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Assessment of radiation safety instructions to patients based on measured dose rates following prostate brachytherapy

Lawrence T. Dauer[1,*], Michael J. Zelefsky[2], Christopher Horan[1], Yoshiya Yamada[2], Jean St. Germain[1]

[1]*Department of Medical Physics, Memorial Sloan-Kettering Cancer Center, New York, NY*
[2]*Department of Radiation Oncology, Memorial Sloan-Kettering Cancer Center, New York, NY*

ABSTRACT

PURPOSE: To validate radiation safety instructions to patients and to evaluate the potential radiation doses to members of the public after ^{125}I or ^{103}Pd prostate implantation.

METHODS AND MATERIALS: Radiation dose rate measurements were made in the immediate postoperative period on 636 consecutive patients with stage T1-T2 prostate cancer who underwent transperineal ^{125}I or ^{103}Pd implantation at Memorial Sloan-Kettering Cancer Center during the period from August 1995 through January 2003.

RESULTS: The mean radiation dose rate at the anterior skin surface following a prostate implant was 37 μSv/hr for ^{125}I and 8 μSv/hr for ^{103}Pd. At 30 cm from the anterior skin surface, these dose rates were reduced to 6 μSv/hr for ^{125}I and 3 μSv/hr for ^{103}Pd. At 1 m from the anterior skin surface the dose rates from both types of implants were reduced to less than 1 μSv/hr. The effect of body weight on dose rates from ^{125}I sources was examined for a select sub-group of patients and the measured dose rate was found to decrease with increasing body weight. In another group of patients, dose rate measurements were made on both lateral skin surfaces and were less than 16.8 μSv/hr in all cases. Assuming a 33% occupancy factor and utilizing the mean measured dose rate for ^{125}I, the time required to reach an effective dose equivalent limit of 5 mSv for caregivers was estimated to be 19 days on contact with the skin surface. Using a similar calculation, the lifetime doses for ^{125}I at a distance of 30 cm from the anterior skin surface, as well as the lifetime doses for ^{103}Pd on contact with the skin surface and at 30 cm from the anterior skin surface can be shown to be less than 5 mSv.

CONCLUSIONS: The large number of cases available for this study permits a validation of radiation safety recommendations and provides concrete information from which the permitted exposure times following implantation can be estimated. The data support the conclusion that patients treated with these implants do not represent a radiation risk to members of the public.

Keywords: Prostate cancer; Brachytherapy; Radiation safety; Dose rate

Introduction

The use of ^{125}I for interstitial implantation was developed in the 1960s and various sites including the prostate were implanted with ^{125}I seeds in the 1970s (1). During this period, the release of patients from medical confinement relied on the so-called "30 mCi or 5 mR/hr" rule, a rule that resulted almost exclusively from the use of ^{131}I sodium iodide for radiopharmaceutical therapy (2). It seemed that this rule could not apply to ^{125}I implants and some alternative approach was needed. In 1970, the National Council on Radiation Protection and Measurements (NCRP) published report number 37 (3) which recommended that patients be released based on a measured exposure rate and an expected total dose to persons in the vicinity of the patient of less than 5 mSv to total decay.

In the 1980s, revised implantation techniques based on the use of ultrasound resulted in a renaissance for the use of ^{125}I seeds in prostate implantation (4, 5). Around the same

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* Corresponding author. Department of Medical Physics, Memorial Sloan-Kettering Cancer Center, Radiation Safety – Box 84, 1275 York Ave., New York, NY 10021. Tel.: +1-212-639-7391; fax: +1-212-717-3010.
E-mail address: dauerl@mskcc.org (L.T. Dauer).

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time, the use of ^{103}Pd seeds was also introduced as an alternate treatment modality. The popularity of seed implantation has continued to increase and this technique has specific appeal to many patients. Currently, more than 40,000 implantations for prostate cancer are performed annually in the US, and the number of permanent implants now exceeds the number of radical prostatectomies (6).

In the United States of America, the Nuclear Regulatory Commission (NRC) regulates the medical uses of radioactive byproduct material and specifies requirements for the release from facility control of patients with radioactive seed implants. Section 274 of the Atomic Energy Act of 1954, as amended, allows the NRC and a State to enter a regulatory agreement (7), whereby the State assumes regulatory authority for these materials. Therefore, requirements discussed in this article may be regulated directly by an "Agreement State" that must have a program for the control of radiation hazards that is compatible with the NRC's program. As such, we will therefore consider the NRC regulations as guiding regulations. According to NRC regulation a licensee may authorize the release from its control of any individual who has been administered implants containing byproduct material if the total effective dose equivalent (TEDE) to any other individual from exposure to the released individual is not likely to exceed 5 mSv and the TEDE to a member of the general public is not likely to exceed 1 mSv (3, 8). In addition, prostate brachytherapy patients are to be given instructions on actions recommended to maintain doses to other individuals as low as is reasonably achievable (ALARA), because the total activity of ^{125}I or ^{103}Pd is typically greater than 2 mCi or 8 mCi activity limits specified in a reference table (8). This requirement is consistent with the NRCP recommendations that all exposures be maintained ALARA (9).

The NRC does not require a specific set of patient instructions. Instead, instructions are left to the discretion of the institution. Release instructions to patients, therefore, have relied on a community consensus developed from literature and practice. They were generally based on limiting time in the vicinity of the patient and special concern with regard to children and pregnant women (10). Typical instructions have included: not holding children in the patient's lap and not sleeping in the "spoon" position (i.e., in close contact with anterior surface of the implanted patient) with a partner (11).

There is little peer-reviewed or corroborating data available regarding measured dose rates or the variability of dose rates among patients following prostate brachytherapy (12, 13). The purpose of this study was to utilize the large data set available at Memorial Sloan-Kettering Cancer Center to broaden our knowledge of exposure and risk, to validate the typical radiation safety instructions given to patients, and evaluate the variability of radiation dose rates to members of the public after ^{125}I or ^{103}Pd prostate implantation.

Methods and materials

Six hundred thirty-six consecutive patients with stage T1-T2 prostate cancer who underwent transperineal ^{125}I (557 cases) or ^{103}Pd (79 cases) implantation at Memorial Sloan-Kettering Cancer Center from August 1995 through January 2003 were studied. Implants were performed as previously described (4, 5).

Radiation dose rate measurements were obtained in the immediate postoperative period (i.e., within 1–2 h) at the surface of the anterior skin at the point of the symphysis pubis and at 100 cm perpendicular from the surface of the anterior skin. A subset of patients were measured at 30 cm perpendicular from the surface of the anterior skin (representing the "lap" area dose rate) and at the skin surface of the right and left lateral torso at the locations of the femoral heads. Dose rate measurements were obtained using a Keithley model 36100 x/γ radiation ionization chamber survey meter calibrated with ^{137}Cs. This unit has generally linear response through the ^{125}I and ^{103}Pd energy range. Calibration-corrected readings for ^{125}I and ^{103}Pd energies were utilized in this study. The radionuclide utilized, either ^{125}I or ^{103}Pd, the total activity (MBq) implanted, dose rate measurements (μSv/hr), and in 38 ^{125}I cases the preoperative weight (kg), were recorded and later evaluated retrospectively.

The lifetime exposure at various distances from the patient was calculated using the following equation (8):

$$D(\infty) = 34.6 T_P \dot{D}(0) E$$

where:

D(∞) = lifetime exposure in μSv;
T_P = physical half-life in days;
$\dot{D}(0)$ = dose rate at a given distance immediately following implantation,
at time t_0 (μSv/hr);
E = Occupancy factor based on the fraction of time a person could be in the vicinity of the implanted patient.

The total dose over a given time period (from time t_o to time t) is calculated using the following equation (8, 13):

$$D(t) = 34.6 T_P \dot{D}(0) E[1 - e^{-0.693 t/T_P}]$$

where D(t) = total dose over a given time period (t_o to t), where $t_0 = 0$.

The length of time to reach a given total dose was calculated by rearranging the prior equation and solving for t:

$$t = \left[\frac{-T_P \ln\left(1 - \dfrac{D(t)}{34.6 T_P \dot{D}(0) E}\right)}{0.693} \right]$$

Calculations were performed using a half life (T_P) of 60.14 days for ^{125}I and 16.96 days for ^{103}Pd. In addition, two sets of calculations were made using the mean dose measurements. In the first set of calculations the occupancy factor was assumed to be 1 (100%) representing the dose to a caregiver who is present for 100% of their time at the distance at which the dose rate was measured (i.e., on contact or at 30 cm from the anterior surface of the patient). In the second set

of calculations the occupancy factor was assumed to be 0.33 representing the dose to a caregiver that is present 1/3 of any day at the given distances. This second set of calculations was intended to represent the typical sleeping arrangement of a caregiver near the patient for 8 out of 24 h or as a conservative estimate for other members of the public in close proximity to the implanted patient.

Results

The ^{125}I and ^{103}Pd results are summarized in Tables 1 and 2. The mean radiation dose rate at the anterior skin surface following an ^{125}I implant was 37.3 μSv/hr (range, 0.9–221 μSv/hr). The mean radiation dose rate at 30 cm from the anterior skin surface, i.e., the lap area, following an ^{125}I implant was 6.0 μSv/hr (range, 0.9–33 μSv/hr). Figures 1 and 2 show the left-skewed variability in dose rate with 90% of the measured values ⩽70 μSv/hr for anterior skin surface and a similar percentage of the measured values ⩽15 μSv/hr for 30 cm.

In both cases, the dose rate was found to correlate directly with ^{125}I implanted activity. Figures 3 and 4 show these correlations.

The mean radiation dose rate at the anterior skin surface following a ^{103}Pd implant was 8.2 μSv/hr (range, 0.9–64 μSv/hr). The mean radiation dose rate at 30 cm from the anterior skin surface, i.e., the lap area, following a ^{103}Pd implant was 2.9 μSv/hr (range, 0.9–15 μSv/hr). Figure 5 shows a similarly left-skewed variability in dose rate similar to that seen with ^{125}I, with 90% of the values ⩽18.6 μSv/hr for dose rates at the anterior skin surface. As in the ^{125}I cases, the dose rate was found to correlate with ^{103}Pd implanted activity (Fig. 6).

All dose rates at 1 m from the anterior skin surface following either an ^{125}I or a ^{103}Pd implant were <1 μSv/hr and dose rates at the lateral skin surfaces were <16.8 μSv/hr. Additionally, for ^{125}I implants, Fig. 7 shows that activity normalized surface anterior dose rates (μSv/hr/GBq) generally decrease with increasing patient weight.

Tables 3 and 4 list the calculated lifetime doses and the time in days to reach the 5 mSv limit specified in the NRC regulations (2). Table 3 shows the results assuming 100% occupancy while Table 4 shows the results assuming 33% occupancy. For 100% occupancy, the lifetime doses from ^{125}I or ^{103}Pd on contact with the anterior skin surface were 77.6 mSv and 4.8 mSv, respectively. The 100% occupancy lifetime doses from ^{125}I or ^{103}Pd at 30 cm from the anterior skin surface were 12.5 mSv and 1.7 mSv, respectively. For 100% occupancy, the times required to reach the 5 mSv limit were 5.8 days and 44.4 days for ^{125}I at contact and 30 cm respectively, while the times required to reach the 1 mSv limit were 1.1 days and 7.3 days, respectively. Because the ^{103}Pd lifetime doses assuming 100% occupancy both at contact and at 30 cm were less than 5 mSv, calculated times to reach 5 mSv are not applicable.

Assuming 33% occupancy, the lifetime doses from ^{125}I or ^{103}Pd on contact with the anterior skin surface were 25.6 mSv and 1.6 mSv, respectively. Using a similar occupancy factor, lifetime doses from ^{125}I or ^{103}Pd at 30 cm from the anterior skin surface were 4.1 mSv and 0.6 mSv, respectively. Again using the same occupancy factor, the time required to reach the 5 mSv regulatory limit was 18.8 days on contact for ^{125}I, while the times required to reach the 1 mSv general public regulatory limit were 3.5 days for contact and 24.1 days for 30 cm. Using ^{103}Pd seeds and assuming 33% occupancy, the time required to reach the 1 mSv general public limit was 24.3 days at the anterior skin surface. Because the calculated lifetime doses using the 33% occupancy with ^{125}I at 30 cm and with ^{103}Pd both on contact and at 30 cm were all less than 5 mSv, calculated times required to reach 5 mSv were not applicable.

The cases discussed above will generally overestimate member of the public doses, as they are based on contact and 30 cm direct dose readings. Using a conservative dose rate of 1 μSv/hr at 1 m as well as a conservative occupancy of 33%, the lifetime doses to members of the public are estimated to be below 0.7 mSv and 0.2 mSv for ^{125}I and ^{103}Pd, respectively. Both of these values are below the 1 mSv general public limit.

Discussion

The study reported here is based a large set of direct dose measurements taken immediately following implantation.

Table 1
^{125}I results summary

Description	Sample size	Mean	Standard deviation (+/−)	Minimum	Maximum
Total activity (GBq)	557	1.50	0.38	0.48	2.67
Surface anterior dose rate (μSv/hr)	545	37.3	31.2	0.88	221
Activity normalized surface anterior dose rate (μSv/hr/GBq)	545	25.3	20.6	0.55	203
30 cm anterior lap dose rate (μSv/hr)	398	6.00	4.90	0.88	32.7
Surface lateral dose rate (μSv/hr)	87	1.92	2.22	0.88	16.8
Pre-operative weight (kg)	38	86.4	11.0	65.9	115

Table 2
^{103}Pd results summary

Description	Sample size	Mean	Standard deviation (+/−)	Minimum	Maximum
Total activity (MBq)	79	4.30	2.34	1.44	11.9
Surface anterior dose rate (μSv/hr)	72	8.19	11.1	0.88	63.6
Activity normalized surface anterior dose rate (μSv/hr/MBq)	72	1.87	1.93	0.12	8.15
30 cm anterior lap dose rate (μSv/hr)	17	2.91	3.57	0.88	15.0
Surface lateral dose rate (μSv/hr)	45	1.38	1.04	0.88	6.19

Such a data set facilitates the useful evaluation of the variability of patient dose rates (Figs. 1, 2, and 5), as well as providing a foundation for generic assumptions using mean values, representing typical patients. The mean dose rates following ^{125}I or ^{103}Pd permanent brachytherapy implantation are generally quite low. In all cases, dose rates were found to be less than the regulatory exposure dose rates at 1 m of 0.01 mSv/hr for ^{125}I or 0.03 mSv/hr for ^{103}Pd (3, 8) that permit patient discharge from the hospital.

There is a marked variability in dose rates measured from patient to patient (Figs. 1, 2, and 5). The wide range of reported dose measurements are due in large part to the variability in total activity implanted and the variability in depth of the prostate. Figure 7 shows that activity normalized surface anterior dose rates (μSv/hr/GBq) generally decrease as patient weight increases. These results are corroborated by the results of Smathers *et al.* (12), who reported that increasing patient weight generally increased the depth at which the prostate was located. Thus, with more overlying tissue as shielding, lower dose rates are expected, and are here generally observed, for heavier patients.

Although differing in methodology and numbers of data points, a few previous studies support the findings of our research. Smathers *et al.* measured dose rates from 38 ^{125}I or ^{103}Pd prostate brachytherapy patients and suggested that patients need not be concerned about being a radiation risk to the general public following their procedure (12). Michalski *et al* (13). measured patient exposures and members of patient family exposures from 44 patients receiving a permanent prostate brachytherapy implant (either with ^{125}I or ^{103}Pd) using optically stimulated dosimeters to measure dose. They concluded that the exposure to family members from those patients was well below the NRC limits (3, 8).

As performed in this present study, direct dose measurements from a large number of prostate brachytherapy implantation patients provides specific information for assessing the typical instructions to patients to keep members of the family and patient caregiver doses as low as reasonably achievable. Although exposure estimates based on measurements made in contact with patients and at 30 cm away will in general overestimate calculations of lifetime exposures to members of the public (13), the present study provides mean directly measured dose rates, calculated lifetime doses as well as the time in days required to reach the 1 mSv member of the public limit and the 5 mSv limit specified in the NRC regulations. These provide useful conservative estimates upon which evaluations of instructions to patients can be based.

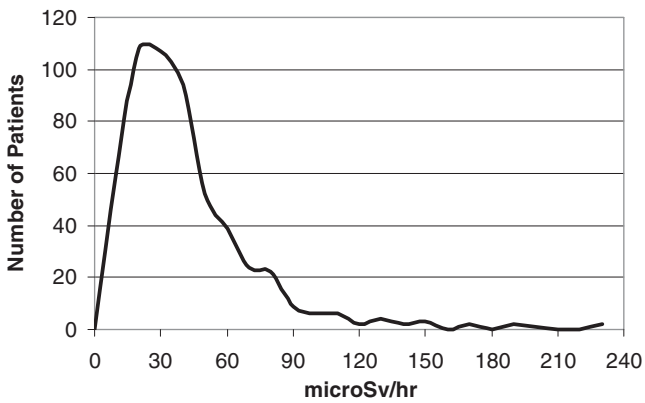

Fig. 1. Histogram of surface anterior dose rate for ^{125}I activity. N = 545, with 90% ⩽70 μSv/hr.

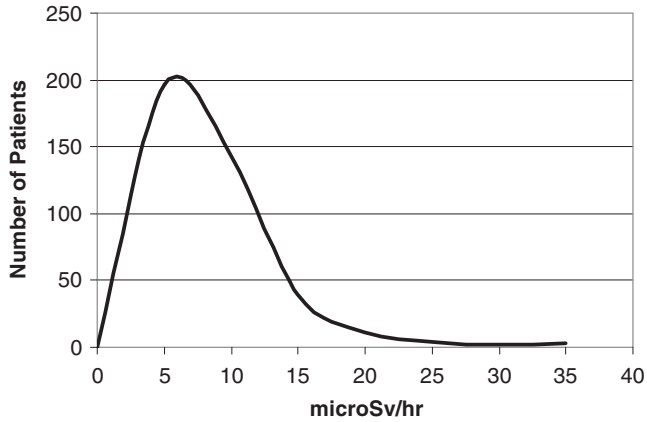

Fig. 2. Histogram of 30 cm anterior dose rate for ^{125}I activity. N = 398, with 90% ⩽15 μSv/hr.

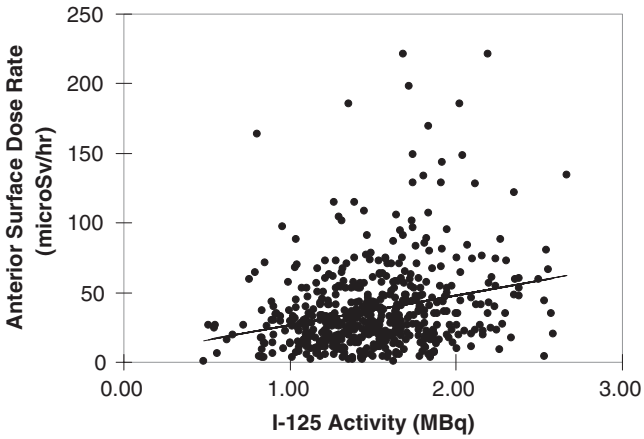

Fig. 3. Surface anterior dose rate correlates with ^{125}I activity. N = 545, Pearson's R = +0.26, $p < 0.005$.

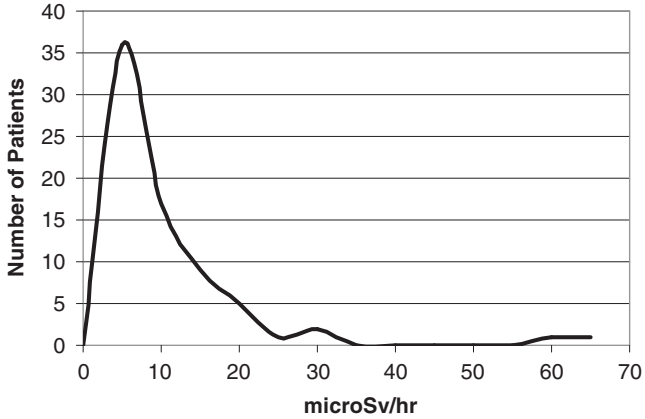

Fig. 5. Histogram of surface anterior dose rate for ^{103}Pd activity. N = 72, with 90% ≤18.6 μSv/hr.

Based on the present research, it will take ~19 days to reach the 5 mSv limit for caregivers (e.g., spouses, partners, etc.) in contact with patients that have received ^{125}I implantation, assuming a 33% occupancy or 8 h/d in close proximity to the patient (e.g., sleeping next to the patient). The lifetime dose, estimated at the 30 cm distance, is less than 5 mSv. This suggests that ^{125}I patients should be provided with instructions to increase distance when sleeping next to a caregiver, but that the distance need not be more than 30 cm (i.e., 1 ft). For ^{103}Pd, allowable exposure times are generally much longer (i.e., up to ~7 times longer) than for ^{125}I due to the lower energies and typically lower initial dose rates from ^{103}Pd. While the lifetime doses for ^{103}Pd at 30 cm are ~3 times less than those at contact, both are less than 5 mSv. Therefore, special instructions to increase distance or reduce time for close contact with caregivers is not a regulatory requirement for ^{103}Pd patients, but may be considered prudent to maintain doses ALARA. The results of this study also suggest that instructions to increase distance and reduce time for close contact (i.e., ~30 cm or nearer) with members of the public (e.g., children, pregnant women, family members, etc.) are appropriate.

There are inherent limitations in any retrospective study. This retrospective study was limited by the lack of specific measured prostate depth (and therefore a more rigorous evaluation of the thickness of overlying tissue) using computed tomography images. Such an approach may be undertaken for future prospective studies.

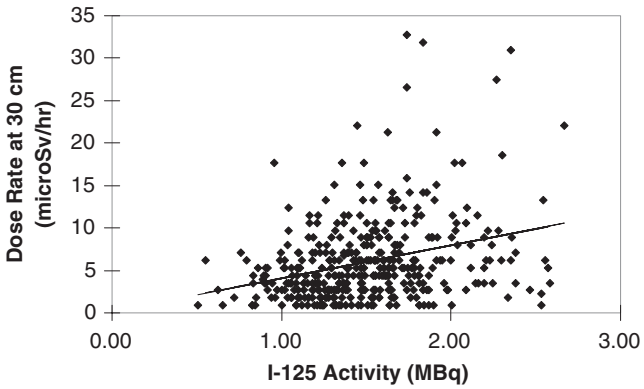

Fig. 4. 30 cm anterior dose rate correlates with ^{125}I activity. N = 398, Pearson's R = +0.31, $p < 0.005$.

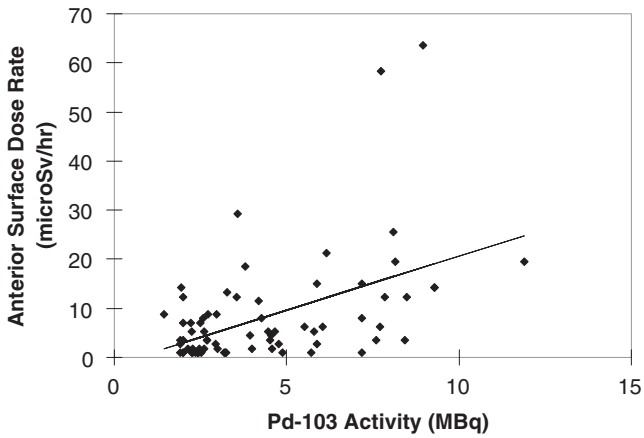

Fig. 6. Surface anterior dose rate correlates with ^{103}Pd activity. N = 72, Pearson's R = +0.48, $p < 0.005$.

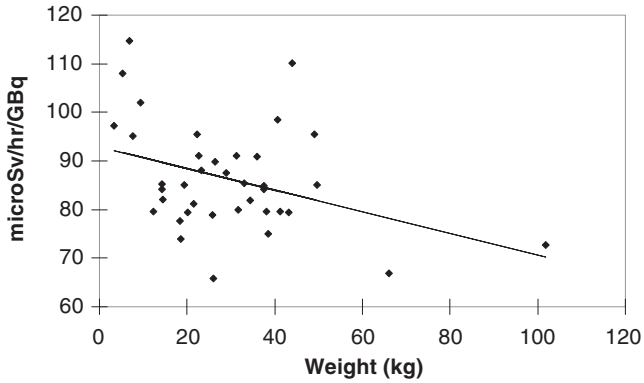

Fig. 7. Normalized surface anterior dose rate correlates with patient weight for ^{125}I. N = 38, Pearson's R = −0.38, $p < 0.02$.

Conclusion

The use of direct dose rate measurements, calculated times to meet regulatory limits, occupancy factor adjustments, and estimates of lifetime doses are appropriate for evaluating radiation exposure risks to patient caregivers and members of the public associated with prostate brachytherapy patients. When applied to a large patient data set, such as in this study, these methods provide information on dose variability as well as providing a foundation for generic assumptions and considerations of standard ALARA instructions using mean values.

This data set provides a basis for the validation of current radiation safety recommendations and provides clinicians with more concrete information regarding allowable exposure times for caregivers and members of the public after prostate implantation. Based on the results of this study, radiation safety ALARA instructions to patients following permanent prostate brachytherapy should include: avoiding close contact, i.e., within 30 cm, with others (including children and pregnant women) for extended periods of time; and avoiding sleeping in the "spoon" position (i.e., in contact) with the primary caregiver.

Table 3
Calculated lifetime doses and times required to reach 5 mSv assuming 100% occupancy (N/A = calculated times are not applicable because lifetime doses are less than 5 mSv)

	^{125}I	^{103}Pd
Contact with anterior skin surface		
Mean dose rate (μSv)	37.3	8.2
Lifetime dose (mSv)	77.6	4.8
Time to reach 5 mSv (days)	5.8	N/A
Time to reach 1 mSv (days)	1.1	5.7
30 cm from anterior skin surface		
Mean dose rate (μSv)	6	2.9
Lifetime dose (mSv)	12.5	1.7
Time to reach 5 mSv (days)	44.4	N/A
Time to reach 1 mSv (days)	7.3	21.7

Table 4
Calculated lifetime doses and times required to reach 5 mSv assuming 33% occupancy (N/A = calculated times are not applicable because lifetime doses are less than 5 mSv)

	^{125}I	^{103}Pd
Contact with anterior skin surface		
Mean dose rate (μSv)	37.3	8.2
Lifetime dose (mSv)	25.6	1.6
Time to reach 5 mSv (days)	18.8	N/A
Time to reach 1 mSv (days)	3.5	24.3
30 cm from anterior skin surface		
Mean dose rate (μSv)	6	2.9
Lifetime dose (mSv)	4.1	0.6
Time to reach 5 mSv (days)	N/A	N/A
Time to reach 1 mSv (days)	24.1	N/A

Patients treated with either isotope (^{125}I or ^{103}Pd) do not represent a radiation risk to members of the public (including children and pregnant women) if these radiation safety ALARA instructions are observed and moderately allowable exposure times are maintained.

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