Radiation Exposure From Outpatient Radioactive Iodine (^{131}I) Therapy for Thyroid Carcinoma

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Context In May 1997, the US Nuclear Regulatory Commission (NRC) revised its patient release regulations, allowing for outpatient administration of larger activities of sodium iodide ^{131}I than previously permitted.

Objective To measure the radiation exposure to household members from patients receiving outpatient ^{131}I therapy for thyroid carcinoma in accordance with the new regulations.

Design Consecutive case series from October 1998 to June 1999.

Setting and Patients Thirty patients who received outpatient ^{131}I therapy following thyroidectomy for differentiated thyroid carcinoma were enrolled, along with their 65 household members and 17 household pets.

Main Outcome Measure Radiation exposure to household members and 4 rooms in each home, as monitored with dosimeters for 10 days following ^{131}I administration.

Results The patients received ^{131}I doses ranging from 2.8 to 5.6 GBq (mean, 4.3 GBq). The radiation dose to 65 household members ranged from 0.01 mSv to 1.09 mSv (mean, 0.24 mSv). The dose to 17 household pets ranged from 0.02 mSv to 1.11 mSv (mean, 0.37 mSv). The mean dose to the 4 rooms ranged from 0.17 mSv (kitchen) to 0.58 mSv (bedroom).

Conclusion In our study, ^{131}I doses to household members of patients receiving outpatient ^{131}I therapy were well below the limit (5.0 mSv) mandated by current NRC regulations.

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In May 1997, the US Nuclear Regulatory Commission revised its patient release regulations.[1] Under the previous rule, patients receiving sodium iodide ^{131}I therapy could not be released from medical confinement until the exposure rate was less than 12.9×10^{-7}C/kg/h (5 mR/h) at a distance of 1 m from the patient or until the patient's radionuclide activity was less than 1.1 GBq. Accordingly, patients treated with large doses of ^{131}I for thyroid cancer typically were hospitalized under virtual isolation conditions for up to several days after treatment.

The new rule allows patients to be released from control by the licensee if the total effective dose equivalent (TEDE) to any other individual resulting from exposure to the treated individual is not likely to exceed 5.0 mSv. US Nuclear Regulatory Commission regulatory guide 8.39 describes 3 options for patient release after ^{131}I therapy in accordance with the new regulatory requirement[2]: release of patients based on administered activity (<1.2 GBq); release of patients based on measured dose rate ($<18.1 \times 10^{-7}$C/kg/h [7 mR/h] at 1 m); and release of patients based on a patient-specific calculation of the likely exposure to the maximally exposed individual (TEDE <5.0 mSv).

The first and second options represent default values and are conservative, chiefly because they assume that elimination of ^{131}I occurs only by physical decay. The objective of this study was to measure the radiation dose to household members from patients who received outpatient ^{131}I therapy for thyroid carcinoma with administered activities exceeding these default criteria, in accordance with these revised regulations.

METHODS

Thirty consecutive patients willing to participate in the study and all of their household members were entered in this study from October 1998 to June 1999. All patients signed a study-specific consent form approved by the Washington University Human Studies Committee. All patients previously had undergone a total thyroidectomy for papillary or mixed papillary-follicular thyroid cancer.

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The estimated TEDE to the maximally exposed person was calculated using the formula given in equation B-5 of regulatory guide 8.39.[2] The TEDE calculated by this method depends on several different variables, including the fractional uptake of ^{131}I in thyroid tissue, the effective half-lives of ^{131}I in thyroid and extrathyroidal tissues, and the occupancy factor (ie, the fraction of time the exposed person resides at a distance of 1 m from the patient). We also used the ^{131}I effective half-life values and the occupancy factors recommended in the guide.[2]

To estimate the fractional uptake of ^{131}I in thyroid tissue before therapeutic administration of ^{131}I, we performed a 48-hour total-body ^{131}I-retention study. Patients scheduled for their first postthyroidectomy ^{131}I treatment received 37 MBq of ^{131}I for the retention study. These patients subsequently underwent whole-body imaging 3 to 5 days after the therapeutic ^{131}I administration. Patients undergoing follow-up evaluation for possible ^{131}I treatment of residual or recurrent cancer received 185 MBq of ^{131}I to allow for both whole-body ^{131}I scintigraphy and the retention study. For the retention study, the patient's total-body counts were measured with a sodium iodide probe at a distance of 3.1 m from the xiphoid process. The measurements were obtained 15 minutes after ^{131}I administration and again at approximately 48 hours. The ratio of the 48-hour activity to the 15-minute activity, corrected for background and decay, was calculated. This fractional whole-body ^{131}I retention was conservatively assumed to represent the thyroidal fraction. This value was used in a patient-specific calculation to determine whether administration of the prescribed activity would permit release of the patient. If the calculated radiation dose to the maximally exposed person was less than 5.0 mSv, the patient qualified for outpatient treatment.

The patients, their household members, household pets, and 4 rooms in their homes (bedroom, bathroom, living room, and kitchen) were continuously monitored with optically stimulated luminescence dosimeters for the first 10 days after outpatient therapeutic ^{131}I administration.

Patients were instructed to sleep alone, drink fluids liberally, and avoid prolonged close personal contact with others for the first 2 days after ^{131}I administration. Patients and family members were told that they could resume normal activities thereafter. All participants were instructed to wear the dosimeters 24 h/d for the 10-day period.

RESULTS

The patient population consisted of 22 females and 8 males, ranging in age from 9 to 76 years old (mean, 42 years). Sixty-five household members participated in this study: 41 males and 24 females, ranging in age from younger than 1 year to 78 years old (mean, 28 years). Thirty household members were younger than 19 years (range, 1-18; mean, 9.4; median, 9.5 years). Doses also were monitored in 17 household pets.

The 48-hour whole-body ^{131}I retention ranged from 0.7% to 21.5% (mean, 8.4%). The patients were treated with 2.8 to 5.6 GBq of ^{131}I (mean, 4.3 GBq). The estimated TEDE to the maximally exposed person (spouse, parent) ranged from 1.63 to 4.83 mSv (mean, 3.12 mSv).

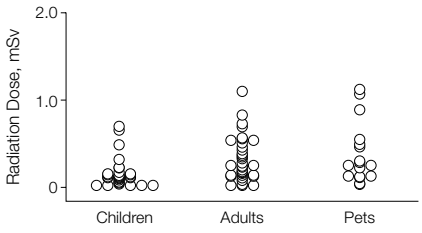
The measured radiation dose to all household members ranged from 0.01 mSv to 1.09 mSv (mean, 0.24 mSv) (FIGURE and TABLE). The dose to household pets was of similar magnitude, ranging from 0.02 to 1.11 mSv (mean, 0.37 mSv). The measured radiation in the patients' homes was greatest in their bedrooms (Table).

COMMENT

Radiation exposure to household members from patients treated with ^{131}I for thyroid carcinoma has been measured or estimated in earlier studies but under different circumstances than in our study.[3,4] Because of the previous regulatory restrictions, none of the prior studies performed in the United States directly measured household members' exposure during the first few days after outpatient administration of ^{131}I. Our study is unique because our patients received therapeutic quantities of sodium iodide and were immediately released.

One limitation of our study was that thyroid bioassays were not performed and internal doses to household members from ingested ^{131}I were not evaluated. However, other investigators have shown that internal doses resulting from contamination and intake of ^{131}I are likely to be much smaller than external exposure to radiation from patients.[5,6] The measured exposures in this study reflect the first 10 days after treatment. However, the 10-day cumulative exposure represents most of the theoretical dose; for the average thyroid uptake in this study, the 10-day cumulative exposure accounts for 84% of

Figure. Radiation Exposure



Measured radiation exposure to 30 children (younger than 19 years), 35 adults, and 17 pets living in the households of 30 patients treated as outpatients with 2.8 to 5.6 GBq of sodium iodide I 131 for thyroid carcinoma. The maximum radiation exposure to household members, mandated by new Nuclear Regulatory Commission regulations, is 5.0 mSv.

Table. Radiation Exposure in Household Rooms

Room	Radiation Dose, mSv		
	Range	Mean (SD)	Median
Bedroom	0.01-2.89	0.58 (0.66)	0.35
Bathroom	0.01-0.76	0.24 (0.22)	0.18
Kitchen	0.01-0.71	0.17 (0.15)	0.14
Living room	0.01-1.90	0.34 (0.39)	0.23

the exposure, to infinity. Another limitation of our study was the potential for noncompliance of family members: if they did not wear their dosimeters as instructed, the reported absorbed doses would be underestimates. One can assume that the doses recorded in the 4 living areas reflect 100% compliance and that household pets were 100% compliant. As expected, among the doses to the living areas, the bedroom doses were the greatest. The bedroom doses and the doses to the pets are of the same magnitude as the doses to the household members, and, therefore, we believe that recorded doses in household members are reasonably accurate. Finally, this is a small series; thus, it is possible that larger exposures than we observed might be encountered in some household members of patients treated with ^{131}I.

Our method of estimating the TEDE to the maximally exposed person is very conservative, because we assume that the total-body ^{131}I retention at 48 hours is the thyroidal component with a long half-life. This study demonstrates that patients can be administered outpatient ^{131}I therapy for thyroid carcinoma and that the resultant radiation exposure to household members is well below the limit mandated by the new US Nuclear Regulatory Commission regulations.[1] Advantages of outpatient ^{131}I therapy for thyroid carcinoma likely include reduced expense of treatment and less psychological strain on patients and their families.

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Investigators are commonly said to be engaged in a search for the truth. I think they themselves would usually state their aims less pretentiously. What the experimenter is really trying to do is to learn whether facts can be established which will be recognized as facts by others and which will support some theory that in imagination he has projected. But he must be ingenuously honest. He must face facts as they arise in the course of experimental procedure, whether they are favorable to his idea or not. In doing this he must be ready to surrender his theory at any time if the facts are adverse to it.

—Walter B. Cannon (1871-1945)