Original Article

Outcome of Radioiodine Treatment in Hyperthyroidism and Predictive Factors of Treatment Failure: A 10-Year Experience

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Objective: To analyze the effectiveness of the first dose of radioiodine (I-131) treatment in patients with hyperthyroidism in Southern Thailand. The second objective was to predict the factors implicated in treatment failure.

Materials and Methods: Patients with hyperthyroidism who received first dose of I-131 between January 2010 and December 2019 at Songklanagarind Hospital were enrolled in the present retrospective study. The data collected included age, gender, duration of the disease, type of disease, thyroid gland size (by palpation), type of antithyroid drug (ATD), ATD dose, and time of withholding ATD before and after I-131 treatment. The effectiveness of the first dose of I-131 treatment was assessed after six months of treatment. Treatment success was defined as a euthyroid or hypothyroid status.

Results: One thousand four hundred twenty-four patients with hyperthyroidism at a median age of 44.5 years and including 73.2% women were included in this study. Graves' disease was the most common cause at 95.8%. The median I-131 dose was 7 mCi. Six months after treatment, 703 patients or 49.4%, achieved treatment success, which increased to 859 patients (60.3%) after 12 months. The authors found three factors that influenced treatment failure, duration of disease of seven months or longer (p=0.001), thyroid gland size of 100 g or larger (p=0.004), and I-131 treatment dose 10 to 19 mCi (p=0.021). The patient cohort was divided into three groups based on thyroid gland size at less than 50 g, 50 to 99 g, and more than 100 g, the I-131 treatment dose that increased the success rate of treatment in each group was 5 mCi or more, 6 mCi or more, and 15 mCi or more, respectively.

Conclusion: A single dose of I-131 could successfully treat hyperthyroidism. The duration of the disease, size of the thyroid gland, and the dose of I-131 treatment had a substantial impact on the result. Thus, the authors recommended early treatment with I-131 at a suitable dose for patients with hyperthyroidism.

Keywords: Radioiodine treatment; I-131; Hyperthyroidism; First dose

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Hyperthyroidism is a disease characterized by inappropriate synthesis and release of thyroid hormones by thyroid gland[1]. The incidence of overt hyperthyroidism is 0.4 per 1,000 in women and 0.1 per 1,000 in men[2]. Untreated hyperthyroidism leads to serious complications, such as cardiovascular dysfunction, neuropsychiatric symptoms, thyroid storm, or death[1]. Graves' disease is the most common cause of hyperthyroidism, followed by toxic multinodular goiter and adenoma[3]. There are three treatment options for hyperthyroidism, antithyroid drug (ATD), radioactive iodine (RAI), and surgical thyroidectomy. RAI treatment involves the use of radioiodine (I-131), a beta-particle-emitting radioisotope that is safe for definitive hyperthyroidism treatment[4]. There are two standard I-131 treatment protocols for inducing hypothyroidism, the first involves administering a fixed I-131 dose, while the second involves calculating the dose based on the size and ability of the thyroid to trap the I-131[1]. de Rooij et al and Canto reported the two methods had equally successful treatment rate, but the fixed I-131 treatment dose method was more straightforward and cost-effective[5,6].

Only a few studies have reported the treatment outcome of single fixed I-131 treatment in the Thai

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population. Therefore, using a large population in southern Thailand, the present study primarily aimed to analyze the effectiveness of the first dose of I-131 treatment in patients with hyperthyroidism. The second purpose was to predict the factors implicated in treatment failure.

Materials and Methods

The present study was a retrospective cohort study approved by the Human Research Ethics Committee of the Faculty of Medicine, Prince of Songkla University (REC number: 64-110-7-1). In total 1,424 patients with hyperthyroidism referred to the Nuclear Medicine Division, Department of Radiology, Songklanagarind Hospital for their first I-131 treatment between January 2010 and December 2019 were included. Patients who had a history of thyroid surgery, aged younger than 18 years, or had undetermined results during the six months follow-up period were excluded.

The data collected included age, gender, duration of the disease, type of disease, thyroid gland size (by palpation), type of ATD such as methimazole (MMI) or propylthiouracil (PTU), or none, ATD dose, and withholding time for ATD use before and after I-131 treatment. All patients completed the preparation protocol, including ATD discontinuation for three to seven days prior to I-131 treatment and 10 to 14 days of low-iodine diet advisory.

Treatment outcomes were assessed six months after the first I-131 treatment, and treatment success or failure was determined. Treatment success was defined as a euthyroid or hypothyroid status according to thyroid function test results as normal serum free thyroxine (FT4) and serum thyroid-stimulating hormone (TSH) levels for euthyroid and high TSH levels for hypothyroid status. Treatment failure was defined as repeated I-131 treatment during follow-up, lack of response to I-131 treatment, or presence of hyperthyroidism as low TSH. Treatment outcomes were reported as percentages.

Statistical analyses were performed using R program version 3.4.0 (R Foundation, Vienna, Austria). Statistical significance was set at p-value less than or equal 0.05. Descriptive statistics were used for the demographic characteristics and to examine the treatment outcomes. Discrepancies in data were described as numbers and percentages. Continuous variables were described as mean±standard deviation (SD) or median (interquartile range, IQR). Univariate and multivariate logistic regression analyses were used to assess factors associated with treatment outcomes. The relationship between outcomes and predictors was presented as odds ratio (OR) and 95% confidence interval (CI). Youden's J statistic was used to determine the optimal duration of treatment, duration of ATD discontinuation before I-131 treatment, and duration of antithyroid treatment after I-131 treatment.

Table 1. Patients' demographic data

Variables	Number of patients (n=1,424)
Sex; n (%)	
Male	381 (26.8)
Female	1,043 (73.2)
Age (years); median (IQR)	44.5 (33.3, 56.4)
Duration of disease (months); median (IQR)	30.5 (12, 60)
Medication; n (%)	
Propylthiouracil (PTU)	312 (21.9)
Methimazole (MMI)	1,079 (75.8)
Antithyroid drug (ATD)	9 (0.6)
None	24 (1.7)
Medication per day (tablets); median (IQR)	3 (2, 4)
Type of disease; n (%)	
Graves' disease	1,364 (95.8)
Multinodular goiter	40 (2.8)
Toxic adenoma	13 (0.9)
Indeterminate etiology	7 (0.5)
Thyroid gland size (g); n (%)	
Median (IQR)	40 (30, 60)
<50	857 (60.1)
50 to 99	487 (34.2)
≥100	70 (4.9)
N/A	10 (0.8)
Family history of hyperthyroidism; n (%)	
Yes	241 (16.9)
No	738 (51.8)
N/A	445 (31.2)
Duration of medication cessation (days); median (IQR)	7 (7, 10)
Duration of restarting medication after I-131 therapy (days); median (IQR)	3 (3, 3)
Treatment dose (mCi); median (IQR)	7 (6, 10)

IQR=interquartile range; N/A=not applicable

Results

One thousand four hundred twenty-four patients were included in the present study. Demographic data are shown in Table 1. Women constituted the majority of the cohort with 1,043 of the patients or 73.2%, with ages ranging from 18 to 95. The median duration of hyperthyroidism before I-131 ablation was 30.5 months (IQR 12, 60). One thousand four hundred patients received ATD treatment before I-131

Table 2. Factors associated with failure of I-131 treatment

	Univariate logistic regression analysis			Multivariate logistic regression		
	Crude odds ratio	95% CI	p-value	Adjusted odds ratio	95% CI	p-value
Sex						
Male	1			1		
Female	0.80	0.63 to 1.01	0.06	0.82	0.64 to 1.05	0.12
Age (years)	1.00	0.99 to 1.01	0.73			
Duration of disease (months)	1.00	1.00 to 1.00	0.02	1.00	1.00 to 1.00	0.03*
Medication						
PTU	1			1		
MMI	0.95	0.74 to 1.22	0.69	0.95		0.71
None	0.30	0.12 to 0.79	0.01	0.40	0.12 to 1.31	0.13
Medication per day (tabs)	1.02	0.99 to 1.06	0.24			
Type of disease						
Graves' disease	1					
Multinodular goiter	1.08	0.57 to 2.02	0.82			
Toxic adenoma	0.61	0.20 to 1.87	0.39			
Indeterminate etiology	1.30	0.29 to 5.82	0.73			
Thyroid gland size (g)	1.02	1.01 to 1.02	<0.001	1.02	1.01 to 1.02	<0.001*
Family history of hyperthyroidism						
Yes	1					
No	0.96	0.72 to 1.28	0.77			
N/A	0.87	0.63 to 1.19	0.38			
Duration of medication cessation (days)	1.00	1.00 to 1.00	0.63			
Duration of restarting medication after I-131 therapy (days)	0.99	0.99 to 1.00	0.14	0.99	0.99 to 1.00	0.16
Treatment dose (mCi)	1.08	1.05 to 1.12	<0.001	1.02	0.97 to 1.07	0.47

PTU=propylthiouracil; MMI=methimazole; I-131=radioactive iodine; N/A=not applicable; CI=confidence interval

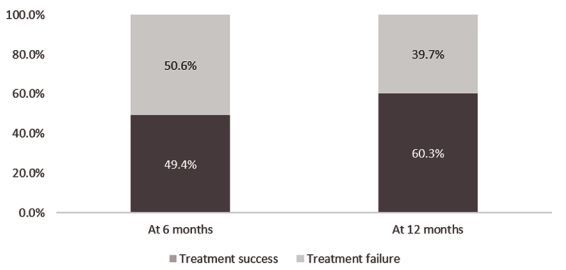

Figure 1. Treatment outcomes at 6 months and 12 months.

ablation with MMI at 75.8%, and PTU at 21.9%, but 24 patients or 1.7% had no prior treatment. Graves' disease was the diagnosed in 1,364 patients (95.8%) of the patients. The median thyroid gland size was 40 g (IQR 30, 60), and more than half of the patients (60.1%) had a thyroid gland size smaller than 50 g. The median dose of I-131 ablation was 7 mCi (IQR 6, 10).

The effectiveness of I-131 treatment in the patients at six months is shown in Figure 1. Seven hundred three patients (49.4%), achieved treatment success at six months, which increased to 859 patients (60.3%) after 12 months, without repeated treatment.

As a secondary outcome, the factors associated with treatment failure were analyzed. Univariate analysis revealed that treatment failure was significantly associated with male gender, a longer disease duration, no treatment before I-131 treatment, a larger thyroid gland size, a shorter duration of ATD therapy after I-131 treatment, and a higher dose of I-131 treatment. According to the multivariate analysis, two independent factors influenced treatment failure, longer duration of disease (OR 1.00, 95% CI 1.00 to 1.00, p=0.03) and larger thyroid gland size (OR 1.02, 95% CI 1.01 to 1.02, p≤0.001) (Table 2).

To determine the optimum cut-off points for factors affecting treatment response according to Youden's J statistic, the duration of the disease, the period of cessation of ATD use before I-131 treatment, and the period prior to resuming ATD use after I-131 treatment were investigated. The optimal cut-off points were duration of disease of seven months or longer (sensitivity 90.2%, specificity 16.4%, PPV 52.5%, and NPV 62.0%), period of cessation of ATD use before I-131 treatment duration of 16 days

Table 3. Factors associated with failure of I-131 treatment after determining the optimum cut-off point by Youden's J statistic

	Univariate logistic regression analysis			Multivariate logistic regression		
	Crude odds ratio	95% CI	p-value	Adjusted odds ratio	95% CI	p-value
Sex						
Male	1			1		
Female	0.80	0.63 to 1.01	0.06	0.85	0.66 to 1.10	0.215
Duration of disease (months)						
<7	1			1		
≥7	2.14	1.41 to 3.35	<0.001	1.70	1.23 to 2.35	0.001*
Medication						
PTU	1			1		
MMI	0.95	0.74 to 1.22	0.69	0.93	0.71 to 1.21	0.57
None	0.30	0.12 to 0.79	0.01	0.40	0.12 to 1.33	0.13
Thyroid gland size (g)						
<50	1			1		
50 to 99	1.47	1.17 to 1.83	<0.001	1.23	0.94 to 1.61	0.124
≥100	5.25	2.83 to 9.73	<0.001	3.45	1.50 to 7.94	0.004*
Duration of medication cessation (days)						
<16	1					
≥16	1.15	0.84 to 1.58	0.395			
Duration of restarting medication after I-131 therapy (days)						
≥4	1			1		
<4	1.48	1.00 to 2.18	0.05	1.11	0.82 to 1.51	0.49
Treatment dose (mCi)						
≤9	1			1		
10 to 19	1.58	0.83 to 3.02	0.167	1.45	1.06 to 1.99	0.021*
≥20	0.61	0.06 to 6.75	0.687	1.59	0.63 to 4.01	0.33

PTU=propylthiouracil; MMI=methimazole; I-131=radioactive iodine

or longer (sensitivity 14.0%, specificity 87.5%, PPV 54.1%, and NPV 49.5%), and the period prior to resuming ATD use after I-131 treatment duration four days or longer (sensitivity 16.1%, specificity 85.7%, PPV 54.3%, and NPV 49.2%).

Univariate analysis showed the same variables as shown in Table 2. Multivariate analysis revealed three factors that influenced treatment failure, duration of disease of less than seven months (adjusted OR 1.70, 95% CI 1.23 to 2.35, p=0.001), thyroid gland size of 100 grams or larger (adjusted OR 3.45, 95% CI 1.50 to 7.94, p=0.004), and I-131 treatment dose of 10 to 19 mCi (adjusted OR 1.45, 95% CI 1.06 to 1.99, p=0.021) (Table 3).

The I-131 treatment doses that increased the treatment success rate in each group based on Youden's J statistic were 5 mCi or larger (sensitivity 91.4%, specificity 14.9%, PPV 56.3%, and NPV 59.2%), 6 mCi or larger (sensitivity 99.1%, specificity 5.6%, PPV 46.2%, and NPV 88.2%), and 15 mCi or larger (sensitivity 100%, specificity 8.8%, PPV 20.0%, and NPV 100%) for thyroid sizes of less than 50 g, 50 to 90 g, and more than 100 g, respectively.

Discussion

The present study revealed the results of patients with hyperthyroidism treated with I-131 at a tertiary hospital over a decade. After a single dose of I-131, 49.4% of the patients achieved treatment success after six months, and this percentage increased to 60.3% after one year. The success rate following I-131 administration in the present study was similar to the previously reported in Thailand. Kuanrakcharoen found a 66.3% success rate in patients with hyperthyroidism after one year[7], and Kiatkittikul et al reported a 50% success rate in patients with Graves' disease after six to nine months of treatment[8]. A retrospective study in Hong Kong[9] reported the use of a fixed 5 to 10 mCi I-131 treatment dose for patients with hyperthyroidism at the 1-year follow-up, 63% of the patients were successfully treated. That study used a dose of I-131 similar to the used in the present study, with a median dose of 7 mCi (IQR 6 to 10).

However, the success rate in the present study was lower than the rates reported in the other countries. Hu et al found that 69.87% of the patients were euthyroid after six months of follow-up[10]. A 10-year cohort study in Australia by Fanning et al reported that 79.3% of patients with Graves' disease achieved remission after 12 months of follow-up[4]. Similarly, a study by Konishi et al in Japan reported a 73.8% success rate 1-year post-treatment[11]. According to Radhi et al, the success rate was as high as 92.7% when patients were administered a fixed dose of I-131 of 15 mCi[12]. In contrast, the authors in the present study may have reported lower success rates due to the I-131 doses used, which were 8 to 15 mCi. In the above-mentioned studies, the I-131 dosages were higher than that used in the present study with a median dose of 7 mCi. The second reason for the lower treatment success rate in the present study could be that this was a tertiary care hospital, and many patients (59.6%) were not followed-up in the present study. The patients were transferred back to their primary care facility for lifelong follow-up. Patients will be referred for a second dose if the disease persisted or relapsed. As a result, the treatment success rate may appear to be lower than it actually is. Third, the apparent low success rate may be due to increased consumption of Thailand's iodized salt. The participants of the present study live in southern Thailand, which is bordered on the east by the Gulf of Thailand and on the west by the Andaman Sea. Regular seafood consumption results in a significant iodine buildup. As a result, preparing patients for the procedure by advising them to avoid iodized salt and seafood before I-131 treatment may impact the rate of success. Tsuruhara et al suggested that a low iodine diet yielded higher I-131 uptake[13]. Therefore, the I-131 treatment may be affected. However, a prospective trial by Santarosa et al showed no difference in the successful treatment of Graves' disease at six months between patients who consumed a low-iodine diet and those who consumed a regular diet[14]. The last reason for the lower success rate in the present study is that I-131 uptake evaluation was not performed prior to I-131 treatment, which might have affected patients with rapid turnover who require a higher dose of I-131 treatment[15].

In the logistic regression analysis, treatment failure was associated with two independent factors, longer disease duration and larger thyroid gland size. After applying an optimal cut-off point according to Youden's J statistic, three factors were found to influence treatment failure, duration of disease of seven months or longer, thyroid gland size of 100 g or larger, and I-131 treatment dose of 10 to 19 mCi. Finessi et al discovered that the duration of antithyroid medication treatment was a factor influencing treatment failure, but they did not mention the duration of the disease[16]. Regarding thyroid gland size, the association between large glands and treatment failure is widely established[1,9,17-21]. The effectiveness of I-131 treatment in hyperthyroidism is highly dependent on I-131 activity. The higher the I-131 activity, the higher the therapeutic success rate. The present report showed that one of the factors affecting the success rate is a 10 to 19 mCi dose of I-131 treatment. This could be explained by the fact that the median dose of I-131 ablation administered in the present study was 7 mCi. Despite the fact that approximately 40% of patients had thyroid gland sizes greater than 50 g, only a small fraction of the patients was treated with doses greater than 10 mCi in the present study. This finding is expected to contribute to real-world practice modifications in the future. If the patient had a large thyroid gland, the appropriate dose of I-131 treatment should be administered to improve the chances of treatment success. Gender had no significant association with treatment response in the present study, similar to the findings of other studies[3,8]. Although Hu et al suggested that male gender is associated with early hypothyroidism[10], the exact reason for the difference in treatment outcomes between male and female patients has not been described.

Therefore, Youden's J statistics was used to estimate the optimal I-131 treatment dose to improve the treatment success rate. According to the American Thyroid Association standards[1], 10 to 15 mCi is a common I-131 dose to induce hypothyroidism. However, it does not state how much I-131 activity is appropriate for different thyroid gland sizes. A fixed dose of I-131 15 mCi has been used in previous investigations to determine the outcome. The present study discovered that using an appropriate dose can help achieve a successful treatment.

The limitation of the present study is that it was a chart review-based retrospective study. Before I-131 treatment, data for characteristics such as thyroid uptake or thyroid function test levels were incompletely reported. Other data, such as weight and thyroid function testing before treatment, should be included in the future research.

As the present study did not follow up with patients after I-131 treatment, treatment response could not be verified. Therefore, the present study may have underestimated the success rate.

Conclusion

In the present study, a single dose of I-131 treatment had a 49.4% success rate after six months, which increased to 60.3% after a year. Treatment failure was caused by a long disease duration of more than seven months, a large thyroid gland of more than 100 g, and the I-131 dose of 10 to 19 mCi. Therefore, to treat hyperthyroidism, I-131 doses should be adjusted based on the size of the thyroid gland.

What is already known on this topic?

The I-131 treatment is safe and has a well-established treatment response in patients with hyperthyroidism.

What this study adds?

A single dose of I-131 treatment was found to be an effective treatment. Longer disease duration and large thyroid gland were associated with treatment failure. This study recommended early treatment with an appropriate dose of I-131 to achieve successful treatment.

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Conflicts of interest

No potential conflicts of interest were disclosed.

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