A Prospective Randomized Study of the Efficacy and Cost-Effectiveness of High and Low Dose Regimens of I-131 Treatment in Hyperthyroidism

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Objective: *To compare the efficacy and cost-effectiveness of high and low dose regimens of I-131 treatment in patients with hyperthyroidism.*

Material and Method: *One hundred fifty patients with proven hyperthyroidism were randomly allocated into the high (74 patients) and low (76 patients) dose regimen of I-131 treatment. Four patients of the high dose group and one patient of the low dose group were excluded because of lost follow-up. A gland-specific dosage was calculated on the estimated weight of thyroid gland and 24-hour I-131 uptake. The high and low I-131 dose regimens were 150 μCi/gm and 100 μCi/gm, respectively. The first mean radioiodine activity administered to the high and low dose group was 10.2 and 8 mCi, respectively. Repeated treatment was given to 25 patients of the high dose group and 40 patients of the low dose group. Clinical outcome and calculated costs for outpatient attendances, and laboratory tests together with initial and subsequent treatments were evaluated for one year after I-131 treatment. Elimination of hyperthyroidism that resulted in either euthyroidism or hypothyroidism was classified as therapeutic success. The cost effectiveness was also compared.*

Results: *At 6 months after treatment, 45 (64.3%) patients receiving high dose and 59 (78.7%) patients receiving low dose were hyperthyroidism. Clinical outcome at one year showed persistence of hyperthyroidism in 21 (30%) patients of the high dose regimen and 36 (48%) patients of the low dose regimen. At one year post treatment, it was demonstrated that the high dose regimen could eliminate hyperthyroidism in a significantly shorter time than the low dose regimen, i.e., 259.6 days and 305.5 days, respectively, p = 0.008). For the persistent hyperthyroid patients, the average total cost of treatment in the low dose group was significantly higher than that of the high dose group, i.e., 13,422.78 baht and 10,942.79 baht, respectively; p = 0.050)*

Conclusion: *A high dose regimen of radioactive iodine treatment is more effective than the low dose regimen. The successful outcome of a high dose regimen occurred significantly earlier than that of the low dose regimen. For the persistent hyperthyroid patients, the average total cost in the low dose group was significantly higher than that of the high dose group.*

Keywords: *Radioiodine treatment, High and low dose regimens, Hyperthyroidism, Cost-effectiveness*

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Radioiodine-131 therapy has been accepted as the most common modality of treatment for hyperthyroidism not only after initial presentation but also after failure of antithyroid drug and surgery[1]. Although it had been used for more than 50 years, there has been no consensus on how to determine the optimal I-131 treatment dose[2]. This may relate to different philosophies regarding the desired outcome after radioiodine treatment. The techniques for its administration vary widely and can be classified into a fixed dose regimen for all patients, a dose corrected for the size of the gland and 24-hour thyroid I-131 uptake, and a regimen of calculated dose to deliver a specific radiation dose to the thyroid[2].

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Since 1956, patients with hyperthyroidism referred to the Division of Nuclear Medicine, Siriraj Hospital have been treated with a calculated low dose regimen based on the estimated weight of the gland and the 24-hour uptake in order to restore euthyroidism. The goal of radioiodine therapy for hyperthyroidism is to destroy sufficient thyroid tissue to cure hyperthyroidism with one dose of I-131 but nearly 40% of the presented patients needed additional doses of I-131 treatment[3]. In the present study, the authors compared the efficacy and cost-effectiveness of high and low dose regimens of I-131 treatment in a prospective randomized trial.

Material and Method

Subjects

One hundred fifty patients (120 women and 30 men with a mean age of 41.4 ± 14.2 years, range 18-77 years) referred to the Division of Nuclear Medicine, Faculty of Medicine Siriraj Hospital for the first radioiodine-131 treatment were enrolled. All patients had proven thyrotoxicosis confirmed by suppressed thyroid-stimulating hormone (TSH), elevated serum thyroid hormones (total T4 and/or total T3) and 24-hour I-131 uptake.

Exclusion criteria included a patient younger than 18 years, a pregnant or lactating patient, a patient who had previously been treated with radioactive iodine or surgery and a patient who refused to be treated by radioactive iodine. All patients were taken off the antithyroid drug 5 to 7 days before I-131 treatment. The protocol was approved by the Siriraj Ethics Committee for Human Experiment and a written informed consent was obtained from each subject.

Therapeutic dose regimen

The dose of I-131 was calculated as follows: dose I-131 = (thyroid weight x dose regimen)/% I-131 uptake at 24 hours. The size and type of goiter was evaluated on the basis of physical examination by two nuclear medicine physicians. The ways to assess thyroid size was relative to the size of a normal thyroid gland (15-20 g for adults), which is usually sufficient for determining the radioiodine dose mentioned by Rivkees et al because even when accurate gland size, uptake and effective I-131 half-times were measured and a fairly high degree of accuracy of delivered dose was obtained, the outcome was still imprecise due to individual variation in the sensitivity of the thyroid to radioiodine[4,5]. The high and low I-131 dose regimens were 150 μCi/gm and 100 μCi/gm, respectively. Patients were treated in blocks of four in random order using a random number generator. The randomization list was generated and the patients were blinded until the end of the follow-up period. Radioiodine therapy was given with standardized radiation protection guidelines and the information that permanent hypothyroidism was a likely outcome from I-131 treatment. Patients were classified into two groups according to the I-131 dose regimen: the high dose group included 74 (49%) patients and the low dose group included 76 (51%) patients. Four patients of the high dose group and one patient of the low dose group were excluded due to lost follow-up (Fig. 1, Table 1). The first mean of radioiodine activity administered to the high and low dose groups was 10.2 ± 5.5 (range 3-24) and 8 ± 4.3 (range 4-27) mCi, respectively (Table 2). All patients were assigned for 1, 3 and 6 months follow-up appointments after treatment. The antithyroid drug was restarted seven days following I-131 therapy in some patients depending on the judgment of the nuclear medicine physician.

Follow-up after I-131 treatment

At six months after I-131 treatment, the repeated dose of I-131 treatment judged by nuclear medicine physicians was given to 25 patients of the high dose group and 40 patients of the low dose group (Table 3). The rest of the persistent hyperthyroidism patients received an antithyroid drug. Patients with

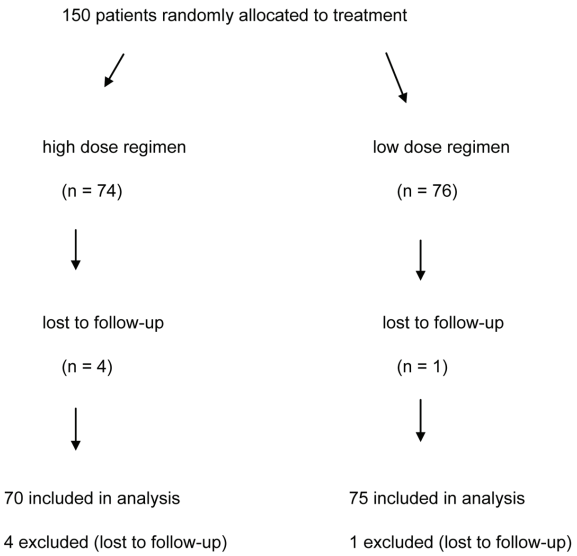

Fig. 1 Flow diagram of a trial comparing high dose with low dose of I-131 treatment for hyperthyroidism

Table 1. Baseline demographic and clinical characteristics of high and low dose groups

Clinical characteristics	High dose group (n = 70)	Low dose group (n = 75)	p-value
Gender: female, n (%)	60 (85.7)	59 (78.7)	0.269*
Age, yr	41.8 ± 14.8	41.3 ± 14.1	0.828*
Duration of hyperthyroidism, yr	4.1 ± 3.3	4.7 ± 4.3	0.663*
Duration of antithyroid drug, yr	3.6 ± 3.3	4.2 ± 4.2	0.548*
Character of thyroid gland, n (%)			
Diffuse enlarged	61 (87.1)	58 (77.3)	0.124*
Nodular enlarged	9 (12.9)	17 (22.7)	
Size of thyroid gland, gm	50 ± 23.8	58 ± 32.0	0.078**

Data are means ± SD
* Unpaired t-test, ** Mann-Whitney U test

Table 2. Clinical characteristics of first I-131 treatment of high and low dose groups

Clinical characteristics	High dose group (n = 70)	Low dose group (n = 75)
First 24-hr I-131 uptake, %	75.8 ± 11.8	75.5 ± 10.9
First I-131 dose, mCi	10.2 ± 5.5	8.0 ± 4.3
Receiving antithyroid drug after first I-131 dose, n (%)	61 (87.1)	67 (89.4)
Complication after first I-131 dose, n (%)		
Nausea	5 (7.1)	3 (4)
Heart failure	1 (1.4)	0 (0)
Thyroiditis	3 (4.3)	1 (1.3)
Result of I-131 treatment, n (%)		
Hyperthyroidism	45 (64.3)	59 (78.7)
Euthyroidism	6 (8.6)	4 (5.3)
Hypothyroidism	19 (27.1)	12 (16.0)

Data are means ± SD

Table 3. Clinical characteristics of the second I-131 treatment of high and low dose groups

Characteristics	High dose group (n = 25)	Low dose group (n = 40)	p-value*
Size of thyroid gland before the 2nd I-131, gm	35.4 ± 13.2	46.7 ± 29.6	0.040
2nd 24-hr I-131 uptake, %	66.2 ± 13.7	72.1 ± 12.5	0.079
2nd I-131 dose, mCi	6.5 ± 1.9	7.1 ± 5.3	
High dose	7.5 ± 1.9 (n = 11)	16.2 ± 8.1 (n = 5)	
Low dose	5.7 ± 1.7	5.8 ± 3.2	0.517
Receive antithyroid drug after 2nd I-131 dose, n (%)	17 (68)	39 (97.5)	0.001
Complication after 2nd I-131 dose, n (%)			
Nausea	0 (0)	1 (2.3)	
Heart failure	1 (2.7)	0 (0)	

Data are means ± SD
* Unpaired t-test

hypothyroidism confirmed by elevated serum TSH were treated with L-T4. Follow-up of all patients ended at one year after I-131 treatment. Clinical outcomes were evaluated. Elimination of hyperthyroidism, which resulted in either euthyroidism or hypothyroidism, was classified as therapeutic success. Time to success was

calculated from the date of first I-131 treatment to the date of successful treatment confirmed by the results of in vitro thyroid function tests.

Evaluation of cost

Costs were evaluated with respect to patient's perspective. The costs were categorized into two groups, which consisted of direct health care and non-health care costs. The present study did not include intangible cost. Direct health care cost included the costs of 24-hr I-131 uptake, I-131 therapy, thyroid hormones measurements, antithyroid drug with all related drugs for the treatment of hyperthyroidism and thyroid hormone replacement in patients who developed hypothyroidism (Table 4). Direct non-health care cost was calculated from the expenditure of the patient for the treatment and follow-up of I-131 *e.g.* travelling, food and accommodation.

Statistical analysis

Results were reported as the percentage, mean and standard deviation. Comparison of success and failure after high and low dose regimens of I-131 treatment were analyzed using X^2 test. The Kaplan-Meier method was used to estimate the time to successful treatment. The log-rank test was used to test the difference in time to success between the high and low dose groups at six months and one year after the first I-131 treatment. The Cox regression model was used to compare the pretreatment weight and type of the thyroid gland for successful outcome of I-131 treatment. A p-value of less than 0.05 was considered statistically significant.

Table 4. Direct health care cost of investigations and treatments

Investigations/treatments	Cost (baht)
24-hr I-131 uptake	1,000
Thyroid stimulating hormone assay	200
Total T4 assay	180
Total T3 assay	200
I-131 therapy	3,000
Drug therapy (price per 1 tablet)	
Propylthiouracil (50 mg)	1
Methimazole (5 mg)	1.50
Thyroxine (0.1 mg)	1
Thyroxine (0.05 mg)	1.50

***** Costs obtained from Faculty of Medicine Siriraj Hospital, 2007

Results

At six months after I-131 treatment, 104 (71.7%) patients remained hyperthyroidism comprised of 45 (64.3%) patients of the high dose group and 59 (78.7%) patients of the low dose group. Euthyroidism and hypothyroidism were achieved in 6 (8.6%) patients and 19 (27.1%) patients of the high dose group together with 4 (6.3%) patients and 12 (16%) patients of the low dose group, respectively (Table 2). One year after I-131 treatment, elimination of hyperthyroidism was achieved in 49 (70%) patients of the high dose group and 39 (52%) patients of the low dose group while 21 (30%) patients of the high dose group and 36 (48%) patients of the low dose group remained hyperthyroid (Table 5). Significant difference in the rate of successful treatment was found at one year in the patients who received the first I-131 treatment with high dose regimen; X^2 test, $p = 0.027$.

No significant difference in the time to successful treatment at six months between the two groups (164.7 ± 3.9 days in the high dose group and 173 ± 2.9 days in the low dose group; Mantel-Cox Log Rank test, $p = 0.063$) (Fig. 2) but at one year post treatment, the high dose group had eliminated hyperthyroidism in a significantly shorter time than the low dose group, *i.e.*, 259.6 ± 12.2 days and 305.5 ± 10.3 days, respectively; Mantel-Cox Log Rank test, $p = 0.008$) (Table 6, Fig. 3).

The average total cost for cure was not significantly different in both groups ($11,016.94 \pm 4,121.77$ baht and $12,153.55 \pm 4,608.00$ baht for the high and low dose groups, respectively; unpaired t-test, $p = 0.121$) but for the persistent hyperthyroid patients, the average total cost in the low dose group was significantly higher than that of the high dose group ($10,942.79 \pm 3,595.08$ baht and $13,422.78 \pm 5,743.13$ baht for the high and low dose groups, respectively; unpaired t-test, $p = 0.050$) (Table 7).

The high first dose of radioiodine treatment was a contributing factor for a successful outcome (Adjusted hazard ratio, 1.63; 95% CI, 1.06-2.51; $p = 0.026$) (Table 8). Cox regression model showed the weight of thyroid gland less than 40 grams to be a significant contributing factor to the success of I-131 treatment (Adjusted hazard ratio, 1.85; 95% CI, 1.18-2.90; $p = 0.007$). Using Cox regression model, the contribution of the type of thyroid gland to successful outcome of radioiodine treatment was not statistically significant (Adjusted hazard ratio, 1.26; 95% CI, 0.67-2.39; $p = 0.476$).

Table 5. Results of I-131 treatment in high and low dose groups

Result of treatment	High dose group (n = 70)	Low dose group (n = 75)	p-value*
Success at 6 months (%)	25 (35.7)	16 (21.3)	0.055
Success at 12 months (%)	49 (70)	39 (52)	0.027

* X^2 test

Table 6. Time to success of the high and low dose regimens of I-131 treatment in hyperthyroidism

Time to success after I-131 treatment	High dose group (n = 70)	Low dose group (n = 75)	p-value*
Six months evaluation, day	164.7 ± 3.9	173 ± 2.9	0.063
Twelve months evaluation, day	259.6 ± 12.2	305.5 ± 10.3	0.008

Data are means ± SD
* Mantel-Cox Log Rank test

Table 7. Costs of treatment in the high and low dose regimens of I-131 treatment

Cost of treatment, baht	High dose group (n = 70)	Low dose group (n = 75)	p-value*
Total	11,016.94 ± 4,121.77	12,153.55 ± 4,608.00	0.121
Failure group	10,942.79 ± 3,595.08	13,422.78 ± 5,743.13	0.050
Success group	11,048.71 ± 4,392.69	10,981.95 ± 2,834.66	0.934

Data are means ± SD
* Unpaired t-test

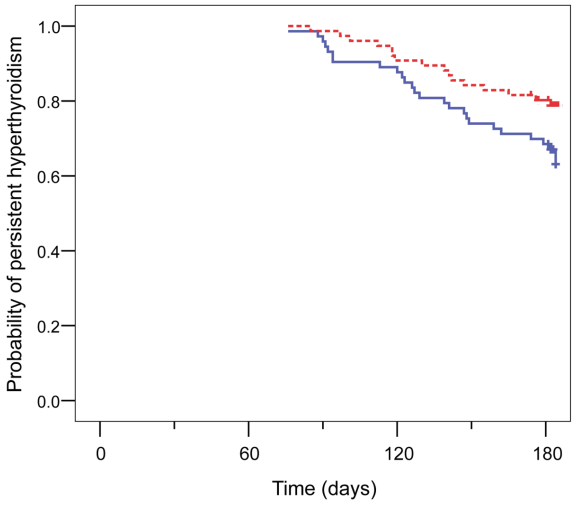

Fig. 2 Kaplan-Meier plot showing probability of persistent hyperthyroidism during the first 6 months after first treatment as a function of time of the high (solid line) and low dose (dotted line) groups

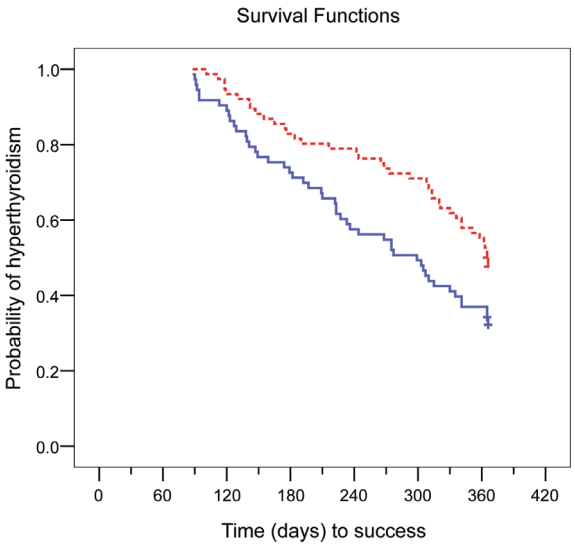

Fig. 3 Kaplan-Meier plot showing probability of persistent hyperthyroidism during 1 year after first treatment as a function of time of the high (solid line) and low dose (dotted line) groups

Table 8. Predictive factors of a successful response to I-131 treatment using Cox regression model

	Adjusted hazard ratio of successful response	95% confidence interval	p-value*
Group of treatment: high dose	1.63	1.06-2.51	0.026
Weight of thyroid gland: < 40 gm	1.85	1.18-2.90	0.007
Type of thyroid gland: diffuse goiter	1.26	0.67-2.39	0.476

* Cox regression model

Discussion

Radioactive iodine was introduced for the treatment of hyperthyroidism by Hertz and Roberts in the United States in 1941 and was first used in Siriraj Hospital in 1956[4]. Because the optimal outcome of I-131 treatment for hyperthyroidism is euthyroidism without post-ablative hypothyroidism, low dose regimen has been used in Siriraj Hospital from the beginning. The disadvantage of a low dose regimen; however, was prolonged hyperthyroidism from treatment failure and the further requirement of additional antithyroid drug or repeated treatment with radioactive iodine. The present prospective study aimed to compare the efficacy and cost-effectiveness of the high and low dose regimens.

Literature review showed that at one year after radioiodine treatment, failure outcomes ranged from 10.8% to 29% (mean 18.6%) in patients receiving high dose regimen and 8.3-51.5% (mean 29.2%) in the low dose regimen[5-15]. The present study showed that at 6 months after I-131 treatment, 45 (64.3%) patients receiving high dose and 59 (78.7%) patients receiving low dose were hyperthyroid and at one year clinical outcome showed persistence of hyperthyroidism in 21 (30%) patients of the high dose group and 36 (48%) patients of the low dose group, which were significantly different ($p = 0.027$). The authors' successful outcome may be rather low compared to previous reports. This was due to the chosen time of follow-up in the authors' prospective study design which is similar to the study by Peters et al who found a success rate of more than 90% in the retrospective study while there was only 71% of success outcome in the prospective study[9]. Although the success outcome at six months in both groups may not be statistically significant, there were two factors that showed tendency of the better results in the high dose regime. These two factors were the decrease in size of the thyroid gland which was significantly decreased in the high dose regime ($p = 0.040$) and the small number of patients receiving antithyroid drug after repeated I-131 treatment in the high dose regime ($p = 0.001$). In addition, the second mean 24-hr I-131 uptake in the high dose regimen showed a tendency to be of lower value than that of the low dose regime, which might reflect lower toxicity of hyperthyroidism in the high dose group after the first I-131 treatment.

The authors' findings showed that it was difficult to reach the aim of euthyroidism, as most of the successful outcomes of both regimes were hypothyroidism. Additionally, at 1 year the patients of the high dose regimen recovered from hyperthyroidism in a significantly shorter time than the low dose group (p-value = 0.008). Average cost of the treatment for the successful outcome in both groups showed no statistical difference ($p = 0.934$) but for the failure outcomes, average cost of the patient receiving a high dose of I-131 were significantly lower than that of the low dose regimen. This was most likely due to the less severe clinical characteristics of the high dose group after initial I-131 treatment and fewer requirements of further medical treatment and follow-up. Successful treatment was significantly demonstrated in patients with thyroid size smaller than 40 grams ($p = 0.007$). Thus radioactive iodine treatment using high dose regime seems to be more effective and appropriate for hyperthyroidism than the low dose regimen, especially in those with severe complications from hyperthyroidism or antithyroid drug.

Hyperthyroidism results in an increase in the heart rate, systolic blood pressure and pulse pressure, left ventricular contractility and the frequency of atrial arrythmias known as atrial fibrillation[16,17]. Atrial fibrillation occurs in 5% to 15% of patients with hyperthyroidism[18]. The prevalence rates are high in older patients with known or suspected underlying organic heart disease[19,20]. One patient in the present study had atrial fibrillation and congestive heart failure after radioiodine treatment, which was most likely due to the severity of hyperthyroidism.

Conclusion

Radioiodine is a safe and easy method for the treatment of hyperthyroidism. The successful outcome of the high dose regimen occurred earlier than that of the other regimen. For the persistent hyperthyroid patients, the average total cost of the low dose regimen was significantly higher than that of the high dose group. Therefore, the high dose regimen is more efficient and cost-effective than the low dose regimen.

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Potential conflicts of interest

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การศึกษาเปรียบเทียบไปข้างหน้าแบบสุ่มเพื่อประเมินประสิทธิภาพ และความคุ้มค่าของต้นทุนประสิทธิผลในการรักษาภาวะไทรอยด์เป็นพิษโดยการใช้ไอโอดีน-131 ด้วยความแรงรังสีสูงและต่ำ

ภาวนา ภูสุวรรณ, มลุลี ตัณฑวิรุฬห์, นภมน ศรีตงกุล, พจี เจาฑะเกษตริน, เชิดชัย นพมณีจำรัสเลิศ, จุฬาลักษณ์ โกมลตรี, กุลธร เทพมงคล, เบญจาภา เขียวหวาน, พงษ์พิชา ตู้จินดา, สุทิน ศรีอัษฎาพร

วัตถุประสงค์: *เพื่อเปรียบเทียบประสิทธิภาพและความคุ้มค่าของต้นทุนประสิทธิผลของการรักษาภาวะไทรอยด์เป็นพิษ ด้วยไอโอดีนรังสีแบบความแรงรังสีสูงและต่ำ*

วัสดุและวิธีการ: *ทำการสุ่มผู้ป่วยไทรอยด์เป็นพิษ 150 ราย ที่ถูกส่งมารับการรักษาด้วยไอโอดีน-131 เป็นสองกลุ่ม โดยผู้ป่วย 74 ราย ได้รับการรักษาด้วยความแรงรังสีสูง ผู้ป่วย 4 ราย ในกลุ่มที่ได้รับความแรงรังสีสูงและ 1 ราย ในกลุ่มได้รับความแรงรังสีต่ำถูกคัดออกเนื่องจากไม่ได้มาตรวจติดตามผล ความแรงรังสีต่อน้ำหนักต่อมไทรอยด์ที่ใช้ในกลุ่มได้รับความแรงรังสีสูงและต่ำคือ 150 ไมโครคูรี/กรัม และ 100 ไมโครคูรี/กรัมตามลำดับ ความแรงรังสีเฉลี่ยของไอโอดีนรังสีที่ใช้รักษาครั้งแรกในกลุ่มความแรงรังสีสูงและต่ำคือ 10.2 และ 8 มิลลิคูรีตามลำดับ มีผู้ป่วย 25 ราย ในกลุ่มความแรงรังสีสูง และ 40 ราย ในกลุ่มได้รับความแรงรังสีต่ำ ได้รับไอโอดีนรังสีซ้ำ ทำการศึกษาผลการรักษาทางคลินิกและค่าใช้จ่ายในการรักษา ซึ่งคิดจากค่าใช้จ่ายในการมารับการตรวจรักษาค่าตรวจทางห้องปฏิบัติการและการรักษาที่เกี่ยวข้องจนครบระยะเวลาหนึ่งปีหลังการรักษาด้วย ไอโอดีน-131*

ผลการศึกษา: *ที่ 6 เดือนหลังรักษาพบผู้ป่วยที่ยังคงมีภาวะไทรอยด์เป็นพิษ 45 ราย (ร้อยละ 64.3) ในกลุ่มได้รับความแรงรังสีสูงและ 59 ราย (ร้อยละ 78.7) ในกลุ่มได้รับความแรงรังสีต่ำ ผลการรักษาที่หนึ่งปีพบว่าผู้ป่วยในกลุ่มที่ได้รับความแรงรังสีสูง 21 ราย (ร้อยละ 30) และผู้ป่วย 36 ราย (ร้อยละ 48) ของกลุ่มได้รับความแรงรังสีต่ำ ยังคงมีภาวะไทรอยด์เป็นพิษ ที่หนึ่งปีหลังการรักษาพบว่ากลุ่มได้รับความแรงรังสีสูงสามารถหายจากภาวะไทรอยด์เป็นพิษได้เร็วกว่ากลุ่มได้รับความแรงรังสีต่ำอย่างมีนัยสำคัญทางสถิติ (259.6 วัน ในกลุ่มได้รับความแรงรังสีสูง และ 305.5 วัน ในกลุ่มได้รับความแรงรังสีต่ำ ค่า $p = 0.008$) ในกลุ่มที่ยังมีภาวะไทรอยด์เป็นพิษที่หนึ่งปีหลังรักษา กลุ่มที่ได้รับความแรงรังสีต่ำจะมีค่าใช้จ่ายเฉลี่ยสูงกว่าอย่างมีนัยสำคัญทางสถิติ (10,942.79 บาท และ 13,422.78 บาท ในผู้ป่วยที่ได้รับการรักษาด้วยความแรงรังสีสูงและต่ำตามลำดับ $p = 0.050$)*

สรุป: *การรักษาด้วยไอโอดีนรังสีความแรงรังสีสูงมีประสิทธิภาพสูงกว่า และทำให้ผู้ป่วยหายจากภาวะไทรอยด์เป็นพิษเร็วกว่าการรักษาด้วยความแรงรังสีต่ำอย่างมีนัยสำคัญทางสถิติ ในผู้ป่วยที่ยังอยู่ในภาวะไทรอยด์เป็นพิษที่หนึ่งปีหลังรักษาด้วยไอโอดีนรังสี พบว่ากลุ่มที่เริ่มต้นการรักษาด้วยความแรงรังสีต่ำมีค่าใช้จ่ายของการรักษาเฉลี่ยสูงกว่ากลุ่มที่เริ่มต้นการรักษาด้วยความแรงรังสีสูงอย่างมีนัยสำคัญทางสถิติ*