

The Ramadan Dilemma: When Should Hypothyroid Patients Take Their Levothyroxine?

Le dilemme du Ramadan: Quand les patients hypothyroïdiens doivent-ils prendre leur lévothyroxine ?

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ABSTRACT

Introduction: Primary hypothyroidism management presents unique challenges during Ramadan fasting. The administration of levothyroxine, which requires an empty stomach, must be adapted to the limited time window for meals. The aim of this study was to identify the most suitable timing for levothyroxine administration during Ramadan and to evaluate the impact of fasting on Thyroid Stimulating Hormone (TSH) levels.

Methods: This was a quasi-experimental study conducted during Ramadan of the Hijir year 1442 (1442 AH). Patients with primary hypothyroidism, who were euthyroid on stable therapy, were divided into two groups based on their preferred intake time: Group A took their treatment at Iftar (just after sunset, 30 minutes before eating), and Group B took it at Suhur (before sunrise, at least three hours after the last meal and 30 minutes before the next). TSH levels were measured before (T0) and two weeks after Ramadan (T1).

Results: Thirty-nine patients were included (18 in Group A, 21 in Group B). A statistically significant increase in TSH levels from T0 to T1 was observed only in Group A (Iftar intake). However, the overall change in TSH was not significantly different between the two groups. Poor adherence to the recommended time interval between medication and meal intake was significantly higher in Group A. In a multivariate analysis, the number of days not fasted and weight change were significantly associated with a TSH variation of 2 μ UI/mL.

Conclusion: This study did not identify a single optimal timing for levothyroxine administration during Ramadan. Adherence to treatment, particularly the time interval between medication and food intake, appears to be a critical factor in maintaining TSH control. Respecting patient preferences is therefore essential to promote compliance.

Key words: Hypothyroidism; Levothyroxine; Ramadan; Fasting; Treatment adherence

RÉSUMÉ

Introduction: La prise en charge de l'hypothyroïdie primaire présente des difficultés pendant le jeûne du Ramadan, car la lévothyroxine doit être administrée à jeun, dans un créneau horaire restreint. Cette étude visait à identifier le moment optimal d'administration de la lévothyroxine pendant le Ramadan et à évaluer son effet sur les taux de TSH (thyroïdostimuline).

Méthodes: Une étude quasi expérimentale a été menée durant le Ramadan 1442 (2021) chez des patients atteints d'hypothyroïdie primaire, euthyroïdiens et sous traitement stable. Les participants ont choisi le moment de leur prise : le groupe A à l'Iftar (juste après le coucher du soleil, 30 minutes avant le repas) et le groupe B au Suhur (avant le lever du soleil, au moins trois heures après le dernier repas et 30 minutes avant le suivant). La TSH a été mesurée avant le Ramadan (T0) et deux semaines après (T1).

Résultats: Trente-neuf patients ont été inclus (18 dans le groupe A, 21 dans le groupe B). Une augmentation significative de la TSH entre T0 et T1 a été observée uniquement dans le groupe A. Cependant, la variation globale de la TSH n'était pas significativement différente entre les groupes. Le non-respect de la période de jeûne recommandée avant et après la prise de lévothyroxine était plus fréquent dans le groupe A. En analyse multivariée, le nombre de jours sans jeûne et la variation de poids étaient significativement associés à une variation de la TSH ≥ 2 μ UI/mL.

Conclusion: Il n'existe pas de moment optimal unique pour l'administration de lévothyroxine pendant le Ramadan. En revanche, le respect des posologies, et notamment de l'intervalle entre la prise du médicament et les repas, s'avère être le principal facteur déterminant de la stabilité de la TSH. Respecter les préférences du patient concernant l'Iftar ou le Suhur pourrait donc améliorer l'observance et favoriser une substitution hormonale thyroïdienne efficace pendant le jeûne.

Mots clés: Hypothyroïdie; Lévothyroxine; Ramadan; Jeûne; Observance du traitement

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INTRODUCTION

Primary hypothyroidism is the most common endocrine disease, affecting 9,3% of women and 1,2% of men (1). The American Thyroid Association (ATA) recommends that levothyroxine treatment be taken in empty stomach, i.e at least three hours after any food intake and 30 minutes without any food intake. Its absorption can vary from 80% with these conditions to 60% in case of concomitant intake (2).

The Holy month of Ramadan, the ninth month of the Islamic calendar and one of the five pillars of Islam, is observed through fasting by healthy adults. During this month, individuals abstain from eating, drinking, and smoking from sunrise to sunset. Meals are consumed before dawn (Suhur) and after sunset (Iftar).

Fasting during Ramadan poses specific challenges for individuals with hypothyroidism, as they must adhere to their levothyroxine treatment while ensuring an appropriate interval between medication intake and meals, despite the limited time window.

To date, only a limited number of studies have investigated the optimal timing for levothyroxine administration during Ramadan fasting. These studies have not reached a consensus on a single ideal timing for levothyroxine intake during this period.

The aim of our study was to identify the most suitable timing for levothyroxine administration during Ramadan and to evaluate the impact of fasting on Thyroid Stimulating Hormone (TSH) levels.

METHODS

Study design

This was a quasi-experimental study performed during Ramadan of year 1442 (April 12nd to May 12 2021). Sunrise was at 04h06 at the beginning of the month and 03h22 at the end of the month. Sunset was at 18h55 at the beginning of the month and 19h20 at the end of the month.

Patients were enrolled in the study during the six weeks preceding Ramadan and were divided into two groups based on their preferred timing of levothyroxine intake during Ramadan: Group A (treatment taken at Iftar) and Group B (treatment taken at Suhur).

Patients in group A were advised to take their treatment just after sunset and wait 30 minutes before any food intake. Patients in group B were advised to take their treatment before sunrise, three hours after any food intake with a 30-minute interval before any subsequent food intake. The flowchart of the study is presented in figure 1.

At baseline (T0), prior to Ramadan, we evaluated treatment compliance, levothyroxine dosage, and body weight. Two weeks after Ramadan (T1), we assessed adherence to the prescribed timing of treatment and re-evaluated body weight.

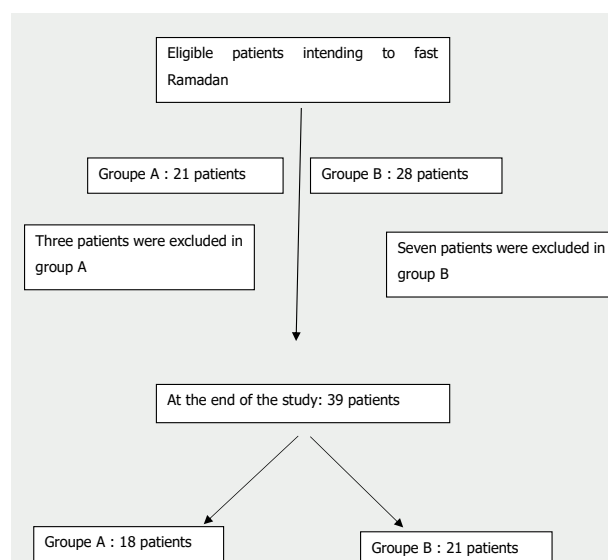


Figure 1. Flowchart of the study

Inclusion and exclusion criteria

We included patients with primary hypothyroidism aged from 18 to 70 years, intending to fast Ramadan and having stable and normal TSH levels for the last three months. We didn't include women intending to have a pregnancy, pregnant women, patients treated for thyroid cancer or patients having a medical contraindication to fasting.

Patients who fasted for fewer than 20 days, altered the timing of their levothyroxine intake during Ramadan, or changed their dosage were also excluded.

Levothyroxine adherence

Levothyroxine adherence before the month of Ramadan was assessed using the Girerd questionnaire (3). This is a six-item questionnaire that is short and easy to use, where each "yes" answer counts as one point. Adherence was considered good if the Girerd score was equal to 0, average if the score was 1 or 2, and poor if it was greater than or equal to 3.

Biochemical analysis

TSH determination was performed on a Cobas®E411 analyser using an immunoenzymatic method.

TSH at T0 was performed during the four weeks preceding Ramadan and TSH at T1 was performed during the two weeks after the end of Ramadan, with a minimum of six weeks between the two TSH levels.

Patients were classified as euthyroid if their TSH levels were within the range of 0.27–4.2 μ UI/mL.

We determined the following parameters:

-Change in TSH levels between T1 and T0 was calculated as follows: **TSH (T1) – TSH (T0)**.

- Change of levothyroxine dose per body weight between T1 and T0 was calculated as follows:

Dose per body weight (T1) – Dose per body weight (T0).

Statistic analysis

The statistical analysis was performed using SPSS version 23.0. Qualitative variables were summarized as numbers and percentages, quantitative variables were summarized as mean, standard deviation and extreme values. Parameters with nonnormal distribution (determined by Shapiro-Wilk test) were summarized by median and extremes.

Comparison of qualitative variables was performed using Chi-square test or Fisher test.

Comparison of continuous variables was performed using the Pearson's test or Spearman's test in nonnormal continuous variables.

Comparison of continuous variables between the two groups was performed using Student's t-test and Mann-Whitney test in case of nonnormal variables.

Comparison of continuous variables from before to after Ramadan was performed with Wilcoxon test.

All p value less than 0.05 were considered statistically relevant.

Ethical approval for the study was obtained from the National Institute of Nutrition and Food Technology Ethics Committee on April 22, 2022.

Informed consent was obtained from all patients prior to their participation in the study

RESULTS

The characteristics of the population and the two study groups are represented in Table 1 Sociodemographic and clinical characteristics of the study population:

Table 1.

	Overall (N=39)	Group A (N=18)	Group B (N=21)	P value
Age years (Median)	52	53	50	0.887
[extreme values]	[19-66]	[19-66]	[27-67]	
Gender (N Women (%))	37 (94.87%)	18 (100%)	19 (90.47%)	0.998
BMI Median (kg/m ²)	29.6	29.4	29.6	0.757
[extreme values]	[21-24]	[21,3-38,3]	[21-43]	
Duration of hypothyroidism Median years	10	10.5	9	0.373
[extreme values]	[2 -30]	[3 – 30]	[2-23]	
Good compliance to levothyroxine (N (%))	16 (41%)	9 (50%)	7 (33.33%)	0.291

No significant differences were observed in the baseline characteristics of the two study groups.

We compared TSH levels, weight and levothyroxine dose per body weight at baseline, and as shown as in table 2, there wasn't a significant difference between the two groups.

Table 2. Baseline Comparison of Weight, Levothyroxine Dose, and TSH Between Groups

	Value		p
	Overall (N=39)	GroupA (N=18)	Group B(N=21)
Weight - Median (kg) [extreme values]	77.33 [55-110]	73 [56-104]	76 [55-110]
Dose of Levothyroxine per body weight - Median (µg/kg) [extreme values]	1.37 [0.27-2.63]	1.44 [0.68-2.34]	1.23 [0.27-2.63]
Median TSH (µUI/ml) [extreme values]	2.06 [0.36-4.09]	1.81 [0.36-3.95]	2.51 [0.6-4.09]

TSH levels before and after Ramadan are presented in Figure 2. The difference in TSH levels was statistically significant only in Group A.

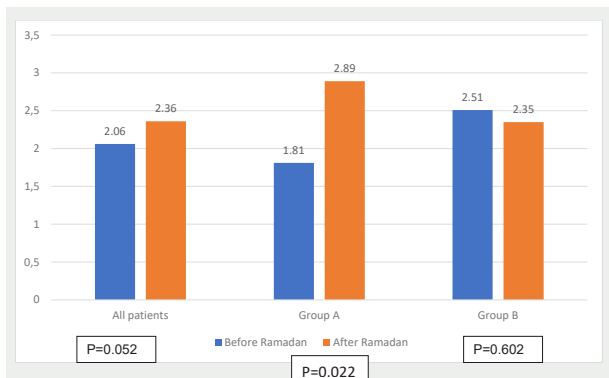


Figure 2. Comparison of TSH levels before and after Ramadan

There was no significant difference in TSH variation between the two groups after Ramadan.

After Ramadan, five of 18 patients in group A had TSH above range versus four of 21 in group B (p=0.706).

We investigated the factors associated with changes in TSH levels that may differ between the two groups (Table 3).

Table 3. Comparison of factors associated with TSH levels change between the two groups

	Group A (N=18)	Group B (N=21)	P value
Number of days not fasted; mean, median, [IQR], (extremes)	1.3, 0, [0-1], (0-7)	2.6, 0, [0-5], (0-9)	0.157
All of Ramadan fasted	4/18	10/21	0.18
Number of days without adherence to timing of treatment; mean, median, [IQR], (extremes)	10.8, 4, [0-30], (0-30)	2.1, 0, [0-2.5], (0-15)	0.037
Adherence to timing of treatment in all days of Ramadan	10/18 (56%)	6/21 (28%)	0.112
Weight change (kg); mean, median, [IQR], (extremes)	-0.67, 0, [-2-0], (-4-2)	-0.91, -1, [-2- 0], (-4-2)	0.545
Change of dose of levothyroxine per body weight (µg/kg); mean, median, [IQR], (extremes)	0.015, 0, [0- 0.031], (-0,4- 0,16)	0.02, 0.019, [0-0.033], (-0.02-0.15)	0.476

IQR: Interquartile range

At baseline, no significant differences were observed between the two groups. As Ramadan began, both groups were similar. However, after Ramadan, a significant increase in TSH levels was observed only in Group A. In the univariate analysis, only the mean number of days without adherence to the timing of treatment was significantly more important in Group A compared to Group B.

We find a significant correlation between the weight change and the TSH change between T0 and T1 ($r=0.382$, $p=0.016$). There was also a significant correlation between dose per body weight and mean TSH change after Ramadan ($r=-0.337$, $p=0.018$).

We conducted a multivariate analysis to investigate the factors associated with changes in TSH levels of 1 $\mu\text{UI/mL}$ and 2 $\mu\text{UI/mL}$. There were no factors that was significantly associated with a TSH change of 1 $\mu\text{UI/mL}$.

When considering a TSH level change of 2 $\mu\text{UI/mL}$, the number of days not fasted ($\beta=4.7$, 95% CI: 1.044-20.718, $p=0.044$) and the mean weight change ($\beta=0.12$, 95% CI: 0.023-0.712, $p=0.019$) were significantly associated with a 2 $\mu\text{UI/mL}$ variation of TSH levels.

DISCUSSION

According to the results of our study, in previously well-controlled hypothyroid patients, Ramadan fasting was associated with nearly-significant increase in TSH level, which rose from 2.06 [0.36–4.09] before Ramadan to 2.36 [0.27–15.36] after Ramadan. A significant increase in TSH levels was observed in the group taking levothyroxine at Iftar, but not in the group taking their treatment at Suhur. We analysed the variables associated with changes in TSH levels, and found that only the mean number of days with poor adherence to the timing of treatment was significantly different between the two groups. A change in TSH levels $> 2 \mu\text{UI/mL}$ was investigated in a study by Karoli et al. (4), where only a shorter meal-levothyroxine interval and concomitant illness were found to be associated with changes in TSH levels.

Studies performed outside of Ramadan showed the intake of levothyroxine at bedtime was non-inferior to intake of levothyroxine in the morning before breakfast (5–10).

In healthy subjects fasting Ramadan, there is a physiologic increase of TSH levels between pre-Ramadan and all samples taken during Ramadan as well as in the first month after Ramadan. Normal TSH levels are restored five months after Ramadan. (11,12).

In hypothyroid patients, the reduced time available for food and drug intake during Ramadan may impair proper levothyroxine absorption, increasing the risk of elevated TSH levels. This increase was confirmed in a meta-analysis performed in 2024 including twelve studies and 1758 patients in the subgroup analysing TSH increase independently from the time of intake (13). Except studies included in this meta-analysis, we found only one study, that also found a significant increase of TSH after Ramadan fasting (14). The mean increase in TSH levels after Ramadan has not been consistently observed in all

studies. Pakdel et al, Zaboony et al, and Dellal et al, as well as our study did not report a significant increase in TSH levels after Ramadan (15–17).

The meta-analysis performed by Belal et al examined compared three timing points of intake of levothyroxine, which were pre-iftar, post iftar and pre-suhur (13). Three studies (17–19) included a group of patients taking their treatment after the iftar, which should be at least after three hours, but the one performed by Dellal et al (17) didn't precise the time-interval between food intake and levothyroxine intake. There was a significant increase of TSH levels (MD=-0.76 [95% CI:-1.12,-0.39], $p < 0.0001$). In our study, a significant increase in TSH levels was observed in patients taking their treatment pre-Iftar (MD = -0.69 [95% CI: -1.03, -0.36], $p < 0.0001$), consistent with findings from three studies that required levothyroxine intake at least 30 minutes before food consumption (18–20). However, unlike our study, a significant increase in TSH levels was also reported for the pre-Suhur timing (MD = -1.19 [95% CI: -2.18, -0.19], $p = 0.02$) in three studies that included this time of intake (17,19,20). No specific timing for levothyroxine intake demonstrated clear superiority.

When analyzing only studies that included patients taking their treatment pre-Iftar and pre-Suhur, we identified one study conducted by Dabouss et al., which reported a significant increase in TSH levels in both groups. However, similar to our findings, no significant difference was observed between the two groups (20).

Fasting during Ramadan not only causes a physiologic increase of TSH levels, it also causes weight change, thus a change of levothyroxine dose per body weight that can affect levothyroxine distribution and TSH levels. In a study performed outside of Ramadan and examining thyroid hormones and weight change, weight loss wasn't associated with TSH levels, only with FT4 (21). In our study, there was a significant positive correlation between weight change and TSH levels. The expected decrease of TSH after weight loss was balanced by the increase of TSH during the month of Ramadan. Therefore, patient presenting weight loss maintain a more stable TSH after Ramadan. The weight change was evaluated in few studies with an inconsistent mean change after Ramadan between studies (17,19,20,22). Only two studies compared TSH and weight change. In the study performed by Dellal et al, patients having an increase in TSH levels had a significant weight increase while patient having a decrease in TSH levels had a significant weight loss with a significant difference between patients with an increase and decrease of TSH levels (17). Similarly, TSH levels increase was independently associated with weight gain in another study (19).

Furthermore, the intake of many drugs and food, such as iron, calcium, antacids during the short time allowed for Muslims to eat can interfere with levothyroxine absorption; which can fall from 80% on empty stomach to 60% with concurrent food ingestion (9,23). In our study, the mean number of days without a good adherence of time-interval between levothyroxine and meals was significantly higher in group A, with a respect of that time-interval during all fasting days being at 56% in group A

and 28% in group B. It can be explained by the impatience of patients, after a 15-hour fast, to delay even more their meals. For group B patients, even though they respected more that interval, the late-night awakening and short time available for suhoor may explain the lack of respect of proper time-interval.

In three randomized controlled trials, patients were assigned to two or three groups with an evaluation of adherence. In the study performed by Dabouss et al, where patients were assigned into two groups (pre-Iftar and Pre-suhur), patients reported that timing of intake was convenient, with a good adherence of treatment but not statistical analysis was performed for that matter (20). In the three groups evaluated by Kaissi et al, there was no statistically significant difference of adherence between groups (59.3-77.1%) but patients taking their treatment at pre-Suhur time were less satisfied of the time of intake (24). Mahzari et al found a lower compliance of levothyroxine in patients taking their treatment four hours after iftar (25).

Adherence to the time interval between levothyroxine intake and food was significantly associated with TSH increase in a few studies (4,19,26), while others did not find such an association (4,18). Respecting patients' preferences can be an effective strategy to improve adherence and mitigate the impact of reduced levothyroxine absorption on TSH increase after Ramadan. The meta-analysis conducted by Belal et al. did not consider factors associated with TSH increase (13).

The strength of our study lies in several key aspects: the T1 samples were collected within two weeks after Ramadan, the two groups were homogeneous at baseline, and we examined factors associated with the increase in TSH, particularly adherence and levothyroxine dose per body weight.

However, the study had some limitations, including the small sample size, the lack of randomization, and the absence of a healthy control group.

CONCLUSIONS

This study is among the few that explore hypothyroidism management during Ramadan fasting and compare multiple timings for levothyroxine intake. While our findings did not identify an optimal timing for levothyroxine administration, adherence to treatment remains a critical factor for maintaining TSH control during Ramadan.

A review of the literature and meta-analyses suggests no clear superiority of any specific timing. Therefore, respecting individual patient preferences is essential to promote compliance and adherence.

Further studies are needed to investigate parameters associated with TSH changes observed in our study, such as levothyroxine adherence and weight change. Additionally, research including a healthy control group is necessary to determine whether the TSH increase is related to reduced levothyroxine absorption or represents a physiological response to Ramadan fasting.

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