Original Article

Residual Radioactivity in Patients with Well-Differentiated Thyroid Cancer Receiving High Dose I-131 Therapy

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Objective: To study residual radioactivity in WDTC patients after receiving high dose I-131 therapy and proportion of patients with residual radioactivity regarding discharged recommendation at different time points. Factors that may correlate to residual radioactivity were also evaluated.

Materials and Methods: Prospective cohort study in 170 thyroid cancer patients treated with I-131 3.7 to 7.4 GBq (100 to 200 mCi). Data were obtained from medical records, interview, and residual radioactivity measured at 24, 48, and 72 hours after receiving I-131. Difference of factors and between subject groups with residual radioactivity within and that exceed the discharge criteria (30 mCi) were evaluated. A p-value less than 0.05 was considered statistically significant.

Results: The median residual radioactivity at 24, 48, and 72 hours were 26.63 mCi (range 10.97 to 117.87), 7.89 mCi (range 1.27 to 76.27), and 3.27 mCi (range 0.25 to 55.47), respectively. Proportions of patients with residual radioactivity regarding discharge recommendation were 59.40%, 92.40%, and, 95.70% at 24, 48, and 72 hours, respectively. Factors correlated with residual radioactivity were age (p<0.001), serum creatinine level (p=0.042), dose received (p=0.005), and 24-hour I-131% uptake (p=0.015), while gender, BMI, fluid intake, and frequency of radiation excretion via urine and stool had no such significant effect.

Conclusion: A very high proportion of patients had residual radioactivity that met the discharge recommendation level at 48 hours after I-131 therapy. This time point may be adjusted for discharge planning. Elderly patients, higher administered dose of I-131, those with high creatinine level, or high 24-hour I-131% uptake should be advised of the risk of residual radioactivity to the public.

Keywords: Residual radioactivity, Well differentiated thyroid cancer, I-131 therapy, Patient discharge

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Well differentiated thyroid cancer (WDTC) is the most common type of thyroid cancer. Following thyroidectomy, I-131 is indicated in most of thyroid cancer patients to destroy residual normal and malignant thyroid tissue(1). Nevertheless, treatment with I-131 has a risk of external radiation exposure to other people because I-131 is a radioactive substance that generates both beta and gamma radiations with a physical half-life of 8.04 days.

According to the International Commission on Radiological Protection (ICRP) 60 and ICRP 103 recommendations, patients treated with more than 1,100 MBq (30 mCi) of I-131 need hospitalization until the radiation exposure decrease to the level causing the radiation dose to other person does not exceed 1 mSv/year(2,3). In Thailand, the guideline of patient release from hospital is referred to the Activity-base recommended by the International Atomic Energy Agency (IAEA BSS-115)(4). In this guideline, the residual radioactivity of I-131 must not exceed 1,100 MBq (30 mCi) for thyroid cancer patients prior to being discharged from the hospital. Several factors could cause high residual I-131 activity and they are assumed to be independent from the activity administered and patient subsets on the basis of age, gender, and body built(5). High residual radioactivity in the patient may expose the public. It could also cause delayed or stochastic effect, which can demonstrate many years or decades after, altering risk for genetic effects or cancer(2). Thus, reduction of

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residual radioactivity in these patients will benefit the public in terms of radiation safety. Moreover, patients with very low residual radioactivity may not need strict instruction for radiation safety together with shorter hospitalized period and possibly have better attitude towards this treatment.

The present study was aimed to evaluate residual radioactivity in WDTC patients after receiving high dose I-131 therapy at 24, 48, and 72 hours, and proportion of patients with residual radioactivity regarding discharge recommendation. Factors that may correlate to residual radioactivity were also evaluated.

Materials and Methods

The present study was ethically approved by the Siriraj Institute Review Board (SIRB), and all patients signed their consent forms after information of the study were given. Prospective cohort study was done in 170 adult well-differentiated thyroid cancer patients, treated with I-131 3.7 to 7.4 GBq (100 to 200 mCi) at Siriraj Hospital between November 2013 and February 2014. Exclusion criteria were patients with contra-indications for I-131 therapy (pregnancy or breast feeding) and did not volunteer to participate in the study. Data were obtained from medical records, patients' interview, diagnostic total body scans (TBS), and radiation exposure measured from patients by calculating the residual radioactivity at each period after receiving high dose of I-131.

Measurement of radiation exposure

The radiation exposure was measured by ionization chamber (IC) survey meter at one-meter distance from the patient after receiving high dose of I-131. The measurements at 24, 48, and 72 hours were performed by the same probe for each patient. The IC survey meter (ICS-311, ALOKA, Japan) was calibrated annually at the Secondary Standard Dosimetry Laboratory (SSDL) of the Office of Atoms for Peace, Thailand.

Residual radioactivity

The activities that the patients released were calculated based on the National Council on Radiation Protection and Measurements (NCRP) Report No.37[6]. The following equation was used to calculate the exposure until time (t) at a distance (r) from the patient:

$$D(t) = \frac{34.6\Gamma Q_0 T_p\,(1-e^{-0.693/T_p})}{r^2} \qquad \text{(Equation 1)}$$

Where D(t)=accumulated exposure at time t, in roentgens; 34.6=conversion factor of 24 hours/day times the total integration of decay (1.44); Γ=specific gamma ray constant for a point source, R/mCi-h at 1 cm; Q_0=initial activity of the point source in millicuries, at the time of the release; T_p=physical half-life in days; r=distance from the point source to the point of interest in centimeters; t=exposure time in days.

Equation 1 is derived from radioactive decay equation as follows:

$$A = A_0 e^{-\lambda t} \qquad \text{(Equation 2)}$$

Where A=activity at time t; A_0=initial activity; $\lambda=0.693/T_p$.

$$\int_t^{t+\Delta t} A\,dt = \int_t^{t+\Delta t} A_0 e^{-\lambda t}\,dt$$
$$\int_t^{t+\Delta t} A\,dt = 1.44 A_0 T_p\,[e^{-\lambda(t+\Delta t)} - e^{-\lambda t}] \qquad \text{(Equation 3)}$$

In the present study, the authors applied basic equation to calculate as follows:

$$Dt_1 = \frac{34.6\Gamma Q_0 T_p\,(1-e^{-0.693t_1/T_p})}{r^2} \qquad \text{(Equation 4)}$$

$$Dt_2 = \frac{34.6\Gamma Q_0 T_p\,(1-e^{-0.693t_2/T_p})}{r^2} \qquad \text{(Equation 5)}$$

Substitute $Q_0\,(1-e^{-0.693t_1/T_p})$ by At_1 and $Q_0\,(1-e^{-0.693t_2/T_p})$ by At_2

Then Equation 4 was divided by Equation 5

$$\frac{Dt_1}{Dt_2} = \frac{At_1}{At_2} \qquad \text{(Equation 6)}$$
$$At_2 = \frac{Dt_2}{Dt_1} \times At_1$$

Score uptake of pre-treatment total body scan (Pre-Rx TBS)

Visual rating intensity of pre-Rx TBS images in patients who had previous I-131 therapy was done in consensus by two investigators (Wongngamrungroj A and Thientunyakit T) accounted by eight frequently positive I-131 uptake areas including salivary glands, neck, stomach, intestine, urinary bladder, lung, bone, and others (if any). The score uptake of each area was defined as follow: 0=no uptake, 1=mild, 2=moderate, and 3=intense uptake (Figure 1). The sum of scores from all areas was recorded as 'total score' and used for statistical analysis.

From pre-treatment I-131TBS image (Figure 1), score uptake at salivary gland=3, neck=1, stomach=3, intestine=2, urinary bladder=2, lung=0, bone=0, and other (mediastinum)=1, so the total score uptake in this case was 12.

Pre-Rx TBS count statistics

The regions of interest (ROIs) were drawn on

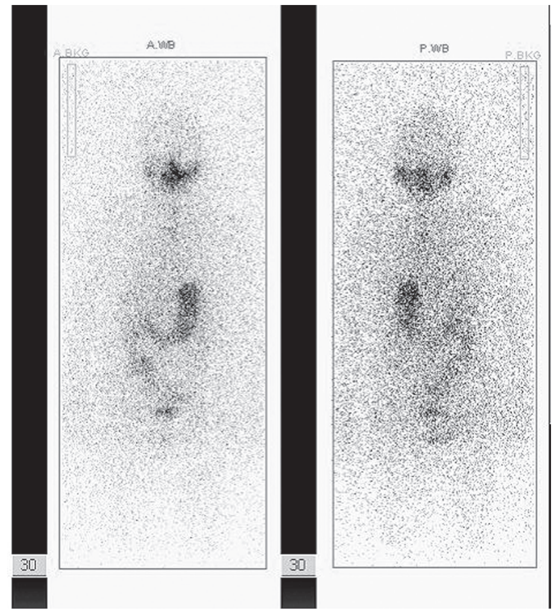


Figure 1. Example of diagnostic whole body scan prior to the 2nd I-131 treatment in a 68 year-old female patient with papillary thyroid cancer. The total score uptake was summation of scores regarding intensity of radioiodine uptake from different regions including salivary gland, neck, stomach, intestine, urinary bladder, lung, bone, and other (in this particular case at mediastinum) observed in both anterior whole body (A.WB) and posterior whole body (P.WB) images.

TBS image and background in both anterior and posterior views to determine the total counts/pixels of the activity. The background pixels were converted to normalize with total body pixels. Then, background counts were subtracted from total body counts in both anterior and posterior views to get the actual counts for calculation using the geometric mean formula (Figure 2):

$$\text{Geometric Mean} = \sqrt[n]{x_1 \cdot x_2} \qquad \text{(Equation 7)}$$

Where x_1=radioactivity counts in anterior view, x_2=radioactivity counts in posterior view, n=number of counts.

From Figure 2, the geometric mean counts of pre-treatment TBS were calculated as the followings:

Anterior view

Total body=138,537 counts at 128,368 pixels

Background=236 counts at 1,100 pixels

Convert pixels of background is 128,368 pixels =128,368×236/1,100 counts

Thus, background=27,541 counts at 128,368 pixels

Background counts were subtracted from total body counts=138,537–27,541 = 110,996 counts at 128,368 pixels

Posterior view

Total body=119,976 counts at 128,368 pixels

Background=203 counts at 1,100 pixels

Convert pixels of background is 157,974 pixels =128,368×203/1,100 counts

Thus, background=23,690 counts at 128,368 pixels

Background counts were subtracted from total body counts=119,976–23,690 = 96,286 counts at 128,368 pixels

Calculated geometric mean from Equation 7

$$\text{Geometric Mean} = \sqrt[2]{110,996 \times 96,286}$$

Thus, geometric Mean of pre-Rx TBS=103,380 counts at 128,368 pixels

Statistical analysis

Results were presented as number and percentage for data group; mean and standard deviation for continuous data with normal distribution; or median, minimum and maximum for continuous data with non-normal distribution. Difference of factors and between subject groups with residual radioactivity within and exceed the discharge criteria (30 mCi) were evaluated using Chi-square test, Fisher's exact test, Independent t-test or Mann-Whitney U test depended on type of factors. A p-value less than 0.05 was considered statistically significant.

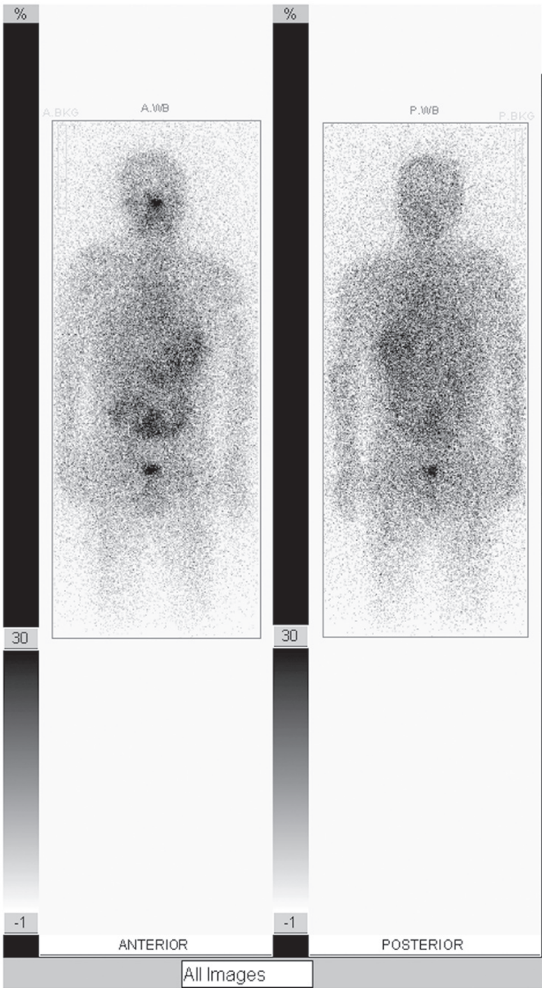
Results

Residual radioactivity in patients with well-differentiated thyroid cancer

Residual radioactivity from 170 patients with well-differentiated thyroid cancer at 24, 48, and 72 hours after receiving high dose I-131 measured by IC survey meter are shown in Table 1. Thirty-one patients were discharged at 48 hours because they were unable to stay during long holiday. However, the median residual radioactivity of these 31 patients were 8.51mCi (range 2.10 to 56.06) using IC. Twenty-eight of these 31 patients (90.32%) had residual radioactivity below 30 mCi on the date of discharge.

Subgroup analysis of residual radioactivity in patient by the number of I-131 therapy (first dose and multiple-dose) is shown in Table 2. The present study revealed that the multiple-dose I-131 subgroup had lower residual radioactivity than the first-dose I-131 subgroup at every time points. Significant difference of residual radioactivity between the two subgroups at 72 hours was found.

The proportions of patients with residual radioactivity less than 30 mCi, according to discharge



TOTALBODY SCAN I-131 [Series ROI And Curve] 04-Jul-13 - Image1

Frame Name	Statistic	Frame	A.WB	A.BKG
ANTERIOR	Avg	0.53	1.08	0.21
	Max	17.00	17.00	2.00
	Med	0.00	1.00	0.00
	Min	0.00	0.00	0.00
	Pix	262144	128368	1100
	Std	1.13	1.42	0.46
	Tot	138537.00	138537.00	236.00
	Var	1.27	2.01	0.21

TOTALBODY SCAN I-131 [Series ROI And Curve] 04-Jul-13 - Image1

Frame Name	Statistic	Frame	P.WB	P.BKG
POSTERIOR	Avg	0.46	0.93	0.18
	Max	13.00	13.00	3.00
	Med	0.00	1.00	0.00
	Min	0.00	0.00	0.00
	Pix	262144	128368	1100
	Std	0.97	1.22	0.42
	Tot	119976.00	119976.00	203.00
	Var	0.95	1.49	0.18

Figure 2. Example of diagnostic whole body scan prior to the 3rd I-131 treatment in a 69 year-old female patient. The score uptake from previous diagnostic total body scan was 3 points and count statistics of scanned images was calculated using regions of interest drawn on anterior whole body (A.WB) and posterior whole body (P.WB) images as well as anterior background (A.BKG) and posterior background (P.BKG) to calculate geometric mean count statistics.

Table 1. Residual radioactivity in all patients after receiving high dose I-131 at 24, 48, and 72 hours in μSv and mCi

Times (hour)	Exposure (μSv)				Radioactivity (mCi)			
	n	Median	Minimum	Maximum	n	Median	Minimum	Maximum
24	170	58.00	22.00	170.00	170	26.63	10.97	117.87
48	170	16.00	2.50	110.00	170	7.89	1.27	76.27
72	139	6.50	0.50	80.00	139	3.27	0.25	55.47

recommendation, after receiving high dose I-131 therapy in all patients and each subgroup are shown in Table 3. In the 170 patients, 92.40% of all patients and 96.30% of patients who received multiple-dose I-131 had residual radioactivity below the discharged recommendation level at 48 hours. Almost 86% of patients received first-dose I-131 had residual radioactivity of less than 30 mCi at 48 hours, and then this number increased to 94.40% at 72 hours. There were no significant differences of the proportion of residual radioactivity among all patients, first-dose I-131 subgroup and multiple-dose I-131 subgroup.

Table 2. Residual radioactivity in each subgroup of patients at 24, 48, and 72 hours after receiving I-131 therapy

Times (hour)	First-dose I-131				Multiple-dose I-131				p-value	Adjusted p-value
	n	Median	Minimum	Maximum	n	Median	Minimum	Maximum		
24	88	26.64	12.44	99.45	82	27.61	10.97	117.87	0.913	1.000
48	88	8.65	2.74	56.06	82	6.75	1.27	76.27	0.026	0.078
72	72	3.72	0.92	43.48	67	2.42	0.25	55.47	0.001	0.003

Table 3. Proportion of patients with residual radioactivity less than 30 mCi at 24, 48, and 72 hours

Time (hour)	All patients		First-dose I-131 subgroup		Multiple-dose I-131 subgroup		p-value
	n	Percentage	n	Percentage	n	Percentage	
24	101/170	59.40	55/88	62.50	46/82	56.10	0.396
48	157/170	92.40	78/88	88.60	79/82	96.30	0.059
72	133/139	95.70	68/72	94.40	65/67	97.00	0.682

Table 4. Comparison of factors between subject groups with residual radioactivity within (less than or equal to 30 mCi) and exceed the discharge criteria (more than 30 mCi)

Variables	Residual radioactivity				p-value*
	n	≤30 mCi	n	>30 mCi	
Sex, %					0.373
Male	29	90.60	3	9.40	
Female	132	95.70	6	4.30	
Dose group (I-131), %					0.170
First-dose	81	92.00	7	8.00	
Multiple-dose	80	97.60	2	2.40	
Age (year), Mean (SD)	161	48.06 (15.56)	9	70.22 (9.55)	<0.001
BMI (kg/m^2), Mean (SD)	161	14.21 (4.41)	8	24.84 (5.94)	0.699
Creatinine (mg/dl), Mean (SD)	161	1.03 (0.28)	9	1.23 (0.40)	0.042
Dose received (mCi), Mean (SD)	161	150.43 (27.87)	9	177.67 (28.34)	0.005
Fluid intake (ml), Median (min-max)	161	6,000 (1,850 to 18,000)	9	5,000 (3,000 to 21,000)	0.409
Urine (time), Median (min-max)	161	31 (13 to 81)	9	30 (21 to 55)	0.933
Stool (time), Median (min-max)	161	4 (0 to 26)	9	5 (3 to 12)	0.185
24-hour % uptakea, Median (min-max)	81	1.91 (0.36 to 10.23)	7	3.65 (2.25 to 9.51)	0.015
Total body scanb, Median (min-max)					
Score uptake	59	7.00 (2 to 12)	1	11.00 (11.00 to 11.00)	N/A
Normalize pre-Rx TBS (counts/pixels)	59	0.18 (0.01 to 4.09)	1	1.57 (-)	N/A

SD=standard deviation; BMI=body mass index; Pre-Rx TBS=pre-treatment total body scan; N/A=not available

[a] First-dose I-131, [b] Multiple-dose I-131

* Values were evaluated using Chi-square test, Fisher's exact test, independent t-test, or Mann-Whitney U test, p-value <0.05 was considered statistically significant

Factors affecting the residual radioactivity in patients with well-differentiated thyroid cancer

The data of various factors in 170 patients were available for analyses except for one patient who could not stand-up, so her body mass index (BMI) data was not included (Table 4). One hundred sixt-one of 170 patients had residual radioactivity of less than 30 mCi on discharge date. Significant difference between two subgroups of patients were found in age, serum creatinine level, and current I-131 dose received. Gender, BMI, dose group of I-131, fluid intake, and frequency of radiation excretion from the body via urine and stool had no significant effect on residual radioactivity. Eighty-eight patients received first-dose of I-131 and underwent pretreatment 24-hour % uptake measurement to estimate postoperative thyroid remnant. Eighty-one of these patients had residual radioactivity of less than 30 mCi and significant difference in 24-hour % uptake result between two subgroups were found.

In eighty-two patients who received multiple-dose of I-131, sixty of them completed a diagnostic TBS prior to treatment while twenty-two patients were admitted due to their high serum Tg level without the need for TBS. Of these patients with diagnostic TBS result, 59 of 60 had residual radioactivity less than 30 mCi. Although both parameters from TBS results in patients who had residual radioactivity higher than 30 mCi tend to be higher than those who had residual radioactivity below 30 mCi, the correlation of these parameters and residual radioactivity could not be analyzed due to too small number (n = 1) of patient subgroup with residual radioactivity higher than 30 mCi.

Discussion

The residual radioactivity at 24, 48, and 72 hours decrease over time after I-131 administration, as a result of effective half-life of I-131 in human body, which decreases more rapidly at the initial period. This result is similar to the study by Ravichandran et al[7], which found the variation of body burden with time post administration indicated tri-exponential clearance pattern in patients with post-operative thyroid carcinoma. Considering number of I-131 treatment, the authors found that patients who received multiple-dose of I-131 had lower residual radioactivity as compared to those who received first-dose of I-131 at every time point. Overall proportion of patients with residual radioactivity less than 30 mCi at 48 hours was very high (92.40%), particularly in those who received multiple-dose I-131 (96.30%). A study by the European Commission reported that 80% of the administered I-131 should be eliminated within 48 hours[8], which is similar to the present study results. Therefore, we may consider shortening the time to release patients from the hospital in patient who receive multiple-dose I-131 from three to two days to reduce the hospitalization cost. However, since this proportion in the patients who received first-dose I-131 was slightly reduced (88.60%), these patients may still need to be discharged at 72 hours or until the residual radioactivity meets discharge criteria level. Nevertheless, the differences of density of population and social cultures among countries should also be taken into account before reducing the duration of hospitalization. For example, in large family especially with pregnant or pediatric members, prolonged hospitalization until 72 hours may still be appropriated. On the other hand, patients who can well separate from others can be released at 48 hours when residual radioactivity is below discharge criteria, to reduce both treatment cost and stress from hospitalization.

Apart from timing for discharge, several authors proposed to reduce criteria of residual radioactivity, for example, Pacilio et al[5] used residual activity of 0.6 GBq (16 mCi) as the release criterion for the patients. Interestingly, despite using strict criteria to release patients based on residual activity, they found that hospitalization time of two days reasonable for patients with I-131 administration up to 3.70 GBq (100 mCi). For patients with 5.55 to 9.25 GBq (150 to 250 mCi) I-131 administration, six to seven days of hospitalization may be required. Another study by Ahmadi Jeshvaghane et al(9) recommended that a release activity limit of 500 MBq (14 mCi) at one meter should be used instead of 1,100 MBq (30 mCi) due to the different lifestyle, socio-economic condition, and cultures. In Thailand, the discharge limit of 30 mCi is still used as recommended by the IAEA BSS although this limit is relatively high as compared to 250 to 800 MBq (7 to 22 mCi) in other recommendations[9]. It should be noted that with this recommended residual activity, the cumulative doses for partners and children in the family could exceed the annual dose limit for the public (1 mSv). Therefore, until the new discharge criteria with lower limit is accepted, behavioral pattern of patients after discharge from the hospital must be clearly emphasized for radiation safety to public, especially avoiding contact with children and pregnant women.

The authors found significant difference of age ($p<0.001$), serum creatinine level ($p=0.042$), dose received ($p=0.005$), and 24-hour I-131% uptake ($p=0.015$) in those with residual radioactivity within and exceed the discharge criteria. Elderly patients showed higher residual radioactivity, which may be explained by their relatively low metabolic rate. Patients with high serum creatinine level that reflect impaired renal function are also expected to have poor radioiodine excretion. Tsuchimochi et al[10] found significant difference in the external exposure dose before and after urination and suggested significant effect of urinary excretion on residual radioactivity. The present study did not directly measure the urinary radioactivity or urinary volume due to the risk of unnecessary radiation exposure to personnel.

However, indirect measurement using number of urination found no significant correlation between frequency of urination and residual radioactivity (p=0.933), so the need for more frequent urination is still questionable. Among patients who received first radioiodine treatment, higher 24-hour I-131% uptake, which indicated larger postoperative thyroid remnant, was correlated with higher residual radioactivity. It is quite interesting that the present study results found no significant correlation between the amount of fluid intake during admission and residual radioactivity, which eliminate the necessity to advise patients to drink a lot of water after I-131 administration aimed for stimulating urinary excretion of radioiodine. However, since the fluid intake by studied patients was relatively large (approximately 1,600 to 2,000 ml/ day with the minimum of 600 ml/day), it might not make significant difference among patients.

Conclusion

Following high-dose I-131 therapy, there was a very high proportion of patients whose residual radioactivity met the discharge recommendation level at 48 hours, particularly in those who received multiple-dose. Thus, these patients may be discharged at 48 hours, while those who receive first-dose I-131 should still be discharged at 72 hours. Rigorous instruction concerning radiation safety is important for patients with high possibility to have residual radioactivity over discharge limit, including old age, renal impairment, high administered dose of I-131, and high 24-hour I-131% uptake, to lower the residual radioactivity both during hospitalization and after discharge.

What is already known on this topic?

WDTC patients treated with I-131 dose higher than 30 mCi need hospitalization until the radiation exposure decrease to the level causing the radiation dose to other person does not exceed 1 mSv/year. The range of admission period for high dose I-131 therapy are from 48 to 168 hours. The residual radioactivity decreases over time after I-131 administration. In addition, several factors could cause high residual I-131 activity and assumed to be independent from the activity administered and patient subsets on the basis of age, gender, and body built.

What this study adds?

Concerning both radiation safety and attitude of patients toward long admission in separated room for I-131 treatment in WDTC patients, proper time point of discharge and factors that may correlate to residual radioactivity should be considered. Since there was a very high proportion of patients whose residual radioactivity met the discharge recommendation level at 48 hours after I-131 therapy, we may confidentially adjust the period of admission to reduce hospitalization cost and proper utilization of the admission room as well as shortening the waiting queue for other patients. The presenters also identify special patients at risk of higher residual activity and should be strictly instructed for lowering residual radioactivity. The results of correlation between the residual radioactivity and some of the present studied factors have not been reported elsewhere.

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Conflicts of interest

The authors declare no conflict of interest.

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