



Thyroxine Replacement Therapy during Ramadan Fasting: Physicians' and Patients' Perceptions and Practices

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Abstract

Objective Thyroxine (T4) therapy is taken on an empty stomach and no food is taken for a short period. During Ramadan fasting (RF), Muslim patients may face difficulties taking levothyroxine as recommended.

Materials and Methods We performed a mixed methods study of an online survey of 218 physicians to explore their perceptions and practices. Also, we interviewed a sample of 172 hypothyroid patients to establish their practices and source of information. Their median age was 46 (17–90) years; they had hypothyroidism for a median of 5 years and took a median thyroxine dose of 100 µg daily. Furthermore, we attempted to explore the effects of RF on available thyroid function tests.

Results Consultants were 58.4%, and the most represented specialty was endocrinology, 46.1%. Regarding the impact of RF on T4 therapy, 52.3% thought the RF was not clinically relevant in most patients on T4 replacement. However, 27.5% thought RF affects T4 replacement therapy in a clinically relevant manner. About 77.1% of respondents reported giving advice routinely to all patients on T4 replacement during RF. One hundred sixty-four respondents were split between recommending taking the medications with *Iftar*, *Suhour*, or other times. Most respondents (73.9%) do not repeat measurements of thyroid hormone levels after Ramadan unless needed during their scheduled clinic visit. On the other hand, 50.3% of the patients confirmed that their physician advised them to take their thyroxine during Ramadan, whereas 40.4% could not recall receiving any advice. About 59.9% of the patients took thyroxine with *Iftar*, 23.8% with *Suhour*, and 16.3% at different times. In those patients where thyroid

Keywords

- ▶ hypothyroidism
- ▶ thyroxine replacement therapy
- ▶ Ramadan fasting
- ▶ Patients' perceptions
- ▶ Physicians' practices

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function tests were available before and after RF, serum thyroid-stimulating hormone and serum-free T4 did not show a specific pattern in the group as a whole and with subgroups.

Conclusion There is variation in the advice that hypothyroid patients receive on taking thyroxine during Ramadan and in their practices. Further studies are needed to determine the best timing for thyroxine replacement.

Introduction

Primary hypothyroidism is a common endocrine disorder.¹ Several studies have demonstrated that optimal and more consistent levothyroxine (LT4) absorption occurs under fasting conditions.² Nonfasting administration of LT4 has been criticized for being associated with higher and more variable serum thyroid-stimulating hormone (TSH) concentrations.³ Subjective improvement was observed with a change in the timing and frequency of LT4 administration.⁴ On the other hand, lower serum TSH concentrations were demonstrated when levothyroxine was taken at bedtime,⁵ and other workers proved that the evening dose of LT4 had an equal lowering effect on TSH as compared to the morning dose.⁶

During Ramadan, Muslims worldwide abstain from food and fluid intake from dawn to sunset for 29 to 30 days. The two main meals are taken just before dawn (*Suhour*) and after sunset (*Iftar*). This prolonged fasting causes several minor metabolic and hormonal changes in the body, which rarely cause any problems for a healthy individual.⁷ However, problems may arise in certain chronic diseases, and thus, patients are advised to consult their physicians before planning to fast.⁸

During Ramadan fasting (RF), patients may find taking LT4 on an empty stomach challenging since the first evening meal is commonly associated with family gatherings and other social activities. Several recommendations were sug-

gested for the supposedly best way of taking LT4 concerning food ingestion. Most of these are based on a direct translation from practices outside Ramadan.^{9–13}

Therefore, we aimed to examine physicians' perceptions regarding the clinical relevance of fasting to LT4 replacement therapy and their practices in advising patients and monitoring them after Ramadan. Second, we wished to ascertain patients' perceptions regarding thyroxine replacement therapy during RF, the source of their knowledge, and related practices.

Materials and Methods

Design

This is a mixed methods study, including physicians' survey and patients' structured interview. Both parts of the study occurred between January and August 2017 at the Center for Diabetes and Endocrinology Clinic, Sheikh Khalifa Medical City, Abu Dhabi, United Arab Emirates.

Physicians' Survey

We studied the physicians' views and practices through an electronic survey using a commercial provider (Survey Monkey, Palo Alto, California, United States). We included a convenience sample of physicians from an email database. The survey (→ **Table 1**) had seven questions with closed-end multiple choices. The domains were (1) professional profile

Table 1 The questionnaire used in the survey of physicians' views and practices on Thyroxine replacement therapy during Ramadan

| |
|--|
| Q1. Please confirm your eligibility and consent. ^a [3 options: I am willing to participate in the survey/I do not wish to participate in this survey] |
| Q2. Please indicate your specialty (5 options: endocrinology/internal medicine with interest and practice in endocrinology/Internal medicine/primary care (GP or family physician)/other (please specify) |
| Q3. Please indicate your current career stage/professional grade (4 options: consultant/specialist/resident/others) |
| Q4. What is your view on the impact of Ramadan fasting thyroxine replacement therapy? [Options: agree; I think Ramadan fasting affects thyroxine replacement therapy significantly in a clinically relevant manner/disagree; I think Ramadan effect is a minor issue and is not clinically relevant in most patients on thyroxine replacement therapy/Neutral. I am aware of the issue but do not feel strongly in favor or against the choices above/No answer; I do not know, or I am not sure] |
| Q5. Do you advise patients on how they should take their thyroxine therapy precisely during Ramadan? [Options: No, I give no specific advice routinely; Yes, I advise all my patients routinely] |
| Q6. If you have answered YES in the preceding question, How do you advise patients to take their Thyroxine therapy during Ramadan? [3 options: I advise patients to take Thyroxine at <i>Iftar</i> time and delay the <i>Iftar</i> for 30–60 minutes/I advise patients to take thyroxine at <i>Suhour</i> and delay the <i>Suhour</i> by 30–60 minutes/I advise patients at any other times they wish but ensure no food before for 2 hours and 1 hour after (e.g., <i>After Taraweeh</i> or <i>Before Bed Time</i>)] |
| Q7. Do you monitor thyroid function tests specifically after Ramadan in patients on thyroxine Replacement therapy? [2 Options: No, unless needed for routine scheduled monitoring visit/Yes, I do it routinely after Ramadan] |

^aConsent is electronically mandated before access to the rest of the questions using a logic built into the survey software.

Table 2 Structured interview instrument for the study/audit of patients' practices taking thyroxine during Ramadan fasting^a

| A. Patients' characteristics |
|---|
| 1. Serial number and 2. Record number (deleted before analysis) |
| 3. Sex: [male, female] |
| 4. Age [free text, years] |
| 5. What is the duration of known hypothyroidism? [free text years] |
| 6. Last change of dose. [free text years] |
| 7. What is your daily thyroxine dose? [free text, µg] |
| B. Questions on thyroxine therapy during Ramadan fasting |
| 8. Source of advice (Who advised you about taking your thyroxine during Ramadan fasting?) [4 Options: doctor, pharmacist, else, none] |
| 9. What is the time of intake of thyroxine: [<i>Iftar</i> , <i>Suhour</i> , other time] |
| 10. What is the time allowed after thyroxine intake [free text minutes] |
| 11. What is the time allowed before thyroxine. [free text (minutes)]. |
| B. Assessment of the impact of Ramadan fasting on thyroid function tests (Subject to availability) ^a |
| 12. Serum TSH [before; after] |
| 13. Serum thyroxine (T4) [before and after] |

Abbreviation: TSH, thyroid-stimulating hormone.

^aWithin 12 weeks before or after Ramadan, retrieved from the patient's medical records during consultations.

and (2) impact of RF on LT4 replacement therapy, (3) advice to patients on how they should take their thyroxine therapy during Ramadan?, and (4) monitoring of thyroid functions after Ramadan. The physician identification and conduct of the study are similar to the previously published studies exploring the management patterns of common endocrine disorders in the Middle East and North Africa.^{14–16}

Patients' Survey

We invited a convenience sample of patients, including consecutive patients receiving LT4 replacement therapy who attended a single endocrine clinic for any clinical encounter during RF and within 12 weeks after that. We enquired about the pattern of LT4 intake during RF and the source of their advice (►Table 2). In addition, available thyroid function tests (TFT) measurements were examined before and after RF when available for up to 12 weeks.

Data Analysis

Descriptive analysis was used to summarize data of the physicians and patients separately. Continuous variables were presented as median (range) or mean (standard deviation), and categorical variables were presented as frequencies (number [percentage]). The percentages were calculated for each separately to adjust for any missing answers. Physicians' advice and patients' practices regarding the timing of intake of levothyroxine during Ramadan were compared using the chi-squared test.

Results

Physicians' Survey

Of the 218 participating respondents, 54.8% were consultants (attending physicians, and the most represented spe-

cialty was endocrinology 46.1%) (►Table 3). Regarding the impact of RF on LT4 therapy, 52.3% of respondents thought the RF effect was not clinically relevant in most patients on LT4 replacement. Whereas just over a quarter of respondents (27.5%) thought RF affects LT4 replacement therapy in a clinically relevant manner. The remainder were undecided (►Table 3).

One-hundred sixty-eight respondents (77.1%) reported giving advice routinely to all patients on LT4 replacement during Ramadan. One-hundred sixty-four of these were split between recommending taking the medications with *Iftar* (18.3%), with *Suhour* (29.3%), or at other times with specific advice on keeping the food-thyroxine-food gaps (►Table 3). Most respondents (73.9%) do not repeat measurements of thyroid hormone levels after Ramadan unless needed during their scheduled clinic visit. In contrast, a smaller proportion (26.2%) indicated that they check TFT routinely after Ramadan.

Patients' Survey

A total of 172 consecutive patients were interviewed. They were 125 females and 47 males. The median age was 46 (17–90) years and had had hypothyroidism for a median duration of 5 years. Their median LT4 daily dose was 100 µg that was stable for 6 months (►Table 4). Over half (50.3%) confirmed their physician's advice on taking their thyroxine during Ramadan, whereas 40.4% could not recall receiving any advice (►Table 4). About 59.9% of the patients took thyroxine with their *Iftar*, 23.8% with their *Suhour*, and 16.3% at other times.

►Table 5 presents the LT4 to food-time gap and the serum TSH and serum T4 (whenever available) in the group as a whole and in the subgroups depending on when they took their LT4. For the *Iftar* subgroup, the food-LT4 gap was

Table 3 Results of the physicians' survey study

| Question and answer options (number of responders) | Responses |
|--|-------------|
| Specialty (217) | |
| ● Endocrinology | 100 (46.1%) |
| ● General medicine with an endocrine interest | 41 (18.9%) |
| ● Primary care | 32 (14.8%) |
| ● Other | 26 (12.0%) |
| ● General internal medicine | 18 (8.3%) |
| Career stage (professional grade) (217) | |
| ● Senior | 119 (54.8%) |
| ● Mid-grade | 67 (30.9%) |
| ● Junior | 15 (6.9%) |
| ● Other grades | 16 (7.4%) |
| Impact of Ramadan fasting on thyroxine therapy? (218) | |
| ● The Ramadan effect is not clinically relevant in most patients on thyroxine replacement | 114 (52.3%) |
| ● Ramadan fasting affects thyroxine replacement therapy in a clinically relevant manner | 60 (27.5%) |
| ● I am aware of the issue but do not feel strongly in favor or against either of the above choices | 29 (13.3%) |
| ● I do not know or am not sure | 15 (6.7%) |
| Do you advise patients on how they should take their thyroxine therapy precisely during Ramadan? (218) | |
| ● Yes, I advise all my patients routinely | 168 (77.1%) |
| ● No, I give no specific advice routinely | 50 (22.9%) |
| How do you advise patients to take thyroxine therapy during Ramadan? (164)^{a*} | |
| ● I advise patients to do it at any other times they wish but ensure no food before it for 2 hours and 1 hour after (e.g., after <i>Taraweeh</i> prayers or bedtime) | 86 (52.4%) |
| ● I advise patients to take thyroxine at <i>Suhour</i> and delay the <i>Suhour</i> by 30–60 minutes | 48 (29.3%) |
| ● I advise patients to take thyroxine at <i>Iftar</i> time and delay the <i>Iftar</i> for 30–60 minutes | 30 (18.3%) |
| Do you monitor thyroid function tests specifically after Ramadan in patients on thyroxine replacement therapy? (218) | |
| ● No, unless needed for a routine monitoring visit | 161 (73.9%) |
| ● Yes, I do it routinely after Ramadan | 57 (26.2%) |

^aIncluded those who answered yes to the preceding question.

120 minutes, and LT4 to food time was 90 minutes (► **Table 5**). In those patients where TFTs were available before and after RF (up to 12 weeks on either side), serum TSH and serum-free T4 did not show a specific pattern in the group as a whole and with subgroups other than outliers who admitted poor compliance (► **Table 5**).

Physicians' Advice versus Patients' Practices

There was statistically significant discordance between the advice most physicians gave and patients' practices in the timing of LT4 intake. More physicians advise patients to take LT4 at any time provided the "food-LT4-food gaps" are maintained. In contrast, most patients take their LT4 with *Iftar* (► **Tables 3** and **4**; ► **Fig. 1**).

Discussion

RF is associated with major changes in meal times that may affect LT4 absorption and TFT in patients with hypothyroidism. Since LT4 has a narrow therapeutic index and is usually administered on an empty stomach, RF poses a challenge for patients on LT4. The fasting patients would have to take their LT4 doses outside of daytime fasting hours. Recently, several studies explored the impact of fasting on thyroid replacement therapy, dose adjustment, and timing of the LT4 intake.^{16–24} However, how much of this information is translated into clinical practice and patients' day-to-day behavior has yet to be established. Therefore, exploring physicians' and patients' knowledge, attitudes, and practices

Table 4 Results of the study of patients' practices in taking thyroxine during Ramadan fasting^a

| Characteristics/Variables | Responses ^a |
|---|--------------------------|
| Sex (male/female) (172) | 47 (27.3%) / 125 (72.7%) |
| Age (years) | 46.4/46.0 (17–90) |
| Duration of known hypothyroidism (years) | 6.9/5.0 (0.33–22) |
| Time since last change of thyroxine dose (months) ^b | 5.5/6.0 (0.5–6) |
| Current daily thyroxine dose (µg) | 105/100 (25–350) |
| Source of advice on taking your thyroxine during Ramadan? (171) | |
| ● Doctor | 86 (50.3%) |
| ● Pharmacist | 4 (2.3%) |
| ● Else | 12 (7.0%) |
| ● None | 69 (40.4%) |
| The time of taking thyroxine (172) | |
| ● With <i>Iftar</i> | 103(59.9%) |
| ● With <i>Suhour</i> | 41 (23.8%) |
| ● At other times | 28 (16.3%) |
| Time allowed after thyroxine intake (minutes) ^c | 31/20 (0–300) |
| What is the time allowed before thyroxine intake (minutes) ^c | 144/120 (0–360) |

^aResults are shown as frequencies (number (%)) for categorical variables; and as mean/median (range) for continuous variables.

^bDurations stated as longer than 6 months were entered as 6 months.

^cFor the whole group with no regard to the time of taking the thyroxine.

Table 5 Results of the thyroid function tests of patients taking thyroxine during RF with no change

| Characteristics/Variables | All | <i>Iftar</i> | <i>Suhour</i> | Other |
|--|-----------------------|----------------------|-----------------------|------------------------|
| Thyroxine-food time gap (minutes) | | | | |
| Before thyroxine | 144/120 (0–360) | 120/120 (120–120) | 131/150 (0–240) | 164/150 (30–360) |
| After thyroxine | 31/20 (0–300) | 20.2/20.0(0–120) | 90/90(0–180) | 73/30 (15–300) |
| Serum TSH (mIU/mL): | | | | |
| Before RF | 5.8/3.2 (1.04–148) | 7.0/3.3(1.05–148) | 4.8/3.9 (1.04–19.13) | 3.6/2.4 (1.25–13.2) |
| After RF | 5.3/3.0 (1.02–97) | 6.3/2.9(1.02–97) | 3.5/2.4 (1.12–20.3) | 4.3/3.3 (1.02–10.9) |
| Serum T4 Before (pmol/L) | | | | |
| Before RF | 16.5/16.2 (3.52–32.9) | 15.9/16.0 (3.5–26.1) | 17.2/16.4 (10.0–32.9) | 17.6/16.9 (8.8–24.8) |
| After RF | 16.6/16.3 (2.7–38.0) | 16.0/16.1 (4.5–38.0) | 16.7/17.7 (2.7–25.8) | 18.8/17.5 (12.7–26.7) |

Abbreviations: RF, Ramadan fasting; TSH, thyroid-stimulating hormone.

is very timely. We chose the mixed methods study to evaluate physicians and patients and explore concordance or otherwise in their practices.

We made several observations. Over half of the physicians thought the RF effect was not clinically relevant in most patients on LT4 replacement. However, unexpectedly, over three-quarters reported routinely advising all patients on how to take their LT4 during RF. More than half recommended taking LT4 at any time with specific instructions about the medication-food time gap. In contrast, 59.9% of the patients

took LT4 with *Iftar*, although more than half (50.3%) confirmed receiving the physician's advice. The available serum TSH and serum-free T4 did not show a specific pattern in the group and subgroups. Furthermore, nearly (¾) 75% of physicians do not request TFTs after Ramadan unless they coincide with a scheduled clinic visit, supporting the notion that they do not consider it clinically relevant. There was a clear discordance between physicians' advice and patients' practices in LT4 timing.

Recent work addressed research questions (a) to the clinical and biochemical impact of RF on treated hypothyroid

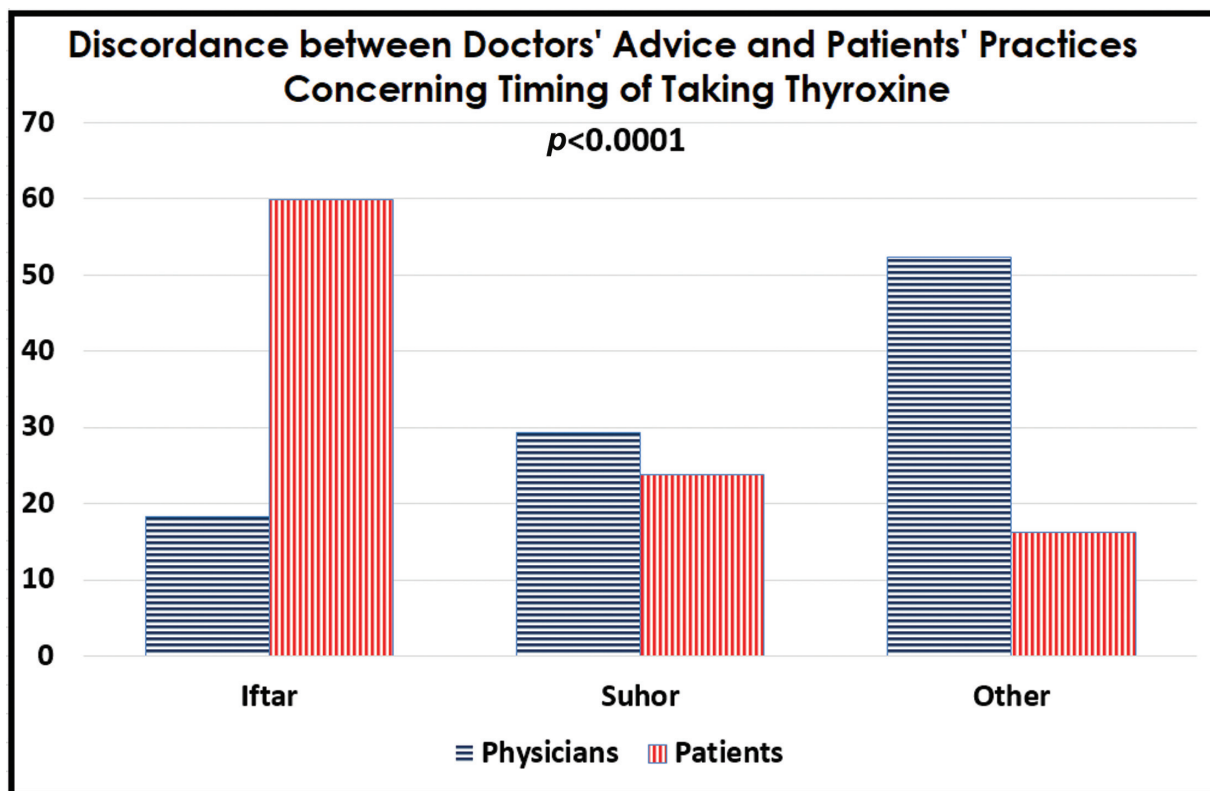


Fig. 1 The discordance between the doctors' advice and patients' practices concerning the timing of taking levothyroxine during Ramadan.

patients and (b) to specifically ascertain how best to optimize the dose or timing of LT4 during RF if needed. Elsherbiny studied the impact of fasting on thyrotropin and thyroid status during RF in 292 previously well-controlled hypothyroid patients (IFTAR study).²¹ RF resulted in a significant increase in post-Ramadan TSH, yet 80% of the patients remained euthyroid after Ramadan, suggesting that post-Ramadan TSH and euthyroidism are related to adherence and pre-Ramadan TSH. El-Kaissi et al retrospectively examined the adherence to levothyroxine, eating patterns, and levothyroxine administration concerning meal times during Ramadan in 112 fasting hypothyroid patients.¹⁹ Levothyroxine-treated hypothyroid patients showed a significant increase in plasma TSH post-Ramadan, amounting to 2.525 standard deviations, with older patients and males more likely to be affected. Moreover, Alkaf et al identified patients with higher TSH before RF at a greater risk of having more pronounced and clinically relevant changes.¹⁷ Indeed, only a smaller group whose thyroid disease appeared to be particularly affected by Ramadan's mealtime and lifestyle changes.

Furthermore, Or Koca et al investigated whether the dose of levothyroxine was changed during RF in 97 patients with a wide age range on a stable dose of LT4 for at least 6 months.²² They demonstrated a significant increase in serum TSH levels after Ramadan but no significant change in serum-free thyroxine (fT4) levels. They suggested making a small increase in LT4 dose before Ramadan in some hypothyroid patients wishing to fast.²²

Dellal et al evaluated the changes in thyroid functions during Ramadan and compared late evening and pre-*Suhour* use of

levothyroxine in hypothyroid patients.¹⁸ The increase in TSH was not significant after Ramadan. While there was an insignificant increase in median TSH, about one-third of patients had lower TSH, indicating the need to evaluate every patient individually and have close follow-up during Ramadan. Clinical studies with larger sample sizes were recommended to help determine the optimal time for levothyroxine use during Ramadan.

El-Kaissi et al in their observational study found no relationship between the time of levothyroxine administration and the change in TSH level.¹⁹ The same group a year later reported a randomized prospective study where hypothyroid patients were randomized to take levothyroxine at one of three times during Ramadan at dusk 30 minutes before *Iftar* meal, 3 or more hours after *Iftar* meal, or at dawn 30 minutes before *Suhour* meal.²⁰ TFTs were performed 3 months before and 6 weeks after Ramadan. Data from patients with at least one blood test before or after Ramadan were analyzed. The result of the study suggested that instructing patients to take levothyroxine at the time of breaking the fast 30 minutes before the *Iftar* meal minimizes unfavorable changes in plasma TSH post-Ramadan.²⁰

Also, Zaboony et al explored the best time for L-thyroxine intake during Ramadan. Fifty patients took L-thyroxine treatment for primary hypothyroidism.²⁴ Patients were divided into three groups with different times of L-thyroxine intake: pre-*Iftar*, post-*Iftar*, and pre-*Suhour* with very precise instructions on the T4-food-T4 gaps. They found no significant differences in TSH control between the groups.²⁰

Al-Qahtani et al evaluated the impact of LT4 timing during Ramadan on TSH levels in post-thyroidectomy patients to

determine the best timing for LT4 intake and identify the predictors of any TSH changes.¹⁶ Patients had stable thyroid function for 6 months before the study period and fast more than or equal to 20 days of Ramadan. They found that fasting patients who took LT4 pre-*Iftar* did not experience significant changes in TSH, whereas those who took LT4 post-*Iftar* or pre-*Suhour* did.

The physicians' part of the study is limited with its sample size and online survey nature, although the questions were direct and few. However, its objective was to explore the physicians' perceptions and practices. The patients' part of the study is limited by its observational nature, the long duration of data collection. Furthermore, TSH may not be the best method for the assessment of thyroid status around RF.

Conclusion

This study combined an assessment of both doctors and patients. Not all physicians think that RF has a clinically meaningful impact, and not all doctors give specific advice consistently. Furthermore, there needs to be more clarity in the advice that hypothyroid patients receive on taking thyroxine during Ramadan and in their practices. Real-world data from the present study did not reveal a major impact on TFT values taken in routine clinic visits. Further studies are needed to establish the relevance of RF to thyroxine replacement to develop evidence-based recommendations. Until then, patients should be offered all possibilities so they can choose the most suitable timing individually. Since various studies have employed different methods, critical appraisal of all the available studies is timely.

Authors' Contributions

S.A.B. adapted the questionnaire and managed the online and patients survey. A.S.B. managed the data collection and analysis. All other authors reviewed the data and contributed to the data analysis and interpretation, drafting, and revising the manuscript and approving its final version.

Compliance with Ethical Principles

The physician survey was approved by the IRB of Sheikh Khalifa Medical City, and all physicians provided informed consent digitally before they could answer the survey questions. The patient section was conducted as a quality improvement exercise; patients provided informed verbal consent for their data to be included in the audit. All data were analyzed anonymously.

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None.

Conflict of Interest

None declared.

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