Cure Rate of Dosimetry-based ¹³¹I Therapy in Hyperthyroidism Management

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What is already known on this topic?

Radioiodine has been increasingly used in hyperthyroidism treatment using an empirical regimen composed of 1 dose that fits all patients. However, this regimen is easy to apply but blind to where the patients' variability is not considered, leading to excessive or inadequate activity administration; therefore, an additional dose may be required for successive therapy.

What this study adds on this topic?

 This study highlights the cure rate of dosimetry-oriented radioiodine therapy, taking into account patients' specific iodine biokinetics for tailoring the therapeutic activity, as it ensures feasible cure from a single dose with no excessive radiation exposure.

Abstract

Background: This study aims to evaluate the effectiveness and cure rate of individualized radioiodine therapy in patients diagnosed with Graves' disease and toxic adenoma.

Methods: A total of 11 patients with toxic adenoma and 20 patients with Graves' disease were enrolled in the study. Radioiodine activities were individually calculated using patient-specific data and a mathematical model to deliver target absorbed doses of 300 Gy for toxic adenoma and 200 Gy for Graves' disease. The mean administered radioactive iodine (RAI) activity was 826 ± 124 MBq for patients with toxic adenoma and 541 ± 215 MBq for those with Graves' disease.

Results: At the 3-month follow-up, 35% of patients with Graves' disease and 54.6% of those with toxic adenoma reached a euthyroid state. Hypothyroidism occurred in 65% of Graves' patients and 45.4% of toxic adenoma patients; all began thyroid hormone replacement therapy and achieved euthyroid status by the 6-month follow-up.

Conclusion: Dosimetry-based RAI therapy achieved complete remission within 3 months following a single administration of ¹³¹I, with no patients requiring a second course of RAI therapy. In contrast to empirical treatment protocols, individualized therapy enhances safety, minimizes risk, and improves clinical outcomes.

Keywords: Dosimetry, Graves' disease, hyperthyroidism treatment, radioiodine therapy, toxic adenoma

Introduction

The thyroid gland contributes to the regulation of the body's metabolic rate by producing the hormones triiodothyronine (T3) and thyroxine (T4). A decreased production of serum T3 and T4 hormones is called hypothyroidism, with the most common causes being Hashimoto's thyroiditis or iodine deficiency.¹ Conversely, excessive production of thyroid hormones is referred to as hyperthyroidism, with the primary causes being Graves' disease, toxic adenoma, and toxic multinodular goiter. While the clinician determines the appropriate treatment for hyperthyroidism, therapeutic options include antithyroid drugs, surgery, or radioactive iodine (131 I, RAI) therapy.²

Nowadays, RAI therapy is widely used in hyperthyroid patients.³ The therapeutic activity can be administered using 2 primary approaches: the fixed-dose method and personalized dosimetry-based treatment. The fixed-dose approach is widely used due to its simplicity, cost-effectiveness, and reliance on clinical judgment. It commonly targets the induction of hypothyroidism to enhance treatment efficacy and minimize recurrence risk, with subsequent L-thyroxine replacement therapy used to restore a euthyroid state. However, determining the appropriate and needed RAI dose depends on multiple factors, including thyroid gland volume, iodine uptake rate, iodine contamination, and the severity of hyperthyroidism. Studies indicate that approximately 22% of patients may require more than 1 RAI administration to achieve successful treatment outcomes.⁴

In the management of hyperthyroidism with radioiodine therapy, a personalized approach guided by pre-treatment dosimetry enables the prediction of a curative ¹³¹I activity to be administered in a single dose. However, the clinical superiority of dosimetry-based treatment compared to fixed-dose protocols remains a subject of ongoing debate.⁵ One controversial issue regarding dosimetry is the

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concern that low doses of ¹³¹I may cause a "stunning effect" that diminishes the effectiveness of the treatment. Additional challenges associated with dosimetry-guided treatment include the requirement for multiple clinic visits to complete uptake measurements and the increased cost of the procedure. Despite these limitations, dosimetry-based therapy offers significant advantages in terms of radiation safety. Furthermore, current clinical guidelines support and recommend its use in radioiodine treatment planning.⁶

To determine the appropriate RAI activity for personalized treatment of hyperthyroid patients, the methods established by the Medical Internal Radiation Dosimetry (MIRD) Committee are commonly used.⁷ This model considers the biokinetics of RAI within the body and the radiation dose delivered to adjacent tissues and organs. These factors are essential for optimizing treatment efficacy while minimizing unnecessary radiation exposure.

This study aims to evaluate the effectiveness of personalized radioiodine therapy guided by dosimetric calculations in patients with Graves' disease and toxic adenoma. Individualized dosimetry was conducted to determine a safe and therapeutically effective ¹³¹l activity for each patient.

Materials and Methods

This study was conducted at the Radionuclide Therapy Unit of the Nuclear Medicine Department, Cerrahpaşa Medical Faculty. A group of patients was randomly selected from individuals presenting to the clinic for hyperthyroidism treatment. All procedures conducted in this study were carried out in strict accordance with the ethical principles outlined in the 1964 Declaration of Helsinki and its later revisions or equivalent ethical standards. The study protocol was approved by the Institutional Clinical Research Ethics Committee of Cerrahpaşa Faculty of Medicine. (document no: 19451483/604-01-02-52947, approval date; 20.02.2015), and written informed consent was obtained from all participants.

Inclusion and Exclusion Criteria

The accepted normal levels of free T3 (fT3), free T4 (fT4), and TSH (Thyroid-stimulating hormone) serum were 2.0-4.4 pg/mL, 0.93-1.7 ng/dL, and 0.27-4.2 μ IU/mL, respectively. The eligible patients should show elevated serum fT3 and fT4 levels and low TSH levels before treatment. Patients with a history of thyroid surgery, a follow-up duration of less than 6 months, or those who were lost to follow-up in the treatment failure group before completing 12 months were excluded from the study.

Uptake Measurement and Dosimetry

Dosimetry was performed using the MIRD method, based on serial radioiodine uptake measurements. Thyroid uptake was assessed under the clinic's standard protocol. Patients received an oral administration of 0.5-1 MBq of ¹³¹I, and uptake measurements were recorded at 2, 24, 48, 72, and 96 hours post-administration. In addition, the volumes of the thyroid gland and nodules were determined using thyroid ultrasonography. Dosimetric calculations were performed according to MIRD Pamphlet No. 11, utilizing Equation 1.8

$$A(MBq) = 5.829 \frac{D_{T}.m}{Umax.Teff}$$
 (1)

Where, A (MBq): The amount of administered 131 I activity, D_T (Gy): The absorbed dose, m: Thyroid mass (g), U_{max}: Maximum uptake, T_{off}: Effective half-life (days).

As part of the study protocol, the target absorbed radiation dose was set at approximately 200 Gy for patients with Graves' disease and 300 Gy for those with toxic adenoma.

Patient Discharge and Post-Treatment Follow-Up

Following the regulations of the Nuclear Regulatory Authority, patients receiving ¹³¹I treatment activity of less than 600 MBq (16.2 mCi) were managed on an outpatient basis, following the provision of both written and verbal radiation safety instructions. However, hospitalization in the radionuclide therapy unit was required for patients receiving ≥600 MBq (16.2 mCi) of ¹³¹I. Discharge was permitted once the radiation dose rate, measured at a distance of 1 m from the abdominal region using an ion chamber detector (Ludlum, model 9DP), dropped below 30 μSv/h.

In this study, patients underwent follow-up evaluations 3 months after receiving radioiodine therapy, during which serum levels of TSH, free T3, and free T4 were assessed. Those who developed biochemical or clinical signs of hypothyroidism were initiated on thyroid hormone replacement therapy. A second follow-up was performed at 6 months post-therapy, with continued monitoring advised at 6-month intervals thereafter.

Statistical Analysis

Statistical analyses were conducted using SPSS software (version 26.0; IBM Corp., Armonk, NY, USA), with a significance level set at P < .05. Data normality was assessed using the Kolmogorov–Smirnov test. Based on the distribution, the non-parametric Mann–Whitney U test was employed to evaluate statistically significant differences in thyroid function test results before and after treatment.

Results

A total of 31 eligible patients were enrolled in the study, including 20 diagnosed with Graves' disease (12 females, 8 males) and 11 with toxic adenoma (7 females, 4 males). The mean age of the participant patients was 58 ± 21 years. All patients had elevated serum fT3 and fT4 levels and low TSH levels before treatment, as shown in Tables 1 and 2. None of the patients had a history of surgical intervention for hyperthyroidism. Among those diagnosed with Graves' disease, 2 patients (10%) presented with ophthalmopathy. Prior to radioiodine therapy, 13 patients (41.9%) were initiated on antithyroid medication with methimazole. After the administration of radioiodine, the methimazole dosage was reduced, and the treatment was continued for an additional 3 months. Dosimetry was performed to deliver a minimum dose of 200 Gy to the Graves' disease group and a minimum dose of 300 Gy to the toxic adenoma group in hyperthyroid patients. The basic parameters for estimating the therapeutic ¹³¹I activity were summarized in (Table 3). Based on the dosimetric calculations, 541 ± 215 MBg of ¹³¹I was administered to patients with Graves' disease and 826 ± 124 MBg to those with toxic adenoma (Table 4).

As demonstrated in Table 5, at the 3-month follow-up, 7 patients (35%) with Graves' disease and 6 patients (54.6%) with toxic adenoma had achieved an euthyroid state after a single dose of RAI. However, hypothyroidism was detected in 13 patients (65%) with Graves' disease and 5 patients (45.4%) with toxic adenoma. This is substantiated by hormone levels at the 3-month follow-up, as seen in Tables 1 and 2. The serum values of 13 Graves' patients with hypothyroidism were as follows: fT3: 1.3 \pm 0.4 pg/mL, fT4: 0.5 \pm 0.3 ng/dL, and TSH: 5.2 \pm 0.6 μ IU/mL. Similarly, the typical levels in toxic adenoma patients with hypothyroidism were: fT3: 1.56 \pm 0.3 pg/mL, fT4: 0.6 \pm 0.2 ng/dL, and TSH: 4.9 \pm 0.6 μ IU/mL. Consequently, thyroid hormone replacement therapy was initiated for those patients with hypothyroid status until proving euthyroid status at the next visit.

Patients who received an ¹³¹I activity ≥600 MBq (16.2 mCi) for treatment were admitted to the radionuclide therapy unit. Dose

Table 1. Thyroid Hormone Levels of Graves' Patients Before Treatment and at 3-Month Follow-Up

		Before Treatment	After Treatment			
Patients No.	fT3 (pg/mL)	fT4 (ng/dL)	TSH (μIU/mL)	fT3 (pg/mL)	fT4 (ng/dL)	TSH (μIU/mL)
1	5.2	2.9	0.01	1.1	0.6	5.6
2	6.4	4.6	0.02	4.2	1.3	0.8
3	5.8	4.5	0.03	1.5	0.8	5.2
4	7.6	4.7	0.01	0.9	0.9	5.2
5	5.8	4.8	0.10	1.2	0.2	6.2
6	5.9	3.9	0.02	1.5	0.5	5.1
7	6.5	5.6	0.04	1.8	0.6	4.5
8	6.8	4.8	0.30	0.8	0.6	4.3
9	6.9	3.8	0.20	1.9	0.5	5.8
10	8.7	3.9	0.20	4.2	1.8	1.4
11	9.8	3.9	0.03	3.7	1.1	1.9
12	7.8	4.2	0.10	1.1	0.9	5.1
13	4.6	5.3	0.04	1.9	0.4	5.8
14	6.5	7.6	0.30	1.2	0.3	4.4
15	7.2	6.2	0.10	2.5	1.3	2.1
16	6.1	3.8	0.01	2.4	1.2	2.7
17	5.6	4.8	0.02	0.7	0.1	4.5
18	5.2	3.9	0.05	1.2	0.2	5.8
19	11.2	7.1	0.09	2.8	0.9	2.3
20	6.0	6.8	0.50	4.1	1.6	1.9
Mean ± SD	6.8 ± 1.6	4.8 ± 1.2	0.11 ± 0.12	2.04 ± 1.2	0.79 ± 0.5	4.03 ± 1.7

fT3, free triiodothyronine; fT4, free thyroxine.

rate measurements were performed 4, 6, 8, and 24 hours after RAI administration. Twelve (60%) out of 20 Graves' patients, and all toxic adenoma patients (100%) were administered with ¹³¹I activity levels above the discharge limit, necessitating admission to the radionuclide therapy unit. Of the admitted patients, 7 (30%) were discharged at 6 hours, 9 (39%) at 8 hours, and 7 (30%) at 24 hours.

The pre-treatment and 6-month post-treatment levels of fT3, fT4, and TSH in Graves' disease patients were statistically compared. The results exhibited a statistically significant difference with the following P values: serum T3 with P = .00032, fT4 with P = .00001, and TSH with P = .00001. Likewise, for patients with toxic adenoma, the pre-treatment and post-treatment serum levels had the following P values: fT3 (P = .00188), fT4 (P = .03078), and TSH (P = .00076).

Discussion

In clinical practice, long-term remission is achieved in less than 50% of patients receiving antithyroid medication. Consequently, those with persistent or recurrent disease may require definitive treatment with either thyroidectomy or RAI therapy. Thyroidectomy is generally recommended for patients with markedly enlarged

thyroid glands, confirmed malignancy, or active thyroid-associated ophthalmopathy. ¹⁰ Radioactive iodine therapy is frequently favored over surgery in many hyperthyroid patients because it is easier to administer, highly effective, and associated with fewer side effects.

lonizing radiation is a proven carcinogen, and numerous studies confirm a dose-dependent relationship between exposure and cancer development. The success rate of RAI treatment in hyperthyroidism is quite high; however, the widely used fixed-dose approach recommends a certain activity range to all patients without considering interpatient variability in terms of thyroid size, iodine uptake, and disease severity. As a result, some patients may receive subtherapeutic or excessive RAI doses, potentially leading to suboptimal outcomes and exceeding recommended radiation safety limits.^{11,12}

Unlike fixed-dose approaches, dosimetry-guided treatment facilitates the delivery of better-specified therapeutic activity to hyperfunctioning thyroid tissue while preserving the surrounding healthy tissue. From the dosimetry perspective, the EANM (European Association of Nuclear Medicine) guidelines suggest an absorbed dose of 300-400 Gy for the ablation of autonomous thyroid nodules. For patients with Graves' disease, a dose of 150 Gy

Table 2. Thyroid Hormone Levels of Toxic Adenoma Patients Before Treatment and at the 3-Month Follow-Up

		Before treatment			After treatment		
Patients No	fT3 (pg/mL)	fT4 (ng/dL)	TSH (μIU/mL)	fT3 (pg/mL)	fT4 (ng/dL)	TSH (μIU/mL)	
1	6.6	3.1	0.01	3.1	1.4	3.1	
2	6.1	3.9	0.02	3.5	1.7	2.6	
3	6.2	4.6	0.03	4.1	1.8	2.9	
4	6.5	3.2	0.01	1.9	0.9	5.5	
5	6.6	4.3	0.1	2.9	1.4	3.2	
6	6.9	4.2	0.06	1.5	0.3	5.2	
7	6.6	5.1	0.04	1.8	0.6	4.2	
8	7.8	5.8	0.03	3.6	1.5	3.1	
9	5.9	5.81	0.02	1.2	0.5	4.3	
10	7.5	3.7	0.2	1.4	0.7	5.3	
11	6.5	4.8	0.03	3.4	1.6	2.2	
Mean ± SD	6.6 ± 0.57	4.4 ± 0.92	0.05 ± 0.05	2.6 ± 1.04	1.13 ± 0.54	3.8 ± 1.2	

fT3, free triiodothyronine; fT4, free thyroxine.

to the thyroid gland is recommended to achieve euthyroid status, while doses between 200 and 300 Gy are advised for complete thyroid ablation.^{13,14} In this regard, the development of hypothyroidism is often viewed as a desirable outcome to lessen the risk of disease recurrence, followed by the initiation of thyroid hormone replacement therapy.

In evaluation, Bachmann et al15 examined the reduction of thyroid volume following RAI therapy in 88 patients with toxic or nontoxic adenomas. The mean thyroid volume was 127 ± 38 mL, the administered RAI activity was 1721 ± 440 MBq, and the average absorbed thyroid dose was 175 ± 45.9 Gy. The ultrasonographic scans revealed a 41.9% reduction in thyroid volume at 3 months and a 65.9% reduction after 1 year, with no recorded increase in volume in any patient. 15 Also, in a 10-year cohort study, it was reported that 79.3% of patients achieved remission following a single fixed dose of 131 I.16 Presently, dosimetry-based therapy has attracted significant attention in molecular therapy, even though conventional fixed-dose protocols remain widely used in radioiodine therapy. In contrast, Zakavi et al¹⁷ conducted a study involving 97 hyperthyroid patients with solitary nodules, dividing them into 2 groups: 1 treated with a fixed RAI dose and the other with a dosimetry-based RAI approach. The findings showed that the dosimetry-based group achieved higher cure rates at 10 months

Table 3. Thyroid Mass, Effective Half-Life, and Time-Integrated Activity Coefficient Measures for Patients with Graves' Disease (n=20) and Toxic Adenoma (n=11)

Parameter	Graves' Disease	Toxic Adenoma			
Mass (g)	31 ± 11	42 ± 23			
Effective half-life (h)	129 ± 22	114 ± 14			
TIAC (h)	118 ± 32	98 ± 27			
TIAC, time-integrated activity coefficient.					

post-treatment compared to the fixed-dose group. 17 Similarly, Amato et al¹⁸ administered an average RAI dose of 303 \pm 135 MBq to 69 hyperthyroid patients based on individualized dose calculations. Antithyroid medication (methimazole) was required in 59.4% of cases. Euthyroidism was achieved in 55 patients (80%) within an average of 3.2 ± 2 months after treatment, while 14 patients (20%) developed hypothyroidism at a mean of 5.6 ± 5.0 months post-therapy.¹⁸ In the current study, the sample size was relatively smaller compared to earlier studies, primarily due to time constraints associated with the sampling process and clinical workload. Nevertheless, at 3 months following RAI therapy, hypothyroidism was observed in 18 out of 31 patients, representing 58% of the sample. Thyroid hormone replacement therapy was subsequently initiated in patients who developed hypothyroidism and reached euthyroid status by the 6-month follow-up. Importantly, complete remission was achieved within 6 months without excessive radiation exposure, and no patient required an additional dose of ¹³¹I in the present study. Whereas it was reported that 11 out of 24 patients with Graves' disease (45.8%) experienced recurrent hyperthyroidism following fixed-dose therapy with 370 MBg, requiring a second course of RAI treatment after 6-9 months of follow-up. Furthermore, in a recent study, a high-volume tertiary center reported that dosimetry-based RAI therapy achieved an 84% success rate in a combined cohort of Graves' disease and toxic multinodular goiter, while effectively reducing radiation exposure in 44% of patients. 19,20

Table 4. Dosimetry-Based ¹³¹ I Activity Amounts for RIT					
Patients	200 Gy	300 Gy			
Graves' disease (n = 20)	541 ± 215 MBq (14.6 ± 5.8 mCi)	-			
Toxic adenoma (n = 11)	-	826 ± 124 MBq (22.3 ± 3.3 mCi)			

Table 5. Evaluation Of Treatment Response After a Single Dose Of				
		Graves' Disease (n = 20)		denoma 11)
Status	3rd Month	6th Month	3rd Month	6th Month

Status	3rd Month	6th Month	3rd Month	6th Month
Hypothyroidism, n (%)	13 (65)	-	5 (45.4)	_
Euthyroid, n (%)	7 (35)	20 (100)	6 (54.6)	11 (100)

On the other hand, it is worth mentioning that antithyroid medications may reduce the effectiveness of RAI therapy in hyperthyroid patients. This adverse effect can be mitigated either by discontinuing the antithyroid drugs before treatment or by increasing the target RAI dose.²¹ In this study, 13 patients (41.9%) were initiated on antithyroid medication with methimazole. After the administration of radioiodine, the methimazole dosage was reduced, and the treatment was continued for an additional 3 months.

A set of study limitations should be acknowledged. First, the extended sampling period resulted in a limited sample size, which may have reduced the statistical power and generalizability. Second, additional variables that may affect the precision of dosimetry—such as antithyroid medication use, smoking status, and other relevant clinical factors—should be systematically evaluated.

In the era of precision medicine, the fixed-dose regimen is considered outdated despite its historically high cure rates, as it often results in unnecessary radiation exposure and lacks alignment with individualized treatment principles. In contrast, dosimetry offers an evidence-based approach that enhances safety, minimizes risk, and optimizes therapeutic outcomes.

The findings indicated that complete remission (euthyroid or hypothyroid status) was achieved within 6 months following dosimetry-based RAI treatment, and none of the patients required an additional ¹³¹I dose. Future research with larger patient cohorts is necessary to validate the results and investigate the dosimetry superiority and the degrading factor, along with the effects of glucocorticoids, smoking, and the use of antithyroid drugs.

Data Availability Statement: The data that support the findings of this study are available on request from the corresponding author.

Ethics Committee Approval: Ethical committee approval was received from the Ethics Committee of İstanbul University-Cerrahpaşa (Approval no: 19451483/604-01-02-52947, Date: February 2, 2015).

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