# Analysis of the strategy of LT4 prescribing and TSH monitoring for thyroid carcinoma after lobectomy

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**Background:** Thyrotropin (TSH) suppression is a critical step in the management of differentiated thyroid carcinoma (DTC). The objectives of this study were to evaluate changes in TSH levels and a strategy of initial levothyroxine (LT4) supplementation for TSH suppression in low-risk differentiated thyroid carcinoma (lr-DTC) patients after lobectomy.

**Methods:** One hundred and ten patients with lr-DTC who received lobectomy were enrolled. Each of the patients was given 50 μg LT4 immediately after lobectomy and were retrospectively analyzed to evaluate the initial dose of LT4 suppression during the first year of follow-up. Risk factors influencing the TSH trend were also evaluated.

**Results:** Median TSH levels decreased significantly after lobectomy and the initiation of LT4 suppression and were stable from 3 to 12 months. Three months after lobectomy, 44.9% of patients fell into the newly recommended first TSH goal (0.35 to 2.0 mIU/L). Insufficient suppression (≥2.0 mIU/L) and oversuppression (<0.35 mIU/L) was observed in 9.4% and 45.8% of the patients, respectively. Preoperative TSH ≥2.0 mIU/L and the coexistence of Hashimoto thyroiditis (HT) were risk factors influencing the TSH trend.

**Conclusions:** The monitoring of TSH could start from 3 months after lobectomy. An initial dose (50 μg) of LT4 could be adequate for initial suppression therapy in most patients. However, individual adjustment of the first dose may be necessary based on preoperative TSH concentration and the presence of HT.

**Keywords:** Thyroid neoplasms; Lobectomy; thyrotropin (TSH); levothyroxine

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## Introduction

Thyrotropin (TSH) suppression is a critical step in the management of DTC. A growing volume of data has suggested that there should not be a one-size-fits-all approach to suppression targets (1-4), and increasing emphasis is now placed on a more comprehensive assessment in which the risk of recurrence is balanced with the potential side effects (4,5). Studies have confirmed that increased TSH suppression for low-risk DTC (lr-DTC) patients does not improve prognosis (5-7). For lr-DTC patient, the current view is that the risk of mortality and recurrence is relatively low, and there is no convincing

evidence that aggressive treatment is beneficial (8,9). Updated guidelines from the American Thyroid Association (ATA) recommend thyroid lobectomy as a reasonable surgical option for lr-DTC, including as an alternative to total thyroidectomy for patients with tumors <4 cm without extrathyroidal extension and other high-risk factors (10,11). The goals for post-operative TSH concentrations have also been changed from mild suppression (0.1–0.5 mIU/L) to levels in the mid to lower reference range (0.5–2.0 mIU/L). Consequently, for patients receiving lobectomy alone, the use of levothyroxine (LT4) for TSH suppression may not be necessary if TSH concentrations could be endogenously supported within the new target range (12).

Previously, we routinely prescribed LT4 for patients with DTC after lobectomy, achieving a mild suppression of TSH consistent with goals at that time (13). However, based on the recommendations for less aggressive TSH suppression, this strategy may require adjustment in lr-DTC patients. Evaluating the TSH trend after surgery is the essential step for adjusting the suppression therapy strategy. Studies have concluded that a percentage of patients have TSH values <2.0 mIU/L after lobectomy; however, few data are available to assess the individual changes in TSH and guide providers on the suitable initial dose of LT4 for patients in this cohort (14-16). The purpose of this study is to find out the factors affecting postoperative TSH suppression and to guide reasonable and standardized individualized TSH suppression according to the recommendations of the guidelines. Analyzing the individual TSH level could help us understand its changing trend.

Despite the uncertainty of TSH outcomes, TSH suppression is still routinely employed in many places. Although in clinical practice, total body weight is used to calculate the posology of LT4 to be administered for thyroid diseases, this study aims to determine when it is ideal and when it may be unnecessary to prescribe LT4. Lee *et al.* reported that TSH suppression is not necessary for patients with lr-DTC who undergo lobectomy. For Lr-DTC patients with TSH suppression after lobectomy, the high preoperative TSH level and the duration of TSH suppression are the key factors affecting the cessation of LT4 (17). However they did not tell us a definite evidence for guiding the choice of postoperative TSH suppression. We performed a retrospective study to analyze changes in TSH concentration before and after thyroid lobectomy in lr-DTC patients to whom we routinely provided an initial dose of LT4 (50 μg) after lobectomy, to evaluate the strategy of TSH monitoring and the initial dose of LT4 for obtaining the recently recommended TSH range in lr-DTC patients. We present the following article in accordance with the MDAR reporting checklist (available at http://dx.doi.org/10.21037/atm-20-4890).

## Methods

### *Study subjects*

The medical records of lr-DTC patients who underwent thyroid lobectomy at our hospital between January 1, 2015, and December 31, 2015, for DTC were retrospectively reviewed. All patients with lr-DTC, as defined by ATA risk classification who received lobectomy, were initially included (12). The exclusion criteria were: previous head or neck radiotherapy, chemotherapy, radioiodine, or thyroid surgery, hyperthyroidism, overt hypothyroidism, or preoperative LT4 supplementation. Subjects were also excluded if preoperative thyroid function testing was absent, or follow-up was less than 12 months.

Guided by standard clinical practice at the time, patients with lr-DTC after lobectomy did not undergo completion thyroidectomy or receive radioactive iodine ablation. None of the patients in this group were overweight. An initial dose of levothyroxine 50 μg to be taken daily more than 30 minutes before breakfast was prescribed, and patients underwent TSH assessments at 1 (1 MO), 3 (3 MO), 6 (6 MO), and 12 (12 MO) months postoperatively.

The collected data included demographic and histopathologic parameters, and TSH concentrations preoperatively (Pre-OP) and during follow-up. The presence of lymphocytic infiltration consistent with Hashimoto thyroiditis (HT) was noted on histopathologic evaluation. The dose adjustments in the lr-DTC patients and the reason for this were noted.

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013), and was approved by the Institutional Review Board of the First Hospital of China Medical University (No.: [2020]25-2). Because of the retrospective nature of the research, the requirement for informed consent was waived.

### *Laboratory measurements*

The reference range for TSH was 0.35–4.94 mIU/L, free thyroxine (FT4) was 9.01–19.05 pmol/L, and free triiodothyronine (FT3) was 2.63–5.7 pmol/L. The intra- and inter-batch variability for TSH, FT4, and FT3 was <5%, <8%, and <7%, respectively. All measurements

 

**Table 1** Demographic and baseline patient characteristics

| Characteristics | DTC Group (n=110) |
|---|---|
| Age (years) | 40.93±10.42 |
| Gender | |
| Male | 27 (24.5%) |
| Female | 83 (75.5%) |
| Coexistence of Hashimoto's thyroiditis | |
| Present | 22 (20.0%) |
| Absent | 88 (80.0%) |
| Preoperative TSH level (mIU/L) | |
| <2.0 | 74 (67.3%) |
| ≥2.0 | 36 (32.7%) |

DTC, differentiated thyroid carcinoma; TSH, thyrotropin.

were performed using immuno-chemiluminescence assays (Abbott Company kit, Chicago, USA). The target range of TSH was set based on the 2015 ATA guidelines for DTC management and standard practice in our hospital's laboratory. Postoperative TSH levels were defined as: <0.35 mIU/L (oversuppression), 0.35–2.0 mIU/L (at goal), ≥2.0 mIU/L (insufficient suppression). HT was diagnosed by surgical histopathology.

### *Statistical analysis*

Demographic and clinical variables were compared using Student's *t*-test or the Mann-Whitney U test as appropriate. The percentages of patients with oversuppression (<0.35 mIU/L), ideal suppression (0.35–2.0 mIU/L), or TSH elevation (≥2.0 mIU/L) were calculated to evaluate the efficacy of the empiric dose of LT4 50 μg daily initiated after lobectomy. Comparisons of TSH changes from the Pre-OP baseline to specified follow-up time points were made using a paired Student's *t*-test or repeated measures ANOVA with Dunnett's post-test. We performed an analysis of risk factors for TSH suppression using binary logistic regression for univariate and multivariate analysis. Pearson's correlation coefficients were calculated for the TSH correlation between time points. Graphs were generated using GraphPad Prism Software version 5.0 (San Diego, CA, USA). All data were analyzed using a statistical software package (SPSS for Windows version 22.0; IBM Inc., Armonk, NY, USA), and a P value <0.05 represented statistical significance.

## Result

### *Baseline information*

A total of 124 patients with lr-DTC who received lobectomy were initially included. After the exclusion criteria was applied, 110 patients who had 12 MO follow-up were included in the analysis. The patients' baseline characteristics are shown in *Table 1*. The mean age of the patients was 40.93±10.42 years, and 83/110 (75.5%) were female. The final histopathologic diagnoses were papillary thyroid carcinoma in all cases, of which 80/110 (72.7%) were papillary thyroid microcarcinoma (PTMC). Pathologic evidence of HT was found in 22/110 (20.0%). No postoperative complications occurred in our group.

### *Individual changes in TSH concentration before and after surgery*

All subjects received the initial dose of 50μg LT4 daily. Three patients received a dose reduction at 6 MO for symptoms of hyperthyroidism. No other dose adjustments were made in any other patients, leaving 107 patients for the analysis after 6 MO. The median TSH level Pre-OP was 1.63 mIU/L (range, 0.37–4.64 mIU/L), and 74/110 (67.3%) patients had a TSH <2.0 mIU/L. The median TSH level was 0.90 mIU/L (range, 0.01–3.93 mIU/L) at 1 MO, 0.38 mIU/L (range, 0.004–2.88 mIU/L) at 3 MO, 0.37 mIU/L (range, 0.01–3.26 mIU/L) at 6 MO, and 0.38 mIU/L (range, 0.04–2.53 mIU/L) at 12 MO. There was a significant decrease in TSH level from Pre-OP to 1 MO and 3 MO (P<0.001 for both; *Figure 1A*), but no significant differences were observed at 3 MO, 6 MO, or 12 MO.

The distributions of postoperative TSH are shown in *Figure 1B*. Postoperatively, TSH concentration <2.0 mIU/L was present in 87.9%, 90.7%, 90.7%, and 92.5% of patients at 1 MO, 3 MO, 6 MO, and 12 MO, respectively. The distributions of TSH into the categories of <0.35 mIU/L, 0.35–2.0 mIU/L, or ≥2.0 mIU/L were similar at 3 MO, 6 MO, and 12 MO. Pearson correlation revealed a significant positive correlation between TSH at 3 MO and 12 MO (Pearson's $r^2$=0.484; P<0.0001; n=107; *Figure 2A*).

### *Changing trend in TSH category from Pre-OP to 3 MO*

Since these data indicated 3 MO as a suitable time point to predict stable serum TSH level over the first year, further analyses utilized the TSH at 3 MO. Changes in the TSH category (<0.35, 0.35–2.0, or ≥2.0 mIU/L) in DTC

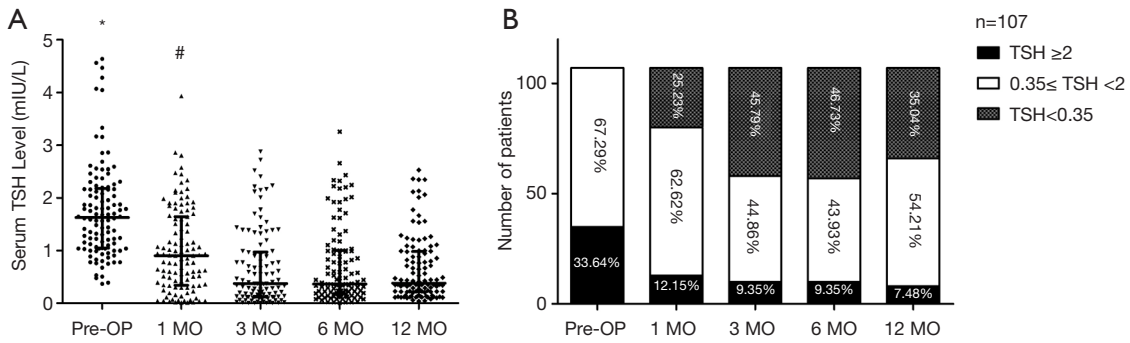


**Figure 1** TSH distributions at different time points after lobectomy. (A) Repeated measures ANOVA with Dunnett's post-test to compare serum TSH levels between different time points in DTC patients. *, Pre-OP compared to other groups, P<0.001; #, 3 MO compared to other groups, P<0.001. TSH level significantly decreased from Pre-OP to 1 and 3 MO, P<0.001. There were no significant differences between 3, 6, and 12 MO. (B) Distributions of TSH levels at different time points after lobectomy. Ideal suppression was shown in 43.93–62.62% of patients with an empiric dose of 50 μg LT4 daily. TSH, thyrotropin; DTC, differentiated thyroid carcinoma.

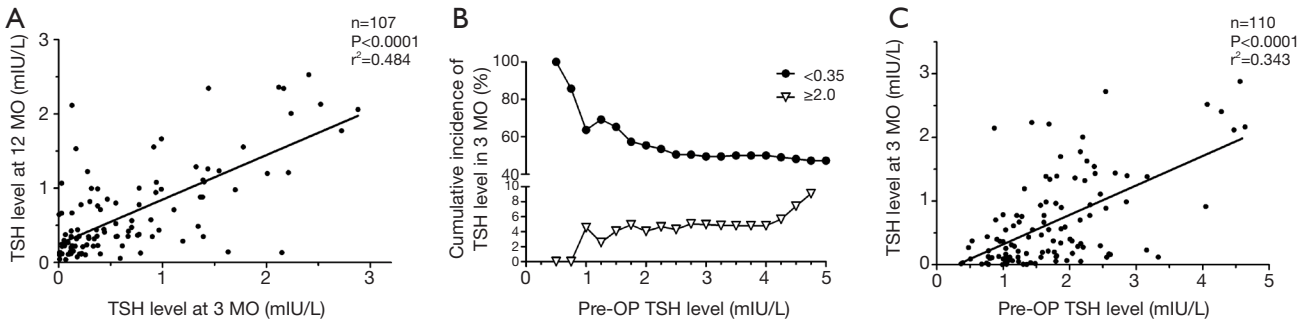


**Figure 2** TSH changing trends and correlations at different time points after lobectomy. (A) Pearson's correlation analysis revealed a significant positive correlation of TSH levels between 3 and 12 MO in DTC patients (n=107). (B) Cumulative incidence of different TSH levels at 3 MO in the subjects whose preoperative TSH was no higher than the different corresponding levels on the x-axis. The stage between each point on the x-axis was 0.25 mIU/L (n=110). (C) Pearson's correlation analysis showed a significant positive correlation between the Pre-OP TSH level and that at 3 MO for DTC patients (n=110). TSH, thyrotropin; DTC, differentiated thyroid carcinoma.

patients from Pre-OP to 3 MO are shown in *Table 2*. At 3 MO, of the patients with a Pre-OP TSH ≥2.0 mIU/L, 18/36 (50%) patients fell into 0.35–2.0 mIU/L, only 7/36 (19.4%) continued to demonstrate a TSH level ≥2.0 mIU/L. In those with Pre-OP TSH between 0.35 to 2.0 mIU/L, 41/74 (55.4%) patients showed a TSH level <0.35 mIU/L, while 30/74 (43.2%) stayed in the same category. The cumulative incidence of patients within each TSH category at 3 MO is shown in *Figure 2B*. The cumulative incidence of TSH ≥2.0 mIU/L at 3 MO stabilized around 5% when Pre-OP TSH was no higher than 4.0 mIU/L and increased to 9.1% when Pre-OP TSH was higher than 4.0 mIU/L. The cumulative incidence of TSH <0.35 mIU/L at 3 MO decreased when Pre-OP TSH was no higher than 2.0 mIU/L and stabilized around 50% with Pre-OP TSH >2.0 mIU/L. Pearson's correlation showed a significant positive correlation between Pre-OP TSH level and that in 3 MO (Pearson's $r^2$=0.343; P<0.0001; n=110) (*Figure 2C*).

### *Risk factors of insufficient and over suppression*

Logistic regression analysis was performed to identify risk factors for predicting a Post-OP (3 MO) TSH level ≥2.0 mIU/L (insufficient suppression) or <0.35 mIU/L (oversuppression). The relevant variables were age, gender, preoperative TSH, and the presence of HT. Preoperative TSH ≥2.0 mIU/L (OR, 6.185; 95% CI, 1.369–27.956; P=0.018) and presence of HT (OR, 4.786; 95% CI,

**Table 2** Changes in TSH category (<0.35, 0.35–2.0, or ≥2.0 mIU/L) from Pre-OP to 3 MO in DTC patients (n=110)

| TSH Pre-OP | TSH 3 MO | | | |
|---|---|---|---|---|
| | Total | TSH <0.35 | 0.35≤ TSH <2.0 | TSH ≥2.0 |
| TSH <0.35 | 0 | 0 | 0 | 0 |
| 0.35≤ TSH <2.0 | 74 | 41 | 30 | 3 |
| TSH ≥2.0 | 36 | 11 | 18 | 7 |
| Total | 110 | 52 | 48 | 10 |

TSH, thyrotropin; Pre-OP, preoperatively; DTC, differentiated thyroid carcinoma.

**Table 3** Univariate and multivariate analysis for the risk factors of insufficient suppression (n=110)

| Characteristics | Univariate | | | Multivariate | | |
|---|---|---|---|---|---|---|
| | Odds ratio | 95% CI | P value | Odds ratio | 95% CI | P value |
| Female gender | 0.375 | 0.097–1.456 | 0.157 | 3.488 | 0.064–1.365 | 0.108 |
| Age | 0.996 | 0.935–1.060 | 0.891 | 1.012 | 0.941–1.084 | 0.734 |
| Preoperative TSH level ≥2.0 mIU/L | 5.713 | 1.381–23.629 | 0.016 | 6.185 | 1.369–27.956 | 0.018 |
| Coexistence of Hashimoto's thyroiditis | 4.882 | 1.272–18.738 | 0.021 | 4.786 | 1.129–20.283 | 0.034 |

**Table 4** Univariate and multivariate analysis for the risk factors of over suppression (n=110)

| Characteristics | Univariate | | | Multivariate | | |
|---|---|---|---|---|---|---|
| | Odds ratio | 95% CI | P value | Odds ratio | 95% CI | P value |
| Female gender | 2.000 | 0.775–5.162 | 0.152 | 0.394 | 0.140–1.112 | 0.079 |
| Age | 0.985 | 0.950–1.022 | 0.426 | 0.972 | 0.934–1.012 | 0.170 |
| Preoperative TSH level <2.0 mIU/L | 2.674 | 1.150–6.217 | 0.023 | 2.881 | 1.167–7.114 | 0.022 |
| Coexistence of Hashimoto's thyroiditis | 0.194 | 0.061–0.619 | 0.005 | 0.180 | 0.053–0.607 | 0.006 |

TSH, thyrotropin.

1.129–20.283; P=0.034) were significantly associated with postoperative TSH level ≥2.0 mIU/L (*Table 3*). Preoperative TSH <2.0 mIU/L (OR, 2.881; 95% CI, 1.167–7.114; P=0.022) was significantly associated with postoperative TSH level <0.35 mIU/L. The presence of HT (OR 0.180; 95% CI, 0.053–0.607; P=0.006) was also found to be negatively associated with the development of oversuppression in the univariate and multivariate analysis (*Table 4*).

## Discussion

Suppression of TSH after the initial therapy for differentiated thyroid carcinoma (DTC) has been advocated based on a reduction in the risk of recurrence and improved survival (2). More recently, however, studies have suggested adverse effects of LT4-induced TSH suppression (12,18-20,21), and increasing data have shown that such suppression may not achieve improved outcomes for lr-DTC patients (1,5,21-23). Therefore, treatment recommendations emphasize balancing the risk of tumor recurrence with possible side effects and advocate less stringent TSH goals within the low reference range (0.5–2.0 mIU/L) for lr-DTC patients (4,12). Since the remaining thyroid may maintain serum TSH within this target range after lobectomy, LT4 therapy may not be necessary (24) and the frequency at which LT4 is required, factors associated with LT4 requirement, the dose needed, and TSH stability achieved by initial dosing

 

are not well understood in this context. Such information is vital, because surgical treatment with lobectomy alone for lr-DTC is considered to be appropriate not only for microcarcinoma (size <1 cm), but also for larger tumors 1–4 cm (12). Cox *et al.* reported that the TSH level rose to >2.0 mIU/L within a year in more than 70% of patients after lobectomy, which demonstrated the need for LT4 after lobectomy; however, no analysis of individual TSH trends was performed (14).

In this retrospective cohort study, we similarly found that 3 MO is a more appropriate time point than 1 MO for initially monitoring TSH after lobectomy and that TSH levels were stable between 3 and 12 MO. Measurement of TSH at 1 MO appeared too early to determine the 3MO TSH concentration. Our finding is important because surgeons do check for TSH early, and this could be a clinical recommendation to change practice and not check at that time point. It will help us make a better strategy for active monitoring. With a first dose of LT4 50 μg daily, 45% of these patients achieved the appropriate TSH suppression range (0.35–2.0 mIU/L). A preoperative TSH ≥2.0 mIU/L and the presence of HT were risk factors of insufficient suppression. Similar to our data, Ahn *et al.* reported that preoperative TSH ≥2.0 mIU/L and Hashimoto's thyroiditis are independent risk factors for hypothyroidism in patients after lobectomy during the mean follow-up period of 56.4 months (15). Lee *et al.* reported that preoperative TSH was >2.5 mIU/L, and positive thyroid microsomal antibody may show the need for LT4 suppression after lobectomy (25).

Our data may be valuable when attempting to achieve appropriate postoperative TSH concentrations for lr-DTC patients following the 2015 ATA guidelines. Patients with a preoperative TSH ≥2.0 mIU/L and/or HT will require postoperative LT4, and the initial dose of 50 μg may prove inadequate. The initial dose of 75 μg may be more suitable for these patients. Conversely, since oversuppression (TSH <0.35 mIU/L) was more frequent in lr-DTC patients with Pre-OP TSH <2.0 mIU/L and the absence of HT, LT4 may not be prescribed to these patients.

The current study has several limitations, including a lack of comparison with untreated lr-DTC patients and the relatively small sample size. Also, HT was defined by histopathology and not by TPO-Ab, so direct assessment of HT as a pre-operative risk factor could not be made. However, this is the first study to evaluate the first dose and describe the details of individual trends of TSH change after lobectomy. Strict conformity with standard clinical practice with very few dose adjustments limited selection bias and enhanced the significance of this study.

## Conclusions

In conclusion, initial TSH assessment might be performed at three months after lobectomy, as it predicts stable serum TSH levels over the first year. An initial dose of LT4 50 μg daily is adequate to maintain TSH lower than 2.0 mIU/L for more than 90% patients, but those with preoperative TSH ≥2.0 mIU/L and/or coexistent HT are more likely to show inadequate suppression. Initial LT4 treatment might not be prescribed for patients with Pre-OP TSH <2.0 mIU/L and the absence of HT.

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## Footnote

*Reporting Checklist:* The authors have completed the MDAR reporting checklist. Available at http://dx.doi.org/10.21037/atm-20-4890

*Data Sharing Statement:* Available at http://dx.doi.org/10.21037/atm-20-4890

*Conflicts of Interest:* All authors have completed the ICMJE uniform disclosure form (available at http://dx.doi.org/10.21037/atm-20-4890). The authors have no conflicts of interest to declare.

*Ethical Statement:* The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013), and was approved by the Institutional Review Board of the First Hospital of China Medical University (NO.: [2020]25-2). Because of the retrospective nature of the research, the requirement for informed consent was waived.



 

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