ORIGINAL ARTICLE

Incorporating Clinical Factors into the Calculation of Radioiodine Dose for Graves' Disease: Improving the Success Rate of Treatment

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Background: There is a hypothesis that additional radioiodine activity for each clinical risk factor would increase the success rate of radioiodine therapy (RIT) for Graves' disease (GD).

Objective: To compare the success rates of RIT using standard and new dosage calculation protocols.

Materials and Methods: The present study was a retrospective cohort study that enrolled 341 GD patients who received RIT between January 2014 and July 2023 at Burapha University Hospital, Thailand. Participants were divided into two groups: those who received protocol 1, a standard radioiodine dosage calculation method, and those who received protocol 2, a risk-modified dosage calculation method. The primary outcome was the success rate of RIT with the two protocols at the 6-month follow-up.

Results: The group receiving protocol 2 displayed a significantly higher RIT success rate than those who received protocol 1 (69.2% versus 49.7%, p<0.001). Based on the measured effects of protocols 1 and 2, the risk of treatment failure was higher in protocol 1 (RR 1.39, 95% CI 1.16 to 1.68, p<0.001) than in protocol 2. After matching analysis with sex and thyroid size, the risk of treatment failure was more conspicuous (RR 1.64, 95% CI 1.20 to 2.25, p=0.001).

Conclusion: The new precision protocol, which incorporates clinical risk factors into radioiodine dosage calculation, significantly improves treatment outcomes in patients undergoing RIT for Graves' disease.

Keywords: Calculated dosage; Graves' disease; Radioactive iodine treatment; Success rate

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Radioactive I-131 therapy (RIT), a safe and highly effective approach for treating Graves' hyperthyroidism[1], has reduced the number of patients requiring thyroidectomy, thereby decreasing both the risk of surgical complications and healthcare costs[2,3]. This approach is also convenient for the patient, given that it can be self-administered via capsules in an outpatient unit without the need for hospitalization. RIT is based on the ability of thyrocytes to take up $Na^{131}I$ via sodium-iodine symporter, in the same manner stable iodine (^{127}I) is absorbed from foods[2]. A recent meta-analysis showed a dose-response relationship between the radiation absorbed dose delivered to the thyroid and therapeutic outcomes of RIT for Graves' disease (GD)[4]. The 2016 American Thyroid Association guidelines recommend a single radioiodine (RAI) dose of 10 to 15 mCi for treating a patient with GD[5]. However, RIT with fixed activities that do not adjust for thyroid volume (TV) and expected kinetics is not recommended given its potential to cause substantial overdosage, particularly in patients with normal or slightly enlarged thyroid glands. In other words, a fixed activity of 15 mCi is more than twice the usual dose requirement to effectively treat GD in a patient with a 20-g thyroid gland[2].

Recently, two concepts have emerged for RIT among patients with GD, namely the concept of an ablative and functional dose. An ablative dose aims

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to induce hypothyroidism as quickly as possible, while a functional dose seeks to correct subclinical or overt hyperthyroidism while preserving thyroid function[2]. In clinical practice, ablative dosing was used in patients with large thyroid sizes of more than 105 g, patients who have recently suffered serious GD complications, and those who have had adverse reactions to antithyroid drugs (ATDs). For patients who do not meet these criteria, radiation exposure should be kept "as low as reasonably achievable" (ALARA), in accordance with radiation protection principles. Administering unnecessarily high RAI activity can result in excessive radiation exposure to the patients, their family, and the public[6]. Moreover, higher RAI doses may impose prolonged radiation safety restrictions, patients required to take extended time off work and potentially leading to loss of income. Therefore, a calculated dose method should be employed. Over the last 10 years, studies have reported the success rates of the calculated dose RIT method for treating GD. However, their results varied between 62.5% to 85.1%, from widely differing study designs, patient preparation techniques, expected kinetics, and durations of therapeutic response assessment[7-11] and new protocol needs to be developed. Besides thyroid size and radioiodine uptake (RAIU), other risk factors for GD, such as sex[12], smoking[13,14], and first-degree family members with autoimmune thyroid diseases[14], have been found to affect the outcomes of RIT. The authors hypothesized that a new method involving increasing the RAI activity by 10% for each of these risk factors in the standard RAI dosage calculation would improve the success rate of RIT. The objective of the present study aimed to compare the success rates of RIT for GD using the standard and risk-modified dosage calculation methods.

Materials and Methods

Study design and participants

The present study was a retrospective cohort study conducted at Burapha University, Queen Sirikit, and Queen Savang Vadhana Memorial Hospitals. The authors enrolled 420 Thai patients with GD aged 18 years or older who received their first calculated RIT dose at the Radiology and Nuclear Medicine Unit, Burapha University Hospital, between January 2014 and July 2023. GD was diagnosed based on clinical presentations (such as diffuse goiter, orbitopathy, or pretibial myxedema), abnormal thyroid function tests [such as subnormal serum thyrotropin (TSH) levels with elevated serum free triiodothyronine (fT3) and/or free thyroxine (fT4) estimates], and high RAIU[5]. None of the participants had undergone RIT or thyroidectomy before. Patients treated between 2014 and 2017 received RAI doses based on thyroid size and 24-hour radioiodine uptake (24-h RAIU) (protocol 1), whereas those treated between 2018 and 2023 received RAI based on new risk modification methods (protocol 2). The sample size for this trial was calculated using the following equation:

$$n = \frac{2(p^*)(1-p^*)(Z_{\alpha/2} + Z_{\beta})^2}{(p_1 - p_2)^2}$$

where n represents the required sample size, $p_1 - p_2$ denotes the difference in RIT success rates between the two groups, namely those treated with protocol 1 (p_1=0.656)[11] and those treated with protocol 2 (estimated p_2=0.800). p* indicated the average of both groups (p*=0.730). Using an alpha value of 5% ($Z_{\alpha/2}$=1.96) and a power of test of 80% (Z_{β}=0.84), each group required a sample size of 150 cases. To account for the potential loss of follow-up, the sample size was increased by an additional 40%, resulting in a requirement of 210 cases per group. Consequently, the total sample size for the present study was 420 cases. From the initial cohort of 420 patients, 79 were excluded due to 1) loss to follow-up or follow-up period shorter than six months (65 patients) or 2) need for high RAI activity for thyroid gland ablation based on the clinician's discretion (14 patients). The percentage of patients excluded from the study was similar for those receiving protocols 1 and 2, at 18.2% and 19.3%, respectively. Ultimately, 341 remaining patients were eligible for the study.

Assays

Blood samples for thyroid function testing in all patients were routinely analyzed in the clinical laboratories of the three institutes using an electrochemiluminescence immunoassay (ECLIA) according to the manufacturer's instructions (Roche). The normal reference ranges for serum fT3, serum fT4, and serum TSH levels were 2.0 to 4.4 pg/mL, 0.93 to 1.7 ng/dL, and 0.27 to 4.2 uIU/mL, respectively.

Procedure

The procedures for both calculated dose protocols were carefully planned and standardized. All female patients of childbearing age were required to undergo pregnancy testing within 24 hours before receiving RIT and were counseled to use contraception for at least six months after treatment. Furthermore, radiation protection guidance was provided for patients and their families. Patients with

inactive moderate ophthalmopathy were treated with RIT in conjunction with corticosteroid therapy[5,15]. Before swallowing the RAI capsule, the patients were required to adhere to a low-iodine diet for seven days. Those taking ATDs were instructed to discontinue these medications for three days before and after RIT. TV was assessed using two ultrasound devices, namely Aplio 200 and Aplio 300 (Toshiba, Tokyo, Japan), both of which were equipped with a 7- to 14-MHz linear transducer. Each thyroid lobe and isthmus was measured in three dimensions (width × depth × length), and the total TV was calculated using the standard ellipsoid volume formula, where TV = 0.52 × (TV of both thyroid lobes and isthmus)[16]. For protocols 1 and 2, the RAI activity was estimated using the following standard calculation formula: RAI activity (μCi) = TV (g) × 200 μCi/g × [1/24-h RAIU (%)][5]. To improve the success rate of RIT with protocol 2, 10% of the RAI activity was added to the RAI dose from the standard calculation method for each clinical risk factor presented (male sex, smoking, and the presence of first-degree family members with autoimmune thyroid diseases)[12]. This protocol was started in January 2018.

The patients ingested a sodium iodide capsule on an empty stomach. To assess thyroid functional status, the authors conducted thyroid function tests and measured the thyroid size six months after RIT. The primary outcome was treatment success or failure. Treatment success was defined as the achievement of euthyroidism, which is normal TSH and fT4 levels, without ATDs or the development of hypothyroidism, which is high TSH and low fT4 levels, requiring levothyroxine therapy within six months following RIT. Treatment failure was defined as continued hyperthyroidism, which is low TSH and high fT4 levels, and/or continued necessity for ATDs after RIT[5].

Statistical analysis

Baseline assessment and follow-up data were obtained using anonymized patient identification numbers from the present study database and the hospital's medical database. Quantitative clinical parameters were reported as mean (standard deviation, SD), median (interquartile range, IQR), or median (range), whereas qualitative parameters were reported as frequency (%). The Mann-Whitney U test was employed to compare continuous baseline variables between the two independent dosage groups. The chi-square test was utilized to assess proportional differences in RIT success rates between the groups. Poisson regression was used to determine the success rates for protocols 1 and 2 while adjusting for confounding factors, including age, sex (male), first-degree family history of GD, current smoking status, and TV when significant. A matched analysis was performed to ensure comparability between the groups with respect to sex and thyroid size. The risk of treatment failure was also reported with risk ratio (RR) and 95% CIs. A p-value of less than 0.05 indicated statistical significance.

Results

The mean age of the GD patients was 38.0 years (SD 11.1), with 24.9% being male. The median thyroid size was 24.7 g (IQR 18.3 to 34.6). The group receiving protocol 2 displayed a significantly higher success RIT rate than those receiving protocol 1 at 69.2% versus 49.7% ($p<0.001$) (Table 1). Based on the effect measures of protocols 1 and 2, the risk of treatment failure was higher among those receiving protocol 1 (RR 1.39, 95% CI 1.16 to 1.68, $p<0.001$), but the median dose of RAI did not differ significantly at 8.0 versus 8.7 mCi ($p=0.252$) (Table 1).

Because the protocol 1 group included a higher proportion of male patients (30.7% versus 19.7%, $p=0.019$) (Table 2) and had a larger median thyroid size (25.9 versus 23.5 g, $p=0.031$) (Table 1). After matching, the RIT success rate remained significantly higher in the protocol 2 group (69.5% versus 50.0%, $p=0.001$) (Table 2), and the risk of treatment failure was higher than before matched analysis (RR 1.64, 95% CI 1.20 to 2.25, $p=0.001$). The median RAI dose was also significantly higher in the protocol 2 group (10.5 versus 8.7 mCi, $p=0.002$) (Table 2).

Discussion

The concept behind the use of RIT for GD is to eliminate hyperthyroidism by shrinking TV and reducing thyroid hormone production. In the authors' clinical practice, they recommend RIT using the calculated dose method to provide individualized RAI activity, delivering a precise radiation dose to the thyroid while minimizing unnecessary radiation exposure[2,6]. In 2021, Andersson & Mattsson studied an I-131 absorbed dose to the thyroid for 15 female patients with hyperthyroidism via the combined EANM method and the ICRP model. They found that the thyroid dose coefficient was 653 mGy/MBq, with a range of 390 to 981[17]. The present study also used this value to calculate the thyroid absorbed dose of patients receiving protocol 1 and found that the median thyroid absorbed dose was 193.3 Gy (96.6 to

Table 1. Patient characteristics and treatment outcomes in patients with Graves' disease 6 months after treatment with two RIT protocols (n=341)

Variables	Protocol 1 (n=153)	Protocol 2 (n=188)	p-value
Age (years); mean [SD]	38.4 [11.2]	37.6 [11.1]	0.318
Male sex; n (%)	47 (30.7)	37 (19.7)	0.019*
First-degree family history of AITD; n (%)	43 (28.1)	56 (29.8)	0.734
Smoker; n (%)	16 (10.5)	24 (12.8)	0.510
Number of cigarettes per day; median (IQR)	10.0 (4.5, 10.0)	10.0 (2.5, 10.0)	0.781
Indication for RAI treatment; n (%)			
Medical failure	69 (45.1)	83 (44.1)	0.861
Relapse or recurrence	60 (39.2)	52 (27.7)	0.024*
Cardiovascular complications	7 (4.6)	16 (8.5)	0.150
Thyrotoxic periodic paralysis	11 (7.2)	17 (9.0)	0.535
Progressive disease	0 (0.0)	15 (8.0)	<0.001*
Adverse reactions to ATDs	6 (3.9)	4 (2.1)	0.329
Thyroid size on US (g); median (range)	25.9 (7.4 to 100.0)	23.5 (6.9 to 84.3)	0.031*
RAI activity (mCi); median (range)	8.0 (4.0 to 28.0)	8.7 (3.5 to 29.6)	0.252
Treatment outcome at 6 months; n (%)	76 (49.7)	130 (69.2)	<0.001*
Euthyroid	34 (22.2)	59 (31.4)	0.059
Hypothyroid	42 (27.5)	71 (37.8)	0.044*
Hyperthyroid	77 (50.3)	58 (30.8)	<0.001*

AITD=autoimmune thyroid diseases; ATDs=antithyroid drugs; IQR=interquartile range; RAI=radioiodine; RAIU=radioiodine uptake; RIT=radioiodine therapy; SD=standard deviation; US=ultrasound

* p<0.05 is considered statistically significant

Table 2. Matched case-control analysis of patient characteristics and treatment outcomes in patients with Graves' disease 6 months after treatment with two RIT protocols (n=256)

Variables	Protocol 1 (n=128)	Protocol 2 (n=128)	p-value
Age (years); mean [SD]	39.1 [10.9]	37.9 [11.9]	0.232
Male sex; n (%)	31 (24.2)	31 (24.2)	1.000
First-degree family history of AITD; n (%)	31 (24.2)	40 (31.3)	0.209
Smoker; n (%)	12 (9.4)	20 (15.6)	0.131
Number of cigarettes per day; median (IQR)	10.0 (4.7, 10.0)	10.0 (3.0, 10.0)	1.000
Indication for RAI treatment; n (%)			
Medical failure	58 (45.3)	59 (46.1)	0.900
Relapse or recurrence	50 (39.1)	33 (25.8)	0.023*
Cardiovascular complications	5 (3.9)	12 (9.4)	0.079
Thyrotoxic periodic paralysis	10 (7.8)	12 (9.4)	0.656
Progressive disease	0 (0.0)	9 (7.0)	0.002*
Adverse reactions to ATDs	5 (3.9)	3 (2.3)	0.472
Thyroid size on US (g); median (range)	28.27 (19.5 to 33.4)	28.5 (25.5 to 34.3)	0.865
RAI activity (mCi); median (range)	8.7 (6.0 to 11.0)	10.5 (6.8 to 13.4)	0.002*
Treatment outcome at 6 months; n (%)	64 (50.0)	89 (69.5)	0.001*
Euthyroid	28 (21.9)	39 (30.5)	0.118
Hypothyroid	36 (28.1)	50 (39.0)	0.064
Hyperthyroid	64 (50.0)	39 (30.5)	0.001*

AITD=autoimmune thyroid diseases; ATDs=antithyroid drugs; IQR=interquartile range; RAI=radioiodine; RAIU=radioiodine uptake; RIT=radioiodine therapy; SD=standard deviation; US=ultrasound

* p<0.05 is considered statistically significant

676.5), which promoted an RIT success rate of only 49.7% (Table 1). Because a greater thyroid absorbed dose has been associated with higher RIT success rates[4], higher RAI activity should be considered. Protocol 2 was developed using a risk-modified method for calculating the thyroid absorbed dose, and

the success rate of RIT with this protocol increased by 19.5%. Although the protocol 1 group had a higher proportion of male patients and larger TVs, the success rate remained significantly higher with protocol 2, even after matched case-control analysis (69.5% versus 50.0%, p=0.001) (Table 2). These findings underscore the benefit of adjusting RAI activity according to individual patient risk profiles.

Notably, protocol 2 (69.2%) promoted a higher success rate after six months than did the calculation method used by Pamnani et al. (63.4%)[8] and Canto et al. (62.5%)[10], with the median RAI activities being 8.7, 6 to 14, and 8.5 mCi, respectively. Although Wong et al.[9] used the same target absorbed dose of the thyroid (200 μCi/g) as in the present study, the median RAI activity was higher at 18.1 versus 8.7 mCi due to the larger TV (median TV 50.2 versus 23.5 g). Wong et al. used a neck palpation technique to estimate the size of the gland, not thyroid ultrasound, and reported a higher success rate (93%)[9]. TV may over- or underestimate the therapeutic RAI activity; a previous study found a 56.6% discordance in TV between manual palpation and ultrasonography techniques[18].

In 2021, Taprogge et al. found that success rates plateaued with increasing radiation absorbed doses, with a dose greater than 300 Gy offering limited benefit[4]. In the present study, the median thyroid absorbed dose in protocol 2 was 210.2 Gy (84.6 to 715.2), which achieved an RIT success rate less than that reported in a meta-analysis by Taprogge et al. at 69.2% versus 81.0%. This finding would seem to imply the need for increasing the thyroid absorbed dose. High thyroid absorbed dose (300 Gy) increased the RIT success rate by 7.0%[4] and would be beneficial for patients who are against repeated RIT for any reason. In the matched case-control analysis presented in Table 2, protocol 2 demonstrated a higher RIT success rate (69.5% versus 63.6%), even though the median thyroid gland size did not differ significantly compared to the present study risk-modified fixed-dose method[12] (28.5 versus 27.0 g).

The present study has been the first to use clinical risk factors of RIT failure to adjust the RAI dose via a calculated dose method in patients with GD, but it also had limitations. It was retrospective with no randomization and involved only one institution where RAIU testing was available. Autoantibodies to the thyroid glands were not determined for diagnosis. The application of protocol 2 needs to consider the resources and financial status of each institute. Finally, the authors did not assess interobserver variations in TV measurements among the three radiologists, given that data were collected retrospectively and one of the radiologists was transferred to another hospital in 2020.

Conclusion

The new protocol of radioiodine dose calculation, which adjusted for clinical risk factors, significantly improves the success rate of RIT in patients with GD.

What is already known about this topic?

The success rate of RIT for GD is mostly dependent on the radiation absorbed dose delivered to the thyroid. The standard calculation formula of RAI activity following TV was low to achieve a success rate. Besides delayed achieving therapeutic outcome, repeated RIT requires patients to leave their work with additional travel costs and loss of income. However, the method to increase RAI activity beyond the standard formula remains a challenge, as to what factors should be used in calculating the radiation dose.

What does this study add?

Incorporating risk factors for GD, such as male sex, smoking, and first-degree family members with autoimmune thyroid diseases, into the calculation of RAI activity can safely and effectively increase the therapeutic outcome.

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Authors' contributions

WA, TR, and SS designed the study and reviewed the literature. WA, TR, and MY collected and extracted the data. JW and WA performed the data analysis. WA and TR drafted the original article. All the authors contributed to the final critical review and approved the final article.

Data availability statement

The data supporting the findings of this study are available from the authors upon reasonable request.

Ethics approval and consent to participate

The present study was conducted in accordance with the 2013 revision of the Declaration of Helsinki.

Ethics approval was obtained from the Institutional Review Board of Burapha University (certificate number: IRB1 084/2567). Owing to the retrospective nature of the present study, the Institutional Review Board waived the need for informed consent.

Clinical trial registration

The present study was registered at the Thai Clinical Trial Registry (TCTR20240831001).

Use of artificial intelligence

No artificial intelligence (AI) tools were used in any part of the research process.

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Conflicts of interest

The authors declare no conflict of interest.

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