Radioiodine (I-131) Dose for the Treatment of Hyperthyroidism in Rajavithi Hospital

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Background: *The main cause of hyperthyroidism is diffuse toxic goiter (Graves' disease), and the treatment of choice after medical therapy failure is radioiodine (I-131). There are two common methods of determining the optimal I-131 dose: calculated dose or fixed dose. The calculated dose method is based on the following formula: 75-200 microcuri/gram of thyroid gland divided by the percentage of radioiodine uptake at 24 hours (24-hour RAIU). As this is quite complex, some centers use fixed doses, such as 5, 10 or 15 mCi because it is simpler. At Rajavithi Hospital, the applied dose of I-131 is determined based on the thyroid gland weight assessed by palpation and other clinical factors.*

Objective: *To study the mean I-131 dose for the initial treatment of hyperthyroidism in Rajavithi Hospital, to find the clinical factors that correlate with I-131 treatment dose, and to devise a formula to predict the optimal I-131 treatment dose.*

Material and Method: *This was a retrospective study of 510 patients with a diagnosis of hyperthyroidism who received initial I-131 treatment at the Department of Nuclear Medicine in Rajavithi Hospital between January 2014 and June 2015. Baseline characteristics including age, sex, age at diagnosis, duration of antithyroid drug (ATD) therapy, gland weight (g), 3-hour RAIU and I-131 treatment dose were reviewed from medical records.*

Results: *The mean age $\pm$ SD was 41.93$\pm$14.11 years (range 14-81 years), and the male to female ratio was 4.1:1. The mean duration of ATD therapy was 3.54$\pm$4.02 years (min-max, 0.8-40.6 years). The mean gland weight was 54.35$\pm$32.95 grams, and the mean 3-hour RAIU was 55.5$\pm$23.69%. The mean I-131 treatment dose was 14.84$\pm$5.71 mCi (min-max, 7-30 mCi). There was no significant correlation between dose and age, age at diagnosis, duration of ATD therapy or 3-hour RAIU. The study showed a significant correlation between I-131 dose and gland size, r = 0.938 (p<0.001), and the regression relationship equation was: I-131 dose = 0.235 gland size, r = 0.938.*

Conclusion: *I-131 is the treatment of choice for hyperthyroidism after medical therapy failure, and there are various techniques for determining the optimal dose. At Rajavithi Hospital, the I-131 dose (mean = 14.84$\pm$5.71 mCi) is estimated based on the gland weight by palpation and other additional clinical factors. The present study provided a practical formula which is simple and practical for use in determining the I-131 dose for the treatment of hyperthyroidism: Dose of I-131 (mCi) = 0.235 x gland size (g).*

Keywords: *Hyperthyroidism, Radioiodine (I-131), 3-hour radioiodine uptake (3-hr RAIU)*

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Hyperthyroidism is a common condition, which causes inappropriately high production of the thyroid hormone. Its approximate incidence is 1.3 percent in the general population, and its prevalence is higher (4-5 percent) in older women[1]. The main causes of hyperthyroidism are diffuse toxic goiter (Graves' disease) 60-80%, and toxic nodular goiter. Graves' disease is an autoimmune disorder associated with high levels of thyroid-stimulating immunoglobulin resulting in increased thyroid activity. A toxic nodular goiter contains autonomously functioning thyroid nodule(s) with resulting hyperthyroidism.

The treatment modalities for hyperthyroidism include antithyroid drugs (ATD), radioiodine (I-131) therapy, and surgery. ATD therapy is the first line of treatment in Thailand, Japan and Europe[2,3]. The treatment of choice for hyperthyroid patients after medical therapy failure is I-131, while very large glands with severe compression undergo thyroidectomy.

Radioiodine (I-131) has been used for more than 60 years and is now widely employed in definitive treatment of hyperthyroidism in the USA because it is safe and effective. There are various techniques that can be utilized to arrive at the optimal I-131 dose, but the two most common methods are the calculated dose and the fixed dose[4-9]. Generally, the calculated dose

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method is used based on the following formula: 75-200 microcuri/g of thyroid gland divided by the percent of radioiodine uptake at 24 hours (24-hour RAIU). This is designed to achieve optimal individualization, but it is quite complex and takes time. Some centers use fixed doses, such as 5 mCi (low dose), 10 or 15 mCi (high dose) for all patients, or an estimated dose based on patients' thyroid gland size because of the fact that these techniques are simple and convenient.

The selected dose varies depending on the aim of the treatment, but the usual administered dosage ranges from 5-20 mCi. The high dose regimen is aimed at curing hyperthyroidism with low rates of recurrence, but it can cause early hypothyroidism resulting in a need for lifelong thyroxine replacement therapy. The goal of the low dose is to achieve euthyroid and avoid early hypothyroidism, which may cause a high rate of relapsed hyperthyroidism and increase the risk of cardiovascular complications from longstanding hyperthyroidism. However, most patients develop hypothyroidism after radioiodine treatment.

At Rajavithi Hospital, the dose for individual patients is estimated based on gland weight by palpation and other additional clinical factors such as age, severity of hyperthyroidism, 3-hour RAIU, duration of ATD therapy, history of adverse drug reaction and underlying cardiovascular disease. The aim is to cure hyperthyroidism and achieve a low rate of recurrence, as Rajavithi Hospital serves as a busy referral center for I-131 therapy in hyperthyroid patients in Ministry of Public Health hospitals, and most patients are referred there from other centers after the failure of long courses of ATD.

The present study aimed to find the mean I-131 dose used for the treatment of hyperthyroidism in Rajavithi Hospital, to find the clinical factors correlated with I-131 treatment dose, and arrive at a formula for predicting the optimal dose of I-131 treatment.

Material and Method

This was a retrospective study of 510 patients with a diagnosis of hyperthyroidism who received initial I-131 treatment at the Department of Nuclear Medicine in Rajavithi Hospital between January 2014 and June 2015. Baseline characteristics including age, sex, duration of ATD therapy, age at diagnosis, gland weight (g), 3-hour RAIU and I-131 treatment dose were reviewed from referral forms and medical records. The present study was approved by the research ethics committee of Rajavithi Hospital (No. 127/2558).

The protocol for I-131 treatment of hyperthyroidism includes discontinuation of ATD for 7 days before I-131 treatment; restriction of high iodine diet for 1 week; checking for the possibility of a patient being pregnant; and administration of a urine pregnancy test. Informed consent must be obtained after patients have received counseling and adequate clinical information about important issues such as clinical outcomes, complications and risk of hypothyroidism, the advisability of delaying pregnancy for at least 4-6 months, and the need for radiation protection to avoid unnecessary exposure to the family and public. Patients' 3-hour RAIU was measured with gamma spectrometer, biodex medical system (Atomlab 930) and neck phantom. The physician estimated thyroid gland size by palpation and determined the I-131 treatment dose. ATD was resumed 3 days after I-131 treatment and maintained for 1-2 months. Pregnant or breast-feeding women are contraindicated for I-131 therapy.

Statistical analysis

All analyses were performed with the statistical program SPSS version 17.0. Data were presented as mean $\pm$ standard deviation (SD) (minimum-maximum) for continuous variables and number (%) for categorical variables. Pearson's correlation was used to find correlations between dose and clinical factors. Simple and multiple linear regression analyses were performed to investigate factors that could be used to predict appropriate treatment doses of Radioiodine. A *p*-value of less than 0.05 was set for statistical significance for all tests.

Results

Five hundred ten hyperthyroid patients were included in this study. The baseline characteristics are shown in Table 1. The mean age $\pm$ SD was 41.93 $\pm$ 14.11 years (min-max, 14-81 years), and the male to female ratio was 4.1:1. The mean duration of ATD therapy was 3.54$\pm$4.02 years (min-max, 0.8-40.6 years). The mean gland weight was 54.35$\pm$32.95 grams (min-max, 20-300 grams), and the mean 3-hour RAIU was 55.5$\pm$23.69% (min-max, 8-100%). All patients received ATD therapy, either propylthiouracil (42.9%) or methimazole (57.1%), before I-131 therapy. The mean I-131 treatment dose was 14.84$\pm$5.71 mCi (min-max, 7-30 mCi).

The I-131 dose was significantly related to gland size ($r = 0.752$; $p<0.001$), but there was no significant correlation with age, age at diagnosis, duration of ATD therapy or 3-hour RAIU using Pearson's correlation (as shown in Table 2). Multiple

Table 1. Baseline characteristics (n = 510)

Characteristics	n (%)
Sex	
Male	101 (19.8)
Female	409 (80.2)
Antithyroid drug therapy	
Methimazole	291 (57.1)
Propylthiouracil	219 (42.9)
	Mean ± SD (min-max)
Age (years)	41.93±14.11 (14-81)
Age at diagnosis (years)	38.52±13.83 (10.28-80.25)
Duration of antithyroid drug therapy (years)	3.54±4.02 (0.8-40.6)
Gland size (gram)	54.35±32.95 (20-300)
3-hour radioiodine uptake (%)	55.50±23.69 (8-100)
Radioiodine (I-131) dose (mCi)	14.84±5.71 (7-30)

Table 2. The relationship between the dose and clinical factors by Pearson's correlation

	Pearson's correlation (r)	*p*-value
Age	0.076	0.088
Duration of antithyroid drug therapy	0.043	0.328
Age at diagnosis	0.071	0.107
Gland size	0.752	<0.001*
3-hour radioiodine uptake	-0.002	0.960

linear regression (Table 3) revealed that the factors that could be used to predict treatment dose of radioiodine were gland size and 3-hour RAIU ($p<0.001$) as shown in model 1. As depicted in model 2, there are two factors which determine the dose (Dose = 0.135 Gland size-0.033 (3-hour RAIU) +9.381; r = 0.762). Model 3, using a single factor (gland size), shows a significant correlation with the I-131 dose, r = 0.938 ($p<0.001$). Therefore, the author selected model 3.2 to determine the I-131 dose with a single factor (gland size). The relationship equation was I-131 dose = 0.235 x gland size, r = 0.938.

Discussion

Since 1997, the author has been treating hyperthyroidism with I-131 to achieve euthyroid using the calculated dose method based on the common formula: gland size (g) x 100-150 mCi /g divided by 24-hour RAIU. Some patients with persistent hyperthyroidism (at least 20-30%)[4,10] suffered chronic hyperthyroidism after 6-12 months of I-131 treatment, and a second or third dose of I-131 treatment was required for these cases.

The majority of the patients was referred from other centers and experienced financial problems in paying the cost of treatment and transportation. They had also received long courses of ATD therapy (duration of ATD therapy, mean = 3.54±4.02 years). Some patients in this group lived in coastal provinces of Thailand where a high iodine diet cannot be easily avoided before I-131 treatment, and this can increase the rate of I-131 treatment failure; for these reasons, a higher dose of I-131 treatment was considered. With the agreement of the referring physicians, endocrinologists and nuclear medicine staffs, a high dose of I-131 was administered in order to achieve rapid cure of hyperthyroidism and lower recurrence rates[11]. The estimated dose (mean I-131 dose =14.84±5.71 mCi, min-max= 7-30 mCi and mean I-131 dose/g = 235 mCi/g) was based on the gland weight by palpation and other clinical factors such as age, 3-hour RAIU, severity of hyperthyroidism, duration of ATD, history of adverse drug reaction and underlying (cardiovascular) disease.

A previous study[11] used a high dose of radioiodine treatment regimen based on the following formula: 8 mCi x100 divided by the 24-hour RAIU measurement. The mean radioiodine dose was 14.6 mCi. (540 MBq). The 261 hyperthyroidism patients were treated with I-131 to determine the clinical outcomes after 1 year of treatment and analyze correlations with age, ATD therapy, thyroid gland size and dose of I-131 retained in the thyroid 24 hours after administration. The cure rate of hyperthyroidism was 86% at 1 year after treatment, while 14% had persistent hyperthyroidism and required repeat treatment of I-131.

About 5-10% of cases had persistent hyperthyroidism in spite of receiving doses of up to 400 mCi (14.8 MBq)/g. The authors found that high doses of I-131 treatment were effective in treating the majority of patients with hyperthyroidism; however, young patients with larger thyroid glands, higher serum T(4) concentrations, higher 24-hour RAIU, and who had undergone ATD therapy for more than 4 months were at higher risk of treatment failure. The study also suggested that a higher dose of I-131 might be appropriate in special circumstances.

Another study[12] suggested that the goal of I-131 treatment should be to cure hyperthyroidism rather than to avoid hypothyroidism. The researchers

Table 3. The correlation between the I-131 dose and clinical factors by linear regression

	Beta	Standard error	*p*-value
Model 1 (3 factors in model)			
Gland size	0.135	0.005	<0.001*
Duration of antithyroid drug	0.037	0.050	0.458
3-hour radioiodine uptake	-0.034	0.007	<0.001*
Constant	9.266	0.491	<0.001*
Correlation coefficient (r)		0.774	
Model 2 (2 factors in model)			
Model 2.1			
Gland size	0.135	0.005	<0.001*
3-hour radioiodine uptake	-0.033	0.007	<0.001*
Constant	9.381	0.465	<0.001*
Correlation coefficient (r)		0.762	
Model 2.2			
Gland size/3-hour radioiodine uptake	6.705	0.244	<0.001*
Correlation coefficient (r)		0.773	
Model 3 (1 factor in model)			
Model 3.1			
Gland size	0.130	0.005	<0.001*
Constant	7.752	0.322	<0.001*
Correlation coefficient (r)		0.752	
Model 3.2			
Gland size	0.235	0.004	<0.001*
Correlation coefficient (r)		0.938	

Dose = 0.135, Gland size +0.037 duration of ATD-0.034 (3-hour radioiodine uptake) +9.266; r = 0.774 (model 1)
Dose = 0.135, Gland size -0.033 (3-hour radioiodine uptake) +9.381; r = 0.762 (model 2.1)
Dose = 6.705, (Gland size/3-hour radioiodine uptake); r = 0.773 (model 2.2)
Dose = 0.13, Gland size +7.752; r = 0.752 (model 3.1)
Dose = 0.235, Gland size; r = 0.938 (model 3.2)

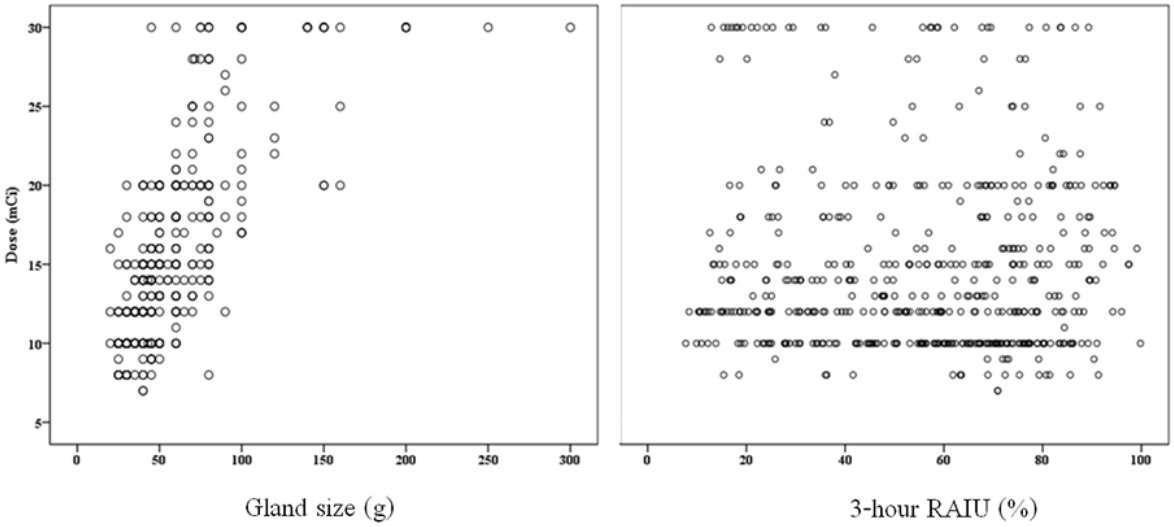

Fig. 1 The correlation between the I-131 dose and gland size, dose and 3-hour radioiodine uptake.

found that the optimal dose for accomplishing cure was 3-10 mCi, and their results showed no significant correlation between cure and age or sex. There was an inverse relationship between cure of hyperthyroidism and gland weight (Chi-square for slope, $0.01<p<0.02$). They concluded that the optimal I-131 dose for cure of hyperthyroidism could be approximated by starting with 10 mCi and increasing it to cater for large thyroid gland or for unusual cases.

Many studies have reported that 24-hour RAIU could be reliably predicted from earlier 2-4 hour radioiodine uptake[13,14]. No significant correlation was found between cure and 24-hour RAIU when 24-hour RAIU was over 30% (Chi-square for slope, $p>0.10$)[11]. To reduce the number of visits from two to a single one, they used 3-hour RAIU measurement alone for the thyroid activity. The very low iodine uptake in hyperthyroid patients, which was the cause of I-131 treatment failure, could be detected by 3-hour RAIU; however, the rapid thyroidol iodine turnover rate of hyperthyroidism, which was also a cause of treatment failure, could not be detected.

The aim of this study was to devise a formula for determining optimal doses of I-131 treatment at Rajavithi Hospital. There is a significant correlation between gland size and the administered dose of I-131, $r = 0.938$ ($p<0.001$). The suggested formula for use with a single factor (gland size) to determine the I-131 dose is: I-131 (mCi) = 0.235 x thyroid gland size (g). This is simple and convenient to use in determining the practical I-131 dose for patients with hyperthyroidism; however, this formula is not suitable for patients with very large glands (>127 gm) because the calculated dose would exceed 30 mCi, and the maximum I-131 dose for outpatients is 30 mCi as recommended by the International Commission on Radiological Protection (ICRP).

There is no consensus about the best method to use in determining I-131 treatment dose for hyperthyroidism. The key factor that can predict the ideal dose is the gland sensitivity for which there is no method of direct measurement. Most patients develop hypothyroidism after I-131 treatment[15,16].

Conclusion

I-131 therapy is the treatment of choice for hyperthyroidism after medical therapy failure, and there are various techniques, which can be used to determine the optimal dose. At Rajavithi Hospital, the applied dose (mean I-131 dose = 14.84 ± 5.71 mCi, min-max = 7-30 mCi) is estimated based on the gland weight by palpation and several other clinical factors. The present study provided a practical formula for determining the dose: I-131 (mCi) = 0.235 x gland size (g). This is simple and convenient to use in determining the I-131 dose for the treatment of hyperthyroidism.

What is already known on this topic ?

The usual dosage of I^{131} treatment for hyperthyroidism will range from 5-20 mCi.

There are two common method to determine the dose, fixed dose or calculated dose based on gland size and uptake.

What this study adds ?

To provide the formula to determine the practical I-131 treatment used for the hyperthyroidism; dose: I-131= 0.235 x gland size (g).

Potential conflicts of interest

None.

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ปริมาณสารรังสีไอโอดีน (I-131) ที่ใช้ในการรักษาผู้ป่วยไทรอยด์เป็นพิษในโรงพยาบาลราชวิถี

พิชิต ควรรักษ์เจริญ

ภูมิหลัง: ภาวะไทรอยด์เป็นพิษมักเกิดจาก Graves' disease การรักษามักเริ่มด้วยการให้ยาต้านไทรอยด์และพิจารณาให้การรักษาด้วยสารรังสีไอโอดีน (I-131) เมื่อการรักษาด้วยยาไม่สำเร็จโดยทั่วไปวิธีการคำนวณปริมาณสารรังสีไอโอดีนจะมีอยู่สองวิธีหลักคือ ใช้สูตรในการคำนวณปริมาณรังสีดังนี้ ขนาดของต่อมไทรอยด์ (กรัม) x 75-200 microcuri แล้วจึงหารด้วยค่าการทำงานของต่อมไทรอยด์ที่ 24 ชั่วโมง บางสถาบันอาจใช้ปริมาณสารเภสัชรังสีคงที่ในผู้ป่วยทุกรายเช่น 5, 10 หรือ 15 mCi เพื่อความสะดวกในโรงพยาบาลราชวิถี มีแนวทางการกำหนดปริมาณรังสี โดยประมาณจากขนาดของต่อมไทรอยด์และพิจารณาปัจจัยทางคลินิกอื่นๆ ประกอบ

วัตถุประสงค์: ศึกษาหาค่าเฉลี่ยปริมาณรังสีไอโอดีนที่ผู้ป่วยได้รับในการรักษาภาวะไทรอยด์เป็นพิษ หาปัจจัยที่มีความสัมพันธ์กับการกำหนดปริมาณรังสีไอโอดีนที่ใช้ในการรักษาและสร้างสมการในการคำนวณปริมาณรังสีไอโอดีนที่ใช้รักษาไทรอยด์เป็นพิษ

วัสดุและวิธีการ: เป็นการศึกษาย้อนหลังโดยการเก็บรวบรวมข้อมูลผู้ป่วย 510 รายที่เข้ารับการรักษาไทรอยด์เป็นพิษ ด้วยรังสีไอโอดีนที่แผนกเวชศาสตร์นิวเคลียร์ โรงพยาบาลราชวิถีตั้งแต่ เดือนมกราคม พ.ศ. 2557 ถึง มิถุนายน พ.ศ. 2558 โดยรวบรวมข้อมูลจากบันทึกเวชระเบียนได้แก่ อายุ, เพศ, อายุที่เป็นโรค, ระยะเวลาที่ใช้ยาต้านไทรอยด์, ขนาดของต่อมไทรอยด์, ค่าการทำงานของต่อมไทรอยด์ที่ 3 ชั่วโมง และปริมาณรังสีไอโอดีนที่ได้รับเพื่อรักษาภาวะไทรอยด์เป็นพิษ

ผลการศึกษา: ผู้ป่วยมีอายุเฉลี่ย 41.93±14.11 ปี (อายุต่ำสุด-อายุสูงสุด, 14-81 ปี) อัตราส่วนผู้ป่วยชายต่อผู้ป่วยหญิงเท่ากับ 4.1:1 ระยะเวลาที่ใช้รักษาด้วยยาต้านไทรอยด์เฉลี่ยเท่ากับ 3.54±4.02 ปี (ต่ำสุด-สูงสุด, 0.8-40.6 ปี), ขนาดของต่อมไทรอยด์เฉลี่ยเท่ากับ 54.35±32.95 กรัม, ค่าการทำงานของต่อมไทรอยด์ที่ 3 ชั่วโมงเฉลี่ยเท่ากับ 55.5±23.69%, ปริมาณรังสีไอโอดีนที่ได้รับเฉลี่ยเท่ากับ 14.84±5.71 mCi (ต่ำสุด-สูงสุด 7-30 mCi) โดยขนาดของต่อมไทรอยด์มีความสัมพันธ์อย่างมีนัยสำคัญทางสถิติกับปริมาณรังสีและได้สมการความสัมพันธ์ดังนี้ปริมาณรังสีไอโอดีน = 0.235x ขนาดของต่อมไทรอยด์ (กรัม), r = 0.938 ($p<0.001$)

สรุป: การรักษาไทรอยด์เป็นพิษจะพิจารณาให้การรักษาด้วยสารรังสีไอโอดีนในกรณีที่การรักษาด้วยยาไม่สำเร็จ อย่างไรก็ตามวิธีการกำหนดปริมาณรังสีที่ใช้รักษายังมีความแตกต่างกันในโรงพยาบาลราชวิถีมีแนวทางการกำหนดปริมาณรังสีโดยประมาณจากขนาดของต่อมไทรอยด์รวมกับพิจารณาปัจจัยทางคลินิกอื่นๆ ประกอบโดยปริมาณรังสีไอโอดีนที่ใช้ในการรักษาเฉลี่ยเท่ากับ 14.84±5.71 mCi และได้สมการความสัมพันธ์ระหว่างปริมาณรังสีที่ใช้ในการรักษากับขนาดของต่อมไทรอยด์ดังนี้ ปริมาณรังสีไอโอดีน = 0.235x ขนาดของต่อมไทรอยด์ (กรัม), r = 0.938 ($p<0.001$) ซึ่งสามารถใช้ในการกำหนดปริมาณรังสีในการรักษาผู้ป่วยไทรอยด์เป็นพิษได้ง่ายและมีประสิทธิภาพ