Journal of
Babol University of Medical Sciences
JBUMS
e-ISSN: 2251-7170 p-ISSN: 1561-4107

Efficacy of Low-Dose versus High-Dose Radioactive Iodine for Thyroid Remnant Ablation in Low- and Intermediate-Risk Papillary Thyroid Carcinoma

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Article Type
Research Paper

Received:
May 11st 2025
Revised:
Jun 23rd 2025
Accepted:
Aug 16th 2025

ABSTRACT

Background and Objective: One of the major challenges in the treatment of thyroid carcinoma is selecting the appropriate dose of radioactive iodine for post-surgical thyroid remnant ablation. For patients with low- and intermediate-risk disease, precise determination of the therapeutic dose remains a matter of uncertainty. The aim of this study was to evaluate the effect of low-dose versus high-dose radioactive iodine on treatment outcomes in this group of patients.

Methods: In this retrospective cohort study, 151 patients with thyroid carcinoma were allocated into two groups: a low-dose group (30 mCi) and a high-dose group (100 mCi). Age, sex, physical health status, laboratory markers, iodine-131 whole-body scan findings, and ultrasonography findings were compared between the two groups before radioiodine ablation and at a 1-year follow-up interval.

Findings: A total of 151 patients were enrolled in the study, of whom 124 (82.1%) were female and 27 (17.9%) were male. Based on the first-year follow-up, among the 151 patients studied, 33 patients (21.9%) were classified as having an indeterminate response (IR) and 118 patients (78.1%) as having an excellent response (ER). No significant difference in treatment success was observed between the groups, and the prescribed dose did not have a significant impact on treatment outcomes.

Conclusion: The findings of the present study demonstrated that low-dose radioactive iodine was as effective as high-dose radioactive iodine in achieving successful ablation in patients with initially low- and intermediate-risk thyroid carcinoma.

Keywords: *Differentiated Thyroid Carcinoma, Radioactive Iodine Therapy, Thyroid Remnant Tissue, Thyroglobulin.*

Cite this article: Gholami A, Nourozi A, Gholinia H, Mousavie Anijdan SH. Efficacy of Low-Dose versus High-Dose Radioactive Iodine for Thyroid Remnant Ablation in Low- and Intermediate-Risk Papillary Thyroid Carcinoma. *Journal of Babol University of Medical Sciences*. 2026; 28: e44.

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Introduction

Thyroid cancer is one of the most prevalent endocrine malignancies, and its incidence has risen substantially over recent decades. Differentiated thyroid cancer (DTC), which constitutes more than 95% of all thyroid cancer cases, generally carries a favorable prognosis, and patients with this malignancy typically have a high likelihood of long-term survival with appropriate management. The primary treatment for DTC comprises thyroid surgery followed by radioactive iodine (^{131}I) therapy, also known as radioiodine remnant ablation (RRA). The objective of RRA is to eliminate residual thyroid tissue following surgery, which, in addition to improving disease-free survival, may also facilitate the treatment of patients with resistant and high-risk lesions. This treatment is typically employed to reduce the probability of disease recurrence and to detect occult and microscopic metastases in surrounding tissues (1, 2).

However, one of the principal challenges in the treatment of DTC is the selection of an appropriate radioactive iodine (RAI) dose. Various studies have demonstrated that the extent of surgery and the precise RAI dose exert a considerable influence on treatment outcomes. In particular, with respect to thyroid surgery, it has been emphasized that experienced surgeons are capable of performing surgery with fewer complications, shorter hospital stays, and superior outcomes compared with less experienced surgeons. In this context, some studies have shown that surgery performed by experienced surgeons is associated with lower complication rates, which in turn improves patients' quality of life following surgery. Alongside these surgical benefits, it should be noted that RRA may also cause certain adverse effects on normal body tissues. These adverse effects include neck pain, salivary gland swelling, dry mouth, taste disturbances, and, in rare cases, the development of secondary cancers. These adverse effects have prompted increased discussion and scrutiny regarding the use of RAI as a therapeutic modality, particularly in patients with low- and intermediate-risk disease who may not require high-dose therapy (3-5).

In 2015, the American Thyroid Association (ATA) stratified patients with DTC into three groups—low-, intermediate-, and high-risk—according to the risk of disease recurrence following surgery. While high-dose RRA is widely accepted in high-risk patients, this treatment remains a subject of uncertainty for patients with low- and intermediate-risk disease. Historically, a fixed dose of 3.7 gigabecquerels (100 millicuries) was administered to treat these patients; however, recent studies have demonstrated that low-dose therapy (1.1 gigabecquerels) achieves approximately the same outcomes as high-dose therapy and may be considered an effective and low-risk option for patients with low- and intermediate-risk disease (6). Therefore, the present study aims to evaluate the effect of RAI dose (low-dose versus high-dose) on treatment outcomes in patients with low- and intermediate-risk DTC. This research may contribute to improving therapeutic practices and selecting the appropriate dose for this patient group, and may offer strategies for reducing adverse effects and additional costs in the treatment of thyroid cancer. In essence, the ultimate objective is to provide more effective treatments with the fewest adverse effects and costs through the use of lower doses. This study may not only assist in optimizing treatment approaches but may also help determine the most effective strategies for reducing treatment-related adverse effects, thereby improving the quality of life of patients with thyroid cancer.

Furthermore, investigating the effect of therapeutic dose in patients with low- and intermediate-risk thyroid cancer may be particularly beneficial in regions with limited medical resources. Many patients in such regions may, for various reasons, be unable to receive more complex treatments, such as high-dose radioactive iodine, and the use of lower doses may be proposed as a suitable alternative for this patient population. In addition, this research may lead to the revision and improvement of treatment guidelines at the international level and may be especially helpful in regions where new protocols for the treatment of thyroid cancer have recently been established.

Methods

The present retrospective, observational, single-center cohort study was conducted following approval from the Ethics Committee of Babol University of Medical Sciences (approval code: IR.MUBABOL.HRI.REC.1403.221). The medical records of all patients with DTC who had undergone total thyroidectomy, with or without neck lymph node dissection, and who had been referred to the Nuclear Medicine Department of Shahid Beheshti Hospital in Babol for RAI therapy were reviewed. In addition, demographic details, medical history, thyroid and neck ultrasonography records, serum levels of thyroid-stimulating hormone (TSH), thyroglobulin (Tg), thyroglobulin antibodies (TgAb), and details of levothyroxine therapy were documented. Furthermore, surgical reports, tissue pathology results, information regarding RAI therapy, radiological findings, and the resulting treatment outcomes were analyzed.

Patients were included in the study if they were over 18 years of age and had a history of total thyroidectomy, with or without neck lymph node dissection, with papillary histology, and if laboratory marker data such as Tg, TSH, and TgAb were available. Patients were excluded if aggressive histological types were present in the thyroid biopsy specimen, if distant metastasis was present, if TgAb was positive at any time during the follow-up period, if they had other malignant tumors or Hashimoto's thyroiditis (due to elevated TgAb levels), if they were taking iodine-containing medications or drugs or foods that affect iodine uptake or metabolism, or if they were pregnant or breastfeeding. Patients with PTC who, according to TNM staging and ATA guidelines, were classified as low-risk (LR)—including T1-2mN0/xM0/x—and intermediate-risk (IR)—including T1-3N1Mx and T3N0Mx—were randomly divided into two groups: low-dose (30 millicuries) and high-dose (100 millicuries).

TSH stimulation was achieved by discontinuing levothyroxine for at least 4 weeks prior to RAI administration, and radioactive iodine was administered orally once the serum TSH concentration exceeded 30 µIU/mL. A low-iodine diet was recommended before ablation. All patients underwent physical examination and biochemical assessment prior to remnant thyroid ablation. Before RAI administration, patients fasted for at least 6 hours and then consumed food after 2 hours. Whole-body scan (WBS) was performed 3 to 7 days after RAI administration using a single-head Siemens gamma camera with a large field of view (SIEMENS Orbiter), equipped with a high-energy, high-resolution collimator.

The 2015 ATA guidelines include a dynamic risk stratification system that classifies patients' response to therapy through the use of serum Tg levels, TgAb, ultrasonography, WBS, CT, PET/CT, and MRI. The response categories are as follows: excellent response, indeterminate response, biochemically incomplete response, and structurally incomplete response. In the present study, the assessment of response to therapy was conducted 12 months after RAI treatment in accordance with the ATA risk stratification system.

A diagnostic WBS was performed 6 months after the administration of radioactive iodine (5 millicuries). At that time, serum concentrations of TSH, stimulated thyroglobulin (sTg), and TgAb were measured, and neck ultrasonography was performed. Serum concentrations of TSH, sTg, and TgAb were measured using an immunometric assay. Successful radioactive iodine ablation of thyroid remnants was defined as a combination of normal neck ultrasonography findings, undetectable serum thyroglobulin concentrations (less than 1 ng/mL), and the absence of abnormal uptake on diagnostic WBS. If any of the above conditions were not met, the case was considered unsuccessful ablation. Ultimately, based on successful ablation, patients were categorized into two groups: excellent response (ER) and indeterminate response (IR). Excellent response (ER), which represents a disease-free status, includes the following: absence of clinical

evidence of residual tumor; absence of pathologically active thyroid tissue in the thyroid bed and/or distant metastases on RAI imaging, ultrasonography; and a TSH-suppressed Tg level of less than 0.2 ng/mL or a stimulated Tg level of more than 1 ng/mL in the absence of interfering antibodies. Instances in which the above criteria were not met were considered indeterminate response (IR).

Data were analyzed using SPSS Statistics 26.0. Results were presented as mean±SD. Data were compared using logistic regression and chi-square tests, and $p<0.05$ was considered significant.

Results

In this study, of the 151 participating patients, 124 (82.1%) were female and 27 (17.9%) were male. The mean age of the patients was 43.29±13.15 years (range: 20-80 years), and the mean tumor diameter was 20.1±10.08 mm, with a range of 6 to 50 mm. The mean pre-ablation Tg level across all patients in the study group was calculated as 3.54±3.22 (range: 0.04-13.4). Of the study population, 84 patients (55.6%) had unifocal disease and 67 patients (44.4%) had multifocal disease. Specifically, in group 1, which comprised patients who received low-dose RAI therapy (30 millicuries), 47 patients had unifocal disease and 34 had multifocal disease. In group 2, which comprised patients who received high-dose RAI therapy (100 millicuries), 37 patients had unifocal disease and 33 had multifocal disease. No significant difference was observed in the number of involved foci between the two groups. The demographic and clinical characteristics of the patients in this study are presented in Table 1. Overall, regional lymph node involvement was observed in 23 patients. When analyzed by group, such involvement was identified in 10 patients in group 1 and 13 patients in group 2; this difference was not statistically significant.

Table 1. Demographic characteristics of the study patients (n=151)

Parameter	All patients	Low-dose group (30 mCi)	High-dose group (100 mCi)	p-value
Number	151	81	70	
Age (years)	43.29±13.15	42.48±12.23	44.23±14.16	0.079
Sex				
Female	124(82.1)	66(81.5)	58(82.9)	0.826
Male	27(17.9)	15(18.5)	12(17.1)	
Risk level				
Low	120(79.5)	66(81.5)	54(77.1)	0.549
Intermediate	31(20.5)	15(18.5)	16(22.9)	
Tumor size (mm)	2.1	1.96	2.25	0.111
LNM	23(15.2)	10(12.3)	13(18.6)	0.365
Multifocality	67(44.4)	34(42)	33(47.1)	0.622
Tg-b (ng/mL)	3.54±3.22	3.38±3.22	3.72±3.22	0.870
Tg-a (ng/mL)	0.57±0.79	0.56±0.73	0.59±0.86	0.846
TSH (µIU/mL)	51.5±16.5	48.78±15.46	54.6±17.29	0.062
Treatment response				
ER	118(78.1)	62(76.5)	56(80)	0.694
IR	33(21.9)	19(23.5)	14(20)	

According to the ATA guidelines, patients were categorized based on their initial risk level. A total of 120 patients were classified into the low-risk group and 31 patients into the intermediate-risk group. Stratified by group, in group 1, 66 patients were identified as low-risk and 15 as intermediate-risk, while in group 2, 54 patients were low-risk and 16 were intermediate-risk; this difference was not statistically significant. The pre-ablation serum Tg level was 3.38±3.22 ng/mL in group 1 and 3.72±3.22 ng/mL in group 2. Additionally, the post-ablation serum Tg level was 0.56±0.73 ng/mL in group 1 and 0.59±0.86 ng/mL in group 2. Among the variables examined, including sex, age, pre- and post-ablation laboratory Tg levels, initial TSH, and residual mass after ablation, no significant differences were observed between the groups.

According to the first-year follow-up data, of the 151 patients studied, 33 (21.9%) were classified as having an indeterminate response (IR), while 118 (78.1%) were classified as having an excellent response (ER). Of the patients identified as ER, 62 (76.5%) belonged to group 1 and 56 (80%) belonged to group 2. Furthermore, of the patients identified as IR, 19 (23.5%) were in group 1 and 14 (20%) were in group 2. No statistically significant difference in treatment success was observed between the two groups, and the prescribed dose did not exert a significant effect on treatment outcomes.

Finally, in the multivariate logistic regression analysis, pre-ablation Tg (Tg-b) was the only variable that was statistically significant in predicting successful ablation ($p<0.001$), such that with increasing serum Tg-b levels, the odds of ER decreased significantly (Table 2). Although other variables, including age, sex, tumor size, multifocality, LNM, received dose, and initial risk level, were not statistically significant in predicting successful ablation, some variables warrant consideration based on their significance levels. These variables include sex, multifocality, and LNM. Regarding sex, women had more than twice the odds (OR=2.67) of being classified in the ER group compared with men ($p=0.085$). In cases of lymph node metastasis (LNM), the odds of ER decreased ($p=0.087$). Unexpectedly, multifocality of the tumor increased the odds of ER (OR=2.599), although this was not statistically significant. Regarding the received dose, although high dose increased the odds of treatment response by 1.8-fold, it did not demonstrate a statistically significant association.

Table 2. Logistic regression analysis of treatment response according to clinicopathological factors

Parameter	OR	95% CI for OR	p-value
Tumor size	0.776	0.465-1.294	0.331
Age	1.013	0.976-1.051	0.49
Sex (female/male)	2.673	0.875-8.172	0.085
LNM (yes/no)	0.272	0.061-1.206	0.087
Multifocal (yes/no)	2.599	0.859-7.863	0.091
Dose (high/low)	1.837	0.075-4.785	0.213
Tg-b	0.704	0.608-0.815	<0.001
ATA Risk (Intermediate/Low)	0.507	0.159-1.618	0.140

Discussion

In the present study, no statistically significant association was found between low- and high-dose radioactive iodine in the successful ablation of patients with initially low- and intermediate-risk thyroid carcinoma. RAI therapy serves as a primary treatment modality for thyroid carcinoma, alongside surgery and thyroid hormone replacement or suppression. RAI therapy may offer numerous benefits, including a reduced prevalence of recurrence and death from thyroid carcinoma, facilitation of patient follow-up,

and the potential for early detection of metastases. Nevertheless, RAI therapy also carries potential risks, as it may cause short-term discomfort in the head and neck, gastrointestinal disturbances, transient impairment of the salivary and lacrimal glands, secondary masses, or fertility abnormalities. Therefore, special considerations regarding RAI therapy should be taken into account for low-risk patients (7). However, the optimal dose of radioactive iodine for thyroid remnant ablation remains unclear. High dose is more effective in eliminating large remnants of normal thyroid tissue and eradicating micrometastases; however, low dose may be equally effective in eliminating small remnants of normal thyroid tissue after total thyroidectomy (8).

The optimal dose of radioactive iodine for thyroid remnant ablation has become a decision-making challenge in patients with initially low- and intermediate-risk thyroid carcinoma. Dose selection is generally based on patient characteristics, tumor characteristics, and initial risk stratification, which is often performed according to the current ATA guidelines (6). According to these guidelines, routine RAI ablation is not recommended for patients with low-risk thyroid cancer; however, the use of low dose is suggested when ablation is deemed necessary. Numerous studies have demonstrated that low-dose RAI is as effective as high-dose RAI for thyroid remnant ablation in patients with low- and intermediate-risk disease. However, differences in patient selection and definitions of treatment response may lead to varying success rates across these studies (5).

Ablation with low doses of RAI in patients with low- and intermediate-risk thyroid carcinoma is an accepted approach, as recommended by the 2015 ATA guidelines. However, considerable controversy surrounds this issue, to the extent that the European Association of Nuclear Medicine and Molecular Imaging has challenged the aforementioned guidelines. Currently, no general consensus recommendation exists regarding the appropriate RAI ablation dose, and this decision should be made within a multidisciplinary approach (9).

In the present study, the effect of low-dose RAI ablation was evaluated in patients with low- and intermediate-risk thyroid carcinoma. Our principal findings indicate that although low-dose ablation is an effective strategy in patients with low- and intermediate-risk thyroid carcinoma, it may be less effective in patients with intermediate-risk carcinomas. In this study, 118 (78.1%) of 151 patients with low- and intermediate-risk papillary thyroid carcinoma achieved an excellent response one year after RAI treatment. Similarly, a study by Dong et al. (10) demonstrated that 87.5% of patients with low- and intermediate-risk disease achieved successful ablation six months after RAI treatment. They also reported that there was no significant difference in the success rate between patients who received low- or high-dose RAI (87.5% vs. 86.5%, respectively). In another study by Yasmin et al. (11), which included 34 patients, no significant difference in treatment response was observed between the low-dose and high-dose RAI groups one year after treatment (82% vs. 76%). In a study conducted in China, 117 patients were assigned to the low-dose group and 111 patients to the high-dose group (3). No significant difference was observed in response rate, recurrence, or survival during a 6- to 10-year follow-up. Survival rates in the low-dose and high-dose groups were 100% and 98.2%, respectively. In our study, consistent with these three studies, no significant difference in treatment success rate was observed between the two groups after one year (76.5% vs. 80%).

However, in contrast to our results, Fallahi et al. conducted a randomized, double-blind, controlled trial and reported better treatment outcomes with high dose (100 millicuries) compared with low dose (30 millicuries) (12). Additionally, in another study conducted in Turkey, a significant difference was observed between the two groups after one year, such that the success rate was 94.5% in the low-dose group and 74% in the high-dose group. This notable difference in their study may be attributable to differences in patient populations and varying definitions of treatment response (5).

When patients were examined independently in the low-risk and intermediate-risk groups, no significant difference was observed between low and high doses. In the low-risk group, 77.3% of patients receiving 30 millicuries and 85.2% of those receiving 100 millicuries were classified in the ER group. In the intermediate-risk group, 73.3% of patients receiving 30 millicuries and 62.5% of those receiving 100 millicuries were classified in the ER group. The results of this study indicate that low-dose ablation is an effective strategy in patients with low- and intermediate-risk thyroid carcinoma. This finding is in conflict with the results of the study by Gómez-Pérez et al. in Spain (13), who stated that although low-dose ablation is an effective strategy in low-risk patients, it may be less effective in patients with intermediate-risk disease.

In two large, randomized, controlled clinical trials, no statistically significant difference was observed between recipients of low-dose and high-dose RAI among low- and intermediate-risk patients with respect to treatment response during long-term follow-up. In ESTIMABL1, conducted by Schlumberger et al., disease recurrence was not associated with the RAI ablation dose level in low-risk carcinoma, and 92% of patients demonstrated an excellent response after low-dose ablation, with a 5-year disease-free survival rate of 98% (98% vs. 87%; p=0.73) (14). In the HiLo study, conducted by Dehbi et al., tumor recurrence rates were compared between low- and intermediate-risk cases receiving doses below 100 millicuries and those receiving higher doses, and no significant difference was found (1-2% recurrence risk at 5 years in both groups) (15). In other studies, additional authors have also reported similar results, concluding that low doses do not differ substantially from high doses in patients with low-risk carcinoma undergoing thyroid remnant ablation (16-19).

In our study, serum thyroglobulin level at the time of ablation (Tg-b) was an independent risk factor for predicting successful ablation, consistent with several similar studies in this field (10, 13, 16). Tg levels after surgery and at the time of RAI ablation have been investigated by many authors as factors influencing treatment response and recurrence rates, and our results appear to be consistent with these findings. Although sTg after surgery has not been standardized, it can provide clinically valuable information (13, 20, 21).

Our study had important limitations. First, it was an observational study that compared a selected sample of patients with initially low- and intermediate-risk thyroid carcinoma treated with low-dose ablation to a group of patients receiving high dose. The limitations of this study included its retrospective design, the limited number of patients, and the short one-year follow-up period. As previously mentioned, thyroid carcinoma is a disease that may progress over a longer period. Therefore, extending this follow-up period may have positive effects on patient outcomes.

In conclusion, the data obtained in our study demonstrated that at the end of the first year, there was no statistically significant difference between the low-dose and high-dose RAI groups, which warrants long-term follow-up to confirm this finding. Therefore, given the unwanted effects of high-dose RAI therapy—such as adverse effects, secondary malignancy, and increased costs—low dose can be used with greater confidence for thyroid remnant ablation in these patients.

Acknowledgment

The authors wish to express their sincere appreciation to the Vice-Chancellor for Research and Technology of Babol University of Medical Sciences for the support provided for this research. We also extend our gratitude to the colleagues of the Nuclear Medicine Department at Shahid Beheshti Hospital in Babol, particularly Ms. Elham Ahmadi Aghouzi, for their valuable assistance.

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