arms at the sides. The minimum measurable dose rate is 0.1 $\mu\text{Sv/h}$.

Data Analysis

Data were analyzed in SPSS Statistics (version 25; IBM) and are represented as mean \pm SD.

RESULTS

Patients

For the evaluation of personnel dose, the first 5 consecutive [^{99m}Tc]Tc-PSMA-I&S RGS procedures that were performed in the context of the prospective TRACE (^{99m}Tc-Based PSMA-Radioguided Assisted Surgery for Prostate Cancer) feasibility study (NL68290.031.18) were measured to audit the estimated effective dose. The 5 patients involved in these procedures had provided informed consent for the TRACE study. The labeling started with $2,123 \pm 854$ MBq, which resulted in $1,284 \pm 473$ MBq of the final product, and 567 ± 26 MBq were 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

TABLE 1
Estimated Variables and Effective Dose for Personnel During Different Steps of [^{99m}Tc]Tc-PSMA-I&S RGS Procedure

Location	Procedure	Step	Personnel	A (MBq)	l (m)	t _s (min/s)	h	t (h)	d (mm)	Γ (μSv m ² MBq ⁻¹ h ⁻¹)	E (μSv)
Radiopharmacy	Labeling	Attaching [^{99m} Tc] pertechnetate	Technologist RP	2,000	0.3	10 s	0.003	0	3	0.023	1.50 × 10 ⁻³
		Labeling	Technologist RP	2,000	2.0	30 min	0.500	0	55	0.023	3.72 × 10 ⁻⁵⁵
		Removal final product	Technologist RP	2,000	0.3	10 s	0.003	0	50	0.023	1.03 × 10 ⁻⁵⁰
	Quality control	Instant thin-layer chromatography	Technologist RP	100	0.3	1 min	0.017	0	2	0.023	4.28 × 10 ⁻³
		High-performance liquid chromatography	Technologist RP	100	2.0	30 min	0.500	0	0	0.023	2.88 × 10 ⁻¹
Nuclear medicine	Syringe preparation	Calibration of vial	Technologist NML	2,000	0.4	10 s	0.003	0	50	0.023	5.81 × 10 ⁻⁵¹
		Preparing syringes	Technologist NML	2,000	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	Technologist NM	550	0.5	3 min	0.050	17	0	0.008	1.24 × 10 ⁻¹
Operating room	Surgery	Patient imaging	Technologist NM	550	3.0	30 min	0.500	17	2	0.008	3.39 × 10 ⁻⁴
		Surgery	Anesthesiology technologist	550	0.5	120 min	2.000	20	0	0.008	3.51 × 10 ⁰
		Scrub nurse	Scrub nurse	550	0.3	120 min	2.000	20	0	0.008	9.74 × 10 ⁰
		Surgical nurse	Surgical nurse	550	2.0	120 min	2.000	20	0	0.008	2.19 × 10 ⁻¹
		Surgeon	Surgeon	550	2.0	120 min	2.000	20	0	0.008	2.19 × 10 ⁻¹

RP = radiopharmacy; NM = nuclear medicine.

for a single procedure with [^{99m}Tc]Tc-PSMA-I&S for the radiopharmacy technologist is 2.93 × 10⁻¹ μSv; the nuclear medicine laboratory technologist receives 1.59 × 10⁻¹⁰ μSv, the nuclear medicine physician receives 3.75 × 10⁻¹ μSv, the nuclear medicine imaging technologist receives 1.24 × 10⁻¹ μSv, the anesthesiology technologist receives 3.51 μSv, the scrub nurse receives 9.74 μSv, the surgical nurse receives 2.19 × 10⁻¹ μSv, and the surgeon receives 2.19 × 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 were to perform all procedures, well below the limit of 6 mSv/y for classified radiation worker category B as set by Dutch legislation (10).

Measured Effective Dose

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

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, 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

RGS using [^{99m}Tc]Tc-PSMA-I&S is designed to aid in the intraoperative 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 producing, administering, and performing imaging or 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 technologists on one hand and for all surgical staff on the other hand. For radiopharmacy and nuclear medicine laboratory personnel, the measured effective dose was higher than the estimated effective dose, probably because of the conditions under which the production is done. In both cases, multiple radioactive sources (e.g., ⁶⁸Ga-generator and ¹⁸F-labeled tracers) are near the workers. These sources do contribute to the measured effective dose but are not considered 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 difference is the fact that biologic excretion of [^{99m}Tc]Tc-PSMA-I&S is not

TABLE 2
Estimated, Measured, and Mean Effective Dose for Personnel During Different Steps of [^{99m}Tc]Tc-PSMA-I&S RGS Procedure

Step	Personnel	E (μSv)						
		Estimated	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Mean ± SD
Labeling	Technologist RP	1.50 × 10 ⁻³	2	2	1	2	1	1.6 ± 0.5
Quality control	Technologist RP	2.91 × 10 ⁻¹	1	0	0	0	0	0.2 ± 0.4
Syringe preparation	Technologist 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	Technologist NM	1.24 × 10 ⁻¹	0	0	0	0	0	0
Surgery	Anesthesiology technologist	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

RP = radiopharmacy; NML = nuclear medicine laboratory; NM = nuclear medicine.

considered. For [¹⁷⁷Lu]Lu-PSMA, it is known that 56% is excreted within 24 h (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. Because a robotic approach was used, the surgeon was estimated to be at a distance of 2 m from the patient. In practice, however, the surgeon was much closer to the patient both during the time-out procedure before surgery and while making incisions, placing trocars, and installing the robot.

Hand Dose

This study did not consider the hand dose (or extremity dose), which would have been the highest for the radiopharmacy technologist and nuclear medicine laboratory technologist. This dose was not considered for 2 main reasons. First, for the nuclear medicine laboratory technologist, preparing 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 550 MBq, this mean hand dose would lead to an extremity dose of 176 μSv. Second, hand

(or finger) dosimeters that can be read after each procedure are not available at our institute. The additional radiation dose of the prepared 5 syringes over several months with ^{99m}Tc is negligible compared with 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

^{99m}Tc is the most common isotope in nuclear medicine procedures worldwide. The radiation burden to personnel at nuclear medicine departments is therefore well known. Although the preparation of [^{99m}Tc]Tc-PSMA-I&S differs from that of 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 (a common procedure with ^{99m}Tc but a different pharmaceutical) and with [⁶⁸Ga]Ga-PSMA (another isotope but a comparable peptide and distribution). For a sentinel lymph node biopsy procedure, the injected activity is much lower than that of [^{99m}Tc]

TABLE 3
Measured and Mean Dose Rate of Patient During Different Steps of [^{99m}Tc]Tc-PSMA-I&S RGS Procedure

Step	Distance (cm)	Dose rate (μSv/h)					Mean ± SD
		Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	
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

Tc-PSMA, ranging from approximately 20 to 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 [$^{99\text{m}}\text{Tc}$]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 because of the shorter half-life of ^{68}Ga (68 min). 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, whereas other staff members present obtain 1–5 μSv /procedure (17). In this study, all surgeries were performed with a robotic approach. Although no data were collected during an open or laparoscopic approach, it is assumed that the dose to the surgeon would be comparable to that to the scrub nurse in this study. In summary, the radiation burden to surgical staff from [$^{99\text{m}}\text{Tc}$]Tc-PSMA-I&S is comparable to that from other surgical procedures with $^{99\text{m}}\text{Tc}$ and is lower than that from intraoperative Cerenkov luminescence imaging procedures with [^{68}Ga]Ga-PSMA.

CONCLUSION

[$^{99\text{m}}\text{Tc}$]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 technologist, nuclear medicine laboratory technologist, nuclear medicine physician, nuclear medicine imaging technologist, scrub nurse, surgical nurse, anesthesiology technologist, and surgeon) is comparable to that of other $^{99\text{m}}\text{Tc}$ -radiopharmaceuticals. [$^{99\text{m}}\text{Tc}$]Tc-PSMA-I&S RGS can therefore be performed safely by all staff members.

DISCLOSURE

No potential conflict of interest relevant to this article was reported.

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