Original Article

갑상선암 환자의 방사선옥소 외래치료시 가족 구성원의 방사선량 측정

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Outpatient Radioablation Therapy for Thyroid Cancer Patients with Minimal Radiation Exposure to the Family Members

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Purpose: Postoperative thyroid remnant radioablation therapy is necessary to reduce the recurrence and mortality rates as well as to prepare the patients for a proper long term surveillance of well-differentiated thyroid cancers. The radiation safety rules of the government require the patient to be isolated in a hospital if the expected radiation exposure to the family members would be greater than 5 mSv (500 mRem). The purpose was to measure the radiation received by the family members of patients who received large doses of NaI-131. **Material and Methods:** We have administered 12 therapy doses ranging from 3.70-5.55 GBq (100 to 150 mCi) to 11 patients, and released them immediately if they met the radiation safety criteria. Informed consent was obtained from the subjects prior to the therapy, and each of them agreed to follow written radiation safety instructions. TLD badges were used to measure the radiation dose received by the family members and the room adjacent to the patient's bed room during the first 72 hours. **Results:** The average dose received by the family members who spent the most time in the closest distance with the patients was 0.04 mSv with a range of 0.01-0.17 mSv. Even the highest dose was only about 3% of the limit set by the government. The average radiation dose to the outer wall of the patient's room was 0.15 mSv. **Conclusion:** It is concluded that I-131 ablation therapy can be administered to outpatients safely to thyroid cancer patients who meet the established radiation safety criteria and follow the instructions. (Nucl Med Mol Imaging 2007;41(3):218-225)

Key Words: thyroid cancer, radioablation, radiation exposure, outpatient therapy

Introduction

Radioablation of postoperative thyroid remnant is increasingly being used to reduce the cancer recurrence and to prepare the patients for a long-term surveillance using radioiodine whole body imaging and also to make it possible to use the serum thyroglobulin level as a thyroid cancer marker.[1-5]

There is no evidence of any harmful effect of the low dose radiation received by the family members of patients treated with I-131 for thyroid cancer or hyperthyroidism.[6] There are, however, guidelines developed by each country to minimize the unnecessary radiation to be received by the people with whom the patients may come into contact shortly after radioablation therapy. The radiation safety rules of the government requires the patient to be isolated in a hospital if the expected radiation exposure to the family members would be greater than 5 mSv (500 mRem).[7] To put 5 mSv in context, it is about twice the natural background ionizing radiation average person receives in a year. To admit such patients, the hospitals are required to

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Table 1. Questionnaires for Occupancy Factor (O.F.).

1. Possibility of keeping a distance of 1 meter or more with another member of the family.
   a. The patient lives alone without any family member (O.F. = 0.125)
   b. Possible for 18 hours or more (O.F=0.25)
   c. Possible for 12 hours (O.F.=0.5)
   d. Not possible for 12 hours (O.F.>0.5)
2. Presence of children in the household.
   a. No children under the age of 13 (Record the highest O.F. from the question 1.)
   b. Children under age 13 present, but they will stay away from the house for 3 days (for 3.7 GBq) or for 4 days (for 5.55 GBq or higher). (Record the highest O.F. from the question 1.)
   c. Children under age 13 present, but unable to stay away from the household. (Record 2 times the highest O.F. from the question 1.)
3. Presence of a pregnant family member.
   a. Yes (Record 2 times the greatest O.F. recorded above.)
   b. No (Go to the question No. 4)

4a. Working with another person within 1 meter.
   a. Not working or can get a break for 5 days. (Record the highest O.F. from the question 1, and go to the question No. 5)
   b. Working less than 3 hours a day (O.F.= 0.125)
   c. Working 3 to 6 hours a day (O.F.=0.25)
   d. Working 6-12 hours a day (O.F.=0.5)
   e. Working more than 12 hours a day (Go to 4b)

4b. Ability to take 3 days off from work place.
   a. Yes (O.F.=0.5)
   b. No (Unable to be treated as outpatient)

5. Time it takes to go back home.
   a. Less than 6 hours by a car driven by other person. (O.F.: Record the highest of A.1 through A.3)
   b. More than 6 hrs by a car driven by other person and unable to keep a distance of 1 meter. (Unable to be treated as outpatient)

The highest O.F. from all questions above: O.F.=__________
or "Unable to be treated as outpatient" is checked. _______

Table 2. Questionnaires for Contamination Factor (C.F.)

1. Number of bathrooms at home:
   a. Only one and it is shared with other family members.
   b. More than one, and I can use one for myself.
2. Cooking for others at home:
   a. I have to prepare meals for my family.
   b. I can have someone else cook for my family.
3. Problem of incontinence.
   a. I have the problem of incontinence.
   b. No, I do not have the problem.

If 1a, 2a, or 3a is marked, find the maximum I-131 dose using the column marked "C.F. 2" on the table 3. Otherwise, use the column marked "C.F. 1".

have installed expensive stainless steel septic tank systems that can hold excreta of the patients sufficiently long time to allow decay of the I-131 before it can be discharged into a regular sewer system. Due to the shortage of such facilities, there are long lists of patients waiting to be treated.

We wanted to measure the radiation dose received by the family members who would spend most time with the patient, and see if it would be within the limit set by the Korea Institute of Nuclear Safety.[7]

Subjects and methods

A total of 11 patients who received ablation therapy between August, 1, 2004 and December, 31, 2005 are included in this study. There were 10 females and 1 male. One female patient received the therapy twice. The mean age was 54 years and ranged from 32 to 74 years. All had a near total thyroidectomy for papillary thyroid cancer. Each subject gave informed consent for I-131 ablation therapy after detailed discussions of the benefits and risks of the treatment and also of the risks of remaining untreated. The radiation safety instructions that they must follow for 7 days were explained.

The NaI-131 ablation therapy was given approximately 6 weeks after the surgery. Thyroxine therapy was withheld for 6 weeks until the I-131 therapy. The pretherapy TSH

Table 3. Maximum I-131 Dose (Gbq) that Can Be Administered to Thyroid Cancer Patient after Thyroidectomy as Outpatient : Based on the O.F. & C.F.

	OF=0.5		OF=0.25		OF=0.125	
% Uptake**	CF1	CF2	CF1	CF2	CF1	CF2
≥5.0%	4.59	4.07	6.62	5.55	8.51	NA*
~2.5%	5.47	4.73	7.47	6.14	9.18	NA*
~1.0%	6.18	5.25	8.10	6.59	9.62	NA*

OF=Occupancy Factor, CF 1=low probability of contamination.
CF 2=high probability of contamination.
*NA= not applicable. O.F. of 0.125 apply for patients who live alone. Therefore, restrictions on the dosage based upon potential contamination in the household do not apply.
**Remnant thyroid uptake. If not available, assume 5% when the remnant size is less than 1/5 of normal lobe[9].

Table 4. Radiation Safety Instruction for I-131 Ablation Therapy Patients

1. Drink a plenty of fluids and empty bladder frequently during the first 24 hours.
2. Flush the toilet 2 times after each use. Men should sit down for urination to reduce contamination of the bath room. Wash hands with soap and water. Use a separate towel.
3. Sleep alone for 7 days.
4. Avoid prolonged close personal contact with others for the first 2 days.
5. Keep 2 arms-lengths between yourself and the next family member when sitting in a living room.
6. Do not prepare food for other family members if possible.
7. Do not have a visitor who is pregnant or very young.
8. Avoid pregnancy for 6 months.
9. No breast-feeding is allowed.

Table 5. *I-131 Therapy Patient Data*

No	Sex	age	Histology	TSH	% Uptake	Rx dose (GBq)	O.F.*	C.F.**	Max.Permissible Dose (GBq)
1	F	73	Papillary ca	36.7	14	3.70	0.25	1	6.62
2	F	69	Papillary ca	150.0	2	3.70	0.5	1	4.59
3	F	32	Papillary ca	-	5	3.70	0.125	1	8.51
4	F	48	Papillary ca	61.0	6	3.70	0.25	1	6.62
5	M	63	Papillary ca	5.5	5	3.70	0.125	1	8.51
6	F	74	Papillary ca	150.0	5	5.55	0.25	1	6.62
7	F	36	Papillary ca	41.8	5	3.70	0.5	2	4.07
8	F	59	Papillary ca	115.0	5	3.70	0.125	2	8.51
9	F	46	Papillary ca	9.8	5	3.70	0.125	1	8.51
10	F	59	Papillary ca	74.0	5	3.70	0.25	1	6.62
11	F	54	Papillary ca	121.0	5	3.70	0.25	2	5.55
12	F	32	Papillary ca	150	5	3.70	0.25	1	8.51

* O.F.=Occupancy factor: The fraction of a day the exposed person resides at a distance of 1 m from the patient, e.g. 0.25=6 hours.
** C.F.=Contamination factor: 1 is low, 2 is high.

was above 30 uIU (range: 5.5 - 150.0 uIU) in most of the cases. Thyroid scan using 370 MBq of Tc-99m pertechnetate or 111 MBq of I-123 was obtained prior to the ablation therapy to confirm the presence of treatable thyroid remnant or metastasis. The patients were placed on a low iodine diet for 2 weeks prior to the therapy.

Each patient was interviewed by the first author to determine occupancy factor (O.F.) (Table 1), contamination factor (C.F.) (Table 2) and the maximum permissible I-131 dose that can be administered to the patient while keeping the exposure to the family members below 5 mSv. (Table 3)[8] The thyroid uptake fraction was measured with I-131 or I-123 when available. In patients who had only a Tc-99m pertechnetate scan postoperatively, and when the remnant size was estimated to be less than 1/5 of a normal lobe, the thyroid uptake fraction of 0.05 was used as suggested by the Appendix B of the U.S. NRC guide 8.39.[9] As required by the regulation, written radiation safety instructions (Table 4) were given to the patient.

The subjects' demographic data, histology of the cancer, TSH level immediately before the therapy, radioiodine uptake by the remnant, administered I-131 activity, occupancy factor, contamination factor and maximal

Table 6-1. Exposure to the Driver, Bedroom Wall and Spouse (mSv)

No	Travel Time (min)	Driver	Living Space (m^2)	Bedroom Wall (72hrs)	Spouse (72 hrs)
1	15	0.01	32.5	0.09	0.01
2	50	0.01	32.0	1.77*	0.01
3	50	Own car	70.0	0.44	None
4	90	0.16	100	0.29*	0.06
5	20	Own car	57.8	0.13	0.02
6	15	0.01	32.5	0.01	0.01
7	10	0.10	25.0	0.08	0.08
8	35	0.11	61.4	0.15	0.01
9	20	0.01	60.0	0.18	0.02
10	20	0.11	61.5	0.01	0.01
11	20	0.01	51.5	0.17	0.17
12	35	0.01	35.7	0.09	0.01
Average	31	0.05	51.6	0.28	0.04

*inner wall

Table 7-1. Changes in Exposure Rates after I-131 Administration: Patient, Patient Bedroom and Second Bedroom Walls (mR/hr)

No	patient (at 1 meter)		Pt bedroom wall (out side)		2nd bedroom wall (inside)	
	day0	day 3	day0	day 3	day0	day 3
1	9.50	1.8	1.80	0.10	0.17	0.03
2	17.60	4.0	1.30	0.200	0.17	0.06
3	11.15	2.7	-	-	-	-
4	15.76	-	-	-	-	-
5	16.89	2.5	1.93	0.04	0.04	0.02
6	28.00	0.5	4.50	0.03	0.30	0.02
7	22.70	1.0	0.15	0.30	0.15	0.03
8	24.00	1.2	0.95	0.05	0.03	0.02
9	14.30	2.2	0.07	0.02	0.03	0.02
10	11.50	0.7	0.30	0.10	0.02	0.02
11	13.60	1.0	2.20	0.05	0.10	0.01
12	19.80	1.8	1.40	0.10	1.40	0.05
average	17.06	1.76	1.46		0.24	0.03

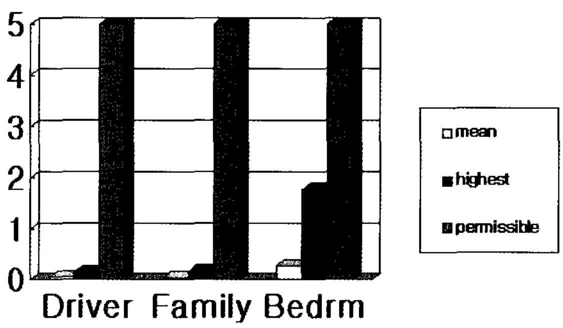

Fig. 1. Exposures to the driver, family member and bedroom wall in comparison to the permissible dose (5 mSv).

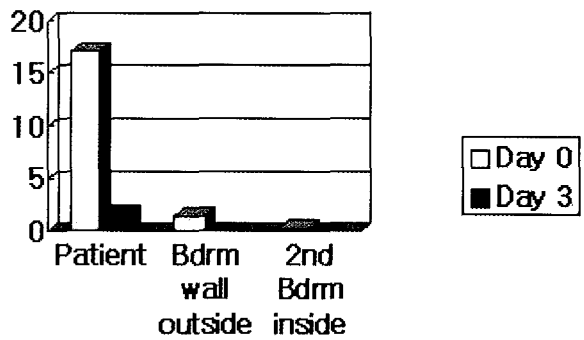

Fig. 2. Change in exposure rates (mean, mR/hr) after I-131 therapy: Patients, patient bedroom and 2nd bedroom walls.

permissible activity for each patient are as listed in the Table 5.

On the day of I-131 therapy, the patient was released immediately after the administration of an ablation dose of I-131 (3.70 - 5.55 GBq), and one of the authors (JWJ) accompanied the patient to his/her house. One thermoluminescent dosimeter (TLD) was attached to the driver of a car or an ambulance during the trip (travel time: 15 - 90 minutes) except for the two patients who drove their own cars. A second TLD was attached to the external surface of the patient's bedroom wall where the patient stayed longest time by himself or herself. In two patients, however, the TLD was attached to the inner wall instead. The patient was allowed to move in and out of the room at will. Size of the living area which included the bedroom, living room, kitchen and the bathroom where the patient may be present were measured. A third TLD was attached to the garment of the closest family member (spouse or parents), who was asked to wear it at all time while staying in the house. The TLD's were retrieved 72 hours after the therapy and were analyzed by a government approved dosimetry service. A survey meter (digital G-M counter) was used to measure the exposure rate from the patient as well as from several different points in the house while the patient was in his/her bed room. The exposure rates were measured on the day of treatment within an hour and 3 days after.

Results

The exposure data from the TLD's are listed in the Table 6-1, and their mean values compared with the permissible dose in Figure 1. The exposure to the driver ranged 0.01 to 0.16 mSv. The TLD on the external surface of the bedroom wall showed a dose range of 0.09 to 0.44 mSv. The two TLD's on the inner surface showed 0.29 and 1.77 mSv respectively. The lower dose was from the patient who had a much larger living space (100 m^2), and the higher one is from the patient had a smaller living space (32 m^2). The average of all the wall TLD readings including the two from the inner surface was 0.28 mSv. The doses to the closest family members averaged 0.04 with a range of 0.01 to 0.17 mSv. There was no direct correlation between the size of the living space and the exposure to the family members. None of the family members received a dose more than 10% of the dose limit of 5 mSv. The survey meter (digital G-M counter) readings are listed in the Table 7-1, and their mean values in the Figure 2. The external radiation dose of the patients immediately after the ingestion of I-131 therapy dose ranged from 9.5 to 28.0 mR/hr at 1 meter. At 72 hours the readings ranged from 0.5 to 4.0 mR/hr at 1 meter. The readings from the outer surface of the patient's bedrooms when the patient was in the room ranged from 0.07 to 4.5 mR/hr on the day of treatment and 0.02 to 0.3 mR/hr after 72 hours. The readings from the second bedroom where the patient's spouse stayed ranged from 0.02 to 0.3 mR/hr on the day of treatment and 0.01 to 0.06 mR/hr after 72 hours. The natural background radiation was 0.03 mR/hr.

Discussion

According to the current Korean government radiation safety regulation,[7] thyroid cancer patients must be isolated in a hospital after I-131 therapy if the administered dose is such that the potential total effective dose equivalent to any individual would be greater than 5 mSv (500 mR). In 1997, the U.S. Nuclear Regulatory Commission has relaxed its regulation and began to allow releasing of patients immediately after the therapy if the family members are not expected to receive more than 5 mSv.[9] In the U.S. NRC guidelines, there are two other lower criteria for the release of patients: 1) total activity administered is below 1.22 GBq (33 mCi), and 2) dose rate at 1 meter is below 0.07 mSv/hr (7 mR/hr). Release of patient who received more than 1.22 GBq is based on patient-specific calculation of the likely exposure to the person who will be with the patient in close proximity. The calculation requires information on the uptake fraction, effective half-life, and an occupancy factor. For postoperative thyroid cancer patients, the maximum thyroidal uptake fraction is assumed to be 0.05, and the effective half-life to be 7.3 days according to the same guideline. The O.F. is the fraction of a day (24 hours) the exposed person resides at a distance of 1 m from the patient. For instance, if a person will spend 6 hours at 1 meter from the patient during a day, the occupancy factor is 0.25. The C.F. tells the risks of cross contamination from sharing a bathroom with the patient, by the patient's handling of food and from urinary incontinence if present. C.F. 1 indicates a low probability of contamination and C.F. 2 a high probability. The maximal permissible dose is lower for patients with C.F. 2. Regarding the intake of individuals exposed to patients administered I-131, the intake is assumed to be in the order of one millionth of the activity administered to the patient. It is considered insignificant, and the U.S. NRC guide[9] did not include C.F. in the formula calculating the maximal permissible doses.

Table 1 and 2 list the questionnaires to determine the O.F. and C.F. respectively. These questionnaires are designed with the ALARA (As low as reasonably achievable) concept, so that the administered I-131 doses will be lower if there is a greater chance of exposure to other individuals. Table 3 shows the maximal permissible therapy doses calculated with patient-specific O.F., C.F. and uptake values. The maximum I-131 dose for any patient with particular combination of the above three factors can be found in this table. Patients with low O.F., C.F. and uptake can receive higher I-131 doses.

All of our subjects agreed to follow the radiation safety instructions (Table 4), and willingly kept a distance from other family members. Our findings of low radiation exposure to the family members (0.01 to 0.17 mSv) is far below the set limit by the Korean government, and are similar to the low level reported by Grigsby, et al[10] in the United States. They treated 30 outpatients with 2.77 - 5.55 GBq of I-131, and found their 65 household members received 0.01 mSv to 1.09 mSv (mean, 0.24 mSv), well within the 5 mSv limit. Venencia et al[11] in Argentine treated 14 patients with 1.11-8.17 GBq (30-221 mCi) of I-131. The accumulated doses to the exposed persons at 1 m from the patient were calculated to be less than 5 mSv when the therapy dose was less than 6.92 GBq. For the calculation, they assumed the worst case situation where a person stayed at 1 m from the patient for 24 hours a day (O.F. of 100%) continuously for 2.5 days.

The external radiation dose rate dropped rapidly during the first 72 hours after the therapy as shown by our data. On the 3rd day, it ranged from 0.5 to 4.0 mR/hr. At this rate it would take a family member to stay within 1 m from the patient for 8 hours a day for 15 days to receive 5 mSv. Thus, the first 72 hours is the important time period for the patients to follow the radiation safety instructions.

The living spaces in our patients ranged from 25m^2 to 100 m^2. We expected the larger the space, the lesser would be the exposure. There was, however, no direct correlation between the living space by itself and the dose received by the family members which was low in all cases. We found the TLD's from the family living space were exposed less in the households where family members were present than those who lived alone. It is because, the patients with family members in the household spent less time in the family room. The highest TLD reading of 1.77 mSv was from the inner wall of a patient whose bedroom size was 15 m^2. This indicates that if a family member stayed continuously for 72 hours near the wall inside the bedroom of the patient, he or she would have received less than 5 mSv. All of our subjects accepted the outpatient therapy well without any problem. They preferred staying in their own home to being alone for a few days in an isolation room in a hospital.

Several studies have shown that radioablation therapy can effectively be administered with the use of human recombinant TSH while keeping the patient on thyroxine therapy and avoiding hypothyroidism.[12,13] Radioiodine administered to euthyroid patients would be eliminated more rapidly from nonthyroidal tissues because there is no hypothyroid-induced renal impairment. This may contribute in further reduction of the radiation exposure to the family members.

One concern in outpatient I-131 therapy is for the very few with motion sickness. Radioiodine itself seldom causes nausea, but there is a remote possibility of vomiting during an automobile trip home in patients with motion sickness. Such patients can be observed for half an hour or so before discharging. A zippered plastic bag may be given to such a patient to contain the vomitus as a precaution. If vomiting happens after most of the radioiodine left the stomach, little I-131 would be present in the vomitus.

Nuclear Medicine specialist and the patient's endocrinologist seem to be the proper individuals to select patients suitable for outpatient radioablation therapy by assessing the patient's ability to follow the radiation safety instructions, the family situation and the possibility of contamination. The same individuals should determine the therapeutic doses of NaI-131, and when necessary, make a decision to admit the patient in isolation facility if it is in the best interest of the patient, the family and the public.

Problems associated with treating all thyroid cancer patients in isolation facility

1. Cost of construction of isolation facility: Isolation room requires shielded wall, separate ventilation system and specialized seamless floor. There is also a need for a CCTV to monitor the patient by the nurses. In addition, to comply with the government regulation for the disposal of excreta containing radioactivity,[14] the medical facility must install a dedicated septic tank system. The cost of which is approximately \200,000,000 per isolation room in 2006 Korean money. This regulation is for the hospital which admits patients who receive so much radioactivity that is expected to expose family members with more than 5 mSv.

2. Patient throughput: One isolation room can handle only one or two patients a week depending on the lengths of stay. Consequently, many thyroid cancer patients are on long waiting lists for the needed radioiodine ablation therapy.

3. Scheduling conflict and prolonged hypothyroidism: Patients must be prepared for the radioiodine therapy requiring 6 weeks off T4 and 2 weeks of low iodine diet. It takes well-coordinated scheduling to admit such patients. Unanticipated delay in scheduling can lead to unacceptably prolonged profound hypothyroidism in some patients.

4. Nurses' perception: Some of the nursing staff may consider wards with radiation-isolation facility less-than-desirable work place.

5. Room contamination: When the room is contaminated with I-131, it needs to be cleaned by an expert Radiation Safety Officer. Some of the hospitals may not have such an individual.

6. Payment by the National Health Insurance Corporation (NHIC): It is known that what NHIC pays the hospital for a patient in an isolation room is only 2 times of what it pays for other patient in a 6-patient room. Consequently, hospital administrators are reluctant to construct isolation rooms that would result in a negative cash flow.

For the reasons discussed above there is a shortage of isolation rooms and a long waiting-list of patients to be treated. Our study showed that outpatient I-131 therapy can be administered to the patients who can meet the patient-release criteria. These criteria can be easily met if they are willing to and can follow the simple radiation safety instructions. The exposure to the family members was very low and less than 3% of the 5 mSv limit set by the Korean government. Outpatient radioiodine therapy can provide the flexibility in treating patients at an optimum time of their choosing and without the morbidity of unintended prolonged hypothyroidism. The needed therapy can be delivered in timely and convenient fashion.

Current radiation "safety" regulations of many countries are based on the linear no-threshold (LNT) hypothesis and the ALARA (as little as reasonably achievable) concept. The LNT hypothesis relating effect and dose -which has been established for high doses and high dose rates- has been used as a scientific fact for the whole dose range.[15] There is, however, no scientific proof that low-dose level radiation is detrimental to human health. On the contrary, many epidemiologic and experimental data suggest that a low-dose radiation has hormesis (beneficial) effect. It is characterized by stimulation of oxidant and immune defenses, repair of DNA, and removal of DNA-damaged cells by apoptosis.[16] Less than expected risk of cancers are routinely found in epidemiological studies of populations exposed to radiation.[17] Therefore, the current stringent regulations established to prevent even the very low level of exposure may not benefit the population as a whole. It is hoped that regulatory authorities take these scientific data into consideration in further rule-making. Nuclear Medicine physicians and scientists can lead the public away from the unfounded emotional and psychological burdens and from misguided belief that all radiation, no matter how small, is detrimental to health.

Our study showed that postoperative thyroid cancer patients who received I-131 ablation therapy can be discharged immediately if they meet the discharge criteria. The radiation exposure to the family members was found to be low, well within and less than 5% of the limit set by the government. The outpatient I-131 therapy will benefit many patients with well-differentiated thyroid cancers by allowing timely postoperative ablation therapy, and by making further management easier. It, also, can save health care cost for the patients and for the government.

요 약

목적: 이 연구에서는 갑상선 암 수술 후 방사선요오드 -131 치료를 받은 환자가 방사선 안전 퇴원 기준에 따라 즉시 퇴원 했을 때 환자의 가족이 받는 방사선량을 측정하여 정부의 허용범위와 비교하고자 하였다. **대상 및 방법:** 의사가 설명한 방사선 안전지침을 이해하고 그대로 준수하기로 동의한 11명의 외래 환자에게 3.70 - 5.55 GBq의 NaI-131을 투여하고 가족과 환자가 생활하는 방 주변의 방사선량을 측정하였다. **결과:** 환자의 가족이 받은 최대 방사선량은 정부의 허용범위 보다 훨씬 적은(5% 이내) 것으로 나타났다. **결론:** 본 연구자들은 외래환자 I-131 치료가 안전하다는 것을 확인하였다. 따라서 외래환자 I-131 치료를 통해 격리 시설 부족으로 인한 치료지연을 줄일 수 있고, 앞으로 갑상선 암 환자 치료 관리에 도움을 줄 수 있을 것으로 확신한다. 또한 환자와 정부의 의료비용 절감 효과도 기대된다.

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