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Impact of Ramadan fasting on thyroid status and quality of life in patients with primary hypothyroidism: A prospective cohort study from Karachi, Pakistan

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Original Article

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**IMPACT OF RAMADAN FASTING ON THYROID STATUS AND QUALITY OF LIFE IN PATIENTS
WITH PRIMARY HYPOTHYROIDISM-A PROSPECTIVE COHORT STUDY FROM KARACHI,
PAKISTAN**

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Conflict of interest:

There is no conflict of interest for this project.

Abstract:

Objectives: Ramadan is the ninth month in the lunar calendar during which Muslims fast from predawn to sunset and major changes occur in their dietary, sleep and physical activity patterns. Most patients with hypothyroidism are unable to comply with the proper timings of Levo-thyroxine (LT4) administration. The objective of the study is to determine the change in thyroid stimulating hormone (TSH) level and quality of life (QOL) before and after Ramadan in patients with primary hypothyroidism.

Methods: This Prospective cohort study included adult patients on stable doses of LT4 who fasted for at least 20 days during the month of Ramadan in the Islamic year 1437 Hijri (June/July 2016). Baseline characteristics and TSH levels were recorded on all consenting patients within 6 weeks prior to Ramadan. Post-Ramadan TSH was tested within 1 to 2 weeks after Eid-ul-Fitr.

Results: During the study period 64 patients with hypothyroidism were enrolled out of which 58 were female. The mean age of participants was 44.2 ± 13.2 years. Average daily dose of LT4 was 95.3 ± 35.4

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mcg. On an average; patients fasted for 26.5 days and missed dose of LT4 on 1.27 days. Mean TSH pre-Ramadan was 2.37 ± 1.35 mIU/L and post-Ramadan it was 4.69 ± 3.87 mIU/L. Mean difference between TSH; pre and post-Ramadan was 2.32 ± 3.80 mIU/L ($p < 0.001$). However, difference in TSH was not significantly different between those who were compliant with meal and LT4 interval versus those who were not (compliant= 2.04 mIU/L, non-compliant=3.15 mIU/L, $p=0.30$). Overall an increase in QOL scores in the domains of physical health, psychological health and social relationships was observed after Ramadan.

Conclusion: We observed statistically significant changes in TSH concentrations after the month of Ramadan in hypothyroid patients who fasted. The change in TSH was not affected by timing of LT4 intake and interval from meal.

Keywords: Hypothyroidism, Ramadan fasting, Quality of life

Introduction:

Fasting in Ramadan is one of the five pillars of Islam. Fasting during daytime is observed by millions of adult Muslims worldwide for 29-30 days every year during the ninth lunar month; 'Ramadan'(1).The duration of fasting depends on the season and the geographical location. Over the last three decades, there has been increased interest in the medical aspects of Muslim fasting during the holy month of Ramadan (2-4). Scientific research has focused on the impact of Ramadan fasting on diabetes mellitus and practice guidelines developed for management of patients with diabetes mellitus who fast during Ramadan(5). However, for other endocrine conditions particularly hypothyroidism; there is a paucity of scientific evidence regarding medical management of the condition during this month(6). Primary

hypothyroidism is a very common condition affecting approximately one in ten adults(7). Many patients with primary hypothyroidism observe fast and are keen to know the optimum timing of intake of Levothyroxine (LT4) and whether an alteration in the timing of intake will affect their Thyroid Stimulating Hormone (TSH) levels.

LT4 is the most widely used medication for thyroid hormone replacement globally(8). TSH is the best marker of thyroid health and is used in clinical practice to guide the dose adjustment of LT4(9). Once an adequate dosing is established and the patient is stable, TSH can be followed up at six-monthly or yearly basis. LT4 conventionally is taken orally in the morning on an empty stomach before breakfast as food and certain medications may interfere with its absorption (8-10). The American Thyroid Association recommends a 60 minutes interval between intake of LT4 and eating or a 3 hour interval after the previous meal(9). The main meals during Ramadan are called Suhoor, which is the meal before dawn and Iftar, which is the meal after the sunset. During Ramadan alterations occur in the usual amount and pattern of food and fluid intake and in daily physical activities and sleeping patterns. The month of Ramadan follows the Islamic lunar calendar, which is 11–12 days shorter than the solar year. Thus the month of Ramadan varies each year and migrates throughout the seasons. During the summer months, Muslims face increasingly prolonged fasting hours, in particular in regions far away from the equator (more than 18 hours a day). During the year 2016, the duration of fasting was around 15 hours in Karachi, Pakistan.

During Ramadan, it is difficult to comply with LT4 intake, especially maintaining the interval between meals and LT4. There is a lack of scientific evidence on the impact of Ramadan fasting on TSH levels and change in quality of life. Therefore, the primary objective of this study was to look at the change in TSH levels in patients with primary hypothyroidism before and after the completion of holy month of Ramadan. In addition, we looked at the change in quality of life associated with fasting.

Material and Methods:

Study design and setting

This prospective cohort study was carried out in outpatient endocrinology clinics at The Aga Khan University Hospital (AKUH), Karachi, Pakistan. The endocrinology clinics at AKUH receive around 120 patients per day; about 10% of these patients have hypothyroidism. Ethics approval was obtained from The Aga Khan University Ethics Review committee. Informed consent was obtained from the patients after explaining details of the study.

Selection of participants

All patients ≥ 18 years presenting to AKUH endocrinology clinics with primary hypothyroidism, having TSH levels checked within 6 weeks prior to Ramadan and intending to fast for at least 20 days during Ramadan in the Islamic year 1437 Hijri i.e. June and July 2016 were included. We excluded patients with change in LT4 dose within 6 weeks prior to Ramadan, women attempting to conceive or pregnant, having a recent addition of drug that impairs LT4 absorption, including antiepileptics, rifampicin, cholestyramine, sucralfate, antacids, raloxifen, steroids, iron or calcium preparations. Moreover, patients who were on suppressive doses of LT4 or those with any end stage organ diseases were also excluded.

Methods and measurements

A medical doctor trained for research data collection, assessed patients for eligibility. Informed consent was obtained after explaining details of the study. All participants were interviewed by the research associate and their medical records were reviewed. Participants were advised to return to clinic within one to three weeks after Ramadan.

Demographics, clinical characteristics, comorbid conditions, concomitant medications, dose and time of LT4 were obtained by structured questionnaire. During the post Ramadan visit patients were asked retrospectively about any acute illnesses during Ramadan, number of days fasted, time interval between LT4 and meals and quality of meals.

Urdu translated and validated version of 26 item World Health Organization Quality of Life-BREF (WHOQOL-BREF) was used to assess the quality of life before and after Ramadan (11). Permission to use the tool was obtained from the Information Evidence and Research (IER) department of WHO. The tool is a generic quality of life instrument and comprised of 26 questions. Two of the questions inquire about general health and overall quality of life. The remaining 24 questions provide a profile of scores on four dimensions of quality of life; physical health, psychological health, social relationships and the environment. Each item has a score from 1 to 5 on a Likert scale. The scores are then transformed into a linear scale between 0 and 100, where 0 indicates least favorable and 100 indicate most favorable quality of life.

On site data was checked by the research officer following patient interviews. In addition, random checks were done by the study investigators to ensure quality and accuracy of data collection and entry.

Outcomes

Change in TSH level pre and post Ramadan was the primary outcome of this study. The pre-Ramadan TSH levels were done within 6 weeks before onset of Ramadan. Whereas, patients were advised to get their post Ramadan TSH levels within one to two weeks after Ramadan.

Serum TSH levels at our center are analyzed on an automated analyzer; ADVIA Centaur (Siemens Diagnostics, NY, US) using Chemiluminescence immunoassay technique. The ADVIA Centaur TSH3-Ultra assay standardization is traceable to the World Health Organization (WHO) 3rd International Standard

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for human TSH (IRP 81/565). The assay normal range is 0.4-4.2 mIU/L. Three level quality control materials are run with each batch of samples. The laboratory participates in proficiency testing survey of College of American Pathologists twice a year with >80% performance when compared with peer group.

Statistical Analysis

Statistical analysis was carried out using statistical package for social sciences (SPSS, version 19.0). Means with standard deviation and median with interquartile ranges were reported for all quantitative variables and frequencies with percentages were reported for all categorical variables. TSH levels pre and post Ramadan were compared using paired sample T-test. Characteristics of study participants pre and post Ramadan were compared using chi square test or fisher exact test. Continuous variables such as age, BMI, time since diagnosis, number of days fasted were compared across the categories of pre and post Ramadan using paired sample T-test and were also compared across the categories of compliance using independent sample T-test or Chi square test. Comparison was also done across different levels of TSH post Ramadan. Change in each domain of QOL was compared across categories of variables such as age, education, gender etc. Results with a p-value of <0.05 were considered to be statistically significant.

Results:

Participant characteristics

Table 1 shows clinical and demographic characteristics of study participants. A total of 64 patients with primary hypothyroidism were enrolled. There were 58 women and 8 men aged between 22 and 70 years with mean age of 44.2 ± 13.2 years. A majority of participants (45.3%) were in the age group of 36-55 years. About half of the participants (51.6%) were obese with a BMI of ≥ 30 . About 25 of the participants

had no comorbid conditions, 17 had hypertension, 15 had dyslipidemia, 10 had diabetes, 8 had pre-diabetes/insulin resistance, 5 had PCOS and 4 had depression/bipolar disease. A small number of patients reported to have osteoporosis, obesity, acidity and cardiovascular disease.

The majority of patients had no known etiology of hypothyroidism (73.4%) followed by a few having autoimmune, post-surgical, post radioactive iodine and congenital etiology of disease (Table 1). Participants were on LT4 for an average of 8.3 years, duration ranging from 2 months to 30 years. Average daily dose of LT4 was 95.3 ± 35.4 mcg.

Response to Ramadan fasting

On an average, patients fasted for about 26.5 days. Mean weight change before and after Ramadan was of 0.22 kg (SD= ± 1.7 , P=0.30). On an average, patients missed dose of LT4 on 1.27 days. Ten participants reported minor illnesses during Ramadan.

Change in TSH before and after fasting in Ramadan

Figure 1 and 2 show changes in TSH pre and post Ramadan. Pre-Ramadan, eight participants had a TSH >4.0 mIU/L which increased to 28 participants having a TSH >4.0 mIU/L post Ramadan (P= 0.28).

Mean difference between TSH pre and Post Ramadan was 2.32 ± 3.80 mIU/L ($p < 0.001$) (Pre-Ramadan mean 2.37 ± 1.35 mIU/L, Post-Ramadan mean 4.69 ± 3.87 mIU/L).

No significant differences in characteristics were observed between those who had a difference in TSH (before and after Ramadan fasting) of ≥ 2.0 mIU/L vs. those having a difference of <2.0 mIU/L. A higher

percentage of participants with TSH > 4.0 mIU/L were obese as compared to those in the category of ≤ 4.0 mIU/L (53.6% vs. 47.2%)(acceptable TSH) although statistically insignificant. A higher number of patients, who had an acceptable TSH post-Ramadan also; had an acceptable TSH pre-Ramadan.

Meal Quality, interval between food and LT4 and effect on TSH

About 75% of the participants were able to keep the interval between meals and LT4 for at least 2 hours post meal and 30 minutes pre meals. The difference in TSH was not significantly different between those who were compliant with meal and LT4 interval versus those who were not (compliant= 2.04 mIU/L, non-compliant=3.15 mIU/L, $p=0.30$) (figure 3) In addition, all the participants were using one or other source of food that interferes with LT4 absorption. Participants reported using deep fried food, fast food, tea/coffee, bakery items, fiber enriched food items, red meat, mayonnaise or oily spreads and dressings, Ghee, milk and milk products (cream, yogurt, cheese, butter) and egg.

Interval between other medications and LT4

About 43 out of 64 participants were compliant with maintaining a recommended interval of four hours between LT4 and other medications. Those who were compliant were younger, less educated, more likely to be married, more likely to stay at home and had a longer duration since diagnosis.

Participants who were working or studying as compared to those staying home were younger ($P=0.06$), were on higher daily dose of LT4 and had a higher mean difference in TSH pre and post Ramadan.

Impact of fasting on Quality of life of patients

WHOQOL BREF scores for different domains pre and post Ramadan fasting are listed in table 2. Overall there was an increase in QOL scores in the domains of physical health, psychological health and social relationships. A reduction in scores was observed in environmental domain. Highest and statistically

significant difference in scores was reported in physical health (mean difference = 9.04, $P < 0.001$). Difference was also observed in general health scores (mean difference=9.37, $P=0.004$) however when participants were asked to self-rate their quality of life the reported difference in scores were not significantly different (mean difference=5.07, $P=0.14$). There was no correlation between change in TSH scores and any of the QOL domain scores. Statistically significant Improvement in physical domain scores were observed most in those who were diagnosed and were on LT4 for less than 10 years and those on lower dose of LT4 (≤ 75 mcg). Those who were staying at home had improved QOL as compared to those who were either working or studying ($p=0.07$). Improvements in psychological and environmental domains were also observed with increasing duration of disease and LT4 use.

Discussion:

Ramadan is the ninth month of the lunar Muslim calendar and fasting in the month of Ramadan is one of the five pillars of Islam and an integral part of faith. Fasting during Ramadan is obligatory for all healthy adult Muslims (1). Those who fast must refrain from eating and drinking from dawn to dusk, and must abstain from using oral medications, sexual activity and smoking during the fasting state. This is the first study reporting the impact of Ramadan fasting on TSH amongst Pakistani hypothyroid patient on LT4. In addition, change in quality of life has never been assessed in patients opting to fast during Ramadan. In our study; the changes in TSH levels pre- and post-Ramadan achieved statistical significance. Data from published research on Hypothyroidism and Ramadan fasting suggest to increase the dose of LT4 by 25-50 mcg daily from beginning of Ramadan and continuing the increased dose until 15-20 days after Ramadan(12). An earlier study conducted on Ramadan fasting amongst normal subjects showed a significant gradual rise in TSH throughout the fasting month,(Pre-Ramadan TSH 3.34 ± 0.337 , near end of Ramadan TSH 4.61 ± 0.375) Though the mean levels remained within normal limits and pre-Ramadan levels were re-attained well after the end of Ramadan (TSH 5 months post-Ramadan

3.48±0.176)(13). Our study showed the mean difference between TSH pre and Post Ramadan to be 2.32 ± 3.80 mIU/L (p<0.001) (Pre-Ramadan mean 2.37 ± 1.35 mIU/L, Post-Ramadan mean 4.69 ± 3.87 mIU/L). This change in TSH could be a temporary phenomenon as can happen if TSH is followed on a longitudinal basis (14). Anderson et al described pre-analytical, analytical and biological variations in TSH and thyroid hormones in serum. This is divided into between- and within-individual variation. The biological variations consist of seasonal and circadian differences. Repeated measurements of thyroid function tests in one individual scatter around an individual mean value (14). During Ramadan, a major change occurs in the sleep, dietary and physical activity patterns of an individual and may contribute to such variation in TSH levels that we observed in our study. The fasting state during Ramadan likewise can put the system in a state of mild non-thyroidal illness and the rise in TSH that is observed after Ramadan could likely be the recovery phase of non-thyroidal illness (15).

There is a scarcity of studies which have specifically looked at the effect of changing the timing of LT4 during Ramadan on TSH level. Some of the published literature postulate that during Ramadan, the proper administration of LT4 is achieved if it is taken an hour before Sahoor; however most of the patients find it difficult to wake up that early and either miss the dose or take it with the meal. The absorption of LT4 is 80% when taken 60 minutes before meal but is reduced to 60% if taken after a meal(16), thus absorption is variable and may alter TSH levels. Still others have reported no significant impact on dose requirement, TSH levels or quality of life in morning vs evening dose of LT4(17). A study from India, on hypothyroid patients fasting during Ramadan, looked at the impact of intake of LT4 2 hours after last meal at bedtime on TSH and found that almost 75% patients could not keep interval of 2 hours between dinner and drug(18). Amongst their study participants; TSH increased in 29 but remained unchanged in 18 patients(13). We did not find an impact on TSH level with interval from meal, those who maintained the interval and those who couldn't had similar changes in TSH levels. A longer duration

of fasting makes it difficult to ensure that the patients will be able to have a bed time dose of LT4 and still able to keep an interval of 2 hours from last meal or whether they will be able to get up before dawn and be able to ingest their LT4 30-60 minutes before sahoor.

Some medications and food products can affect the absorption of LT4 such as iron sulphate, calcium preparations, cholestyramine, resin, sucralphate, aluminum antacids, raloxifene, activated charcoal, various soya products and food and herbal remedies(8, 9). We did not find any effect of fatty food or concomitant medications on TSH levels pre or post-Ramadan.

Different studies have looked at impact of mild and overt thyroid hormone deficiency on health related quality of life(19). Some studies have shown that the quality of life scores improve in those who are adequately replaced with thyroid hormone but usually stay lesser than their counterparts who do not have any degree of hypothyroidism (20-22). Few studies have specifically shown improvement in tiredness in patients who were treated with LT4 in both overt and subclinical hypothyroidism (21, 23). A recent study from Iran did not show any significant difference in QOL in patients with hypothyroidism and normal (euthyroid) controls but the comparison of mental health level of patients and normal people reached a significant p-value of <0.001(24). Even in those patients who are euthyroid on thyroid hormone replacement; presence of thyroid autoimmunity i.e. higher anti-TPO and anti-TG levels per se has been associated with significantly lower quality of life domain score ($p < 0.001$) compared to antibody negative groups(25). Under-treatment of patients with hypothyroidism likewise adversely affects the health related quality of life as compared to appropriately treated patients(26).

We observed improvement in QOL scores in domains of physical health, psychological health and social relationships. This change could be due to the psychological impact of spiritual rewards associated with this Holy month and increased social interactions at the festive time of Eid-ul Fitr that marks the end of Ramadan and is a time of reunion with family and friends.

The strength of our study is that it was done in routine clinical setting and we left the choice of timing of LT4 intake to the patient's convenience. Secondly, we had a diverse study sample consisting of patients from different ages, back grounds and disease durations. Even though our study was conducted in a large teaching hospital and had a diverse sample, it was a single center study and might not represent general population of the city therefore the generalizability of the results is limited. Similarly; lack of a control group is another limitation which otherwise would have been useful relative to the QOL component of the study. We checked TSH before Ramadan and then 1-2 weeks after Ramadan considering the need of 6-8 weeks for TSH changes to occur but failure to test TSH in the beginning of Ramadan and end of Ramadan is our study limitation. Similarly, our subjects reported to us on what they did during Ramadan; 1-2 weeks after Ramadan. The accuracy of their self -report relative to compliance is of low reliability and is another limitation.

In conclusion, Islamic fasting results in statistically significant changes in TSH concentrations and is not affected by timing of LT4 intake and interval from meal. Islamic fasting improves the quality of life scores in the domains of physical and psychological health and social interactions. Based upon our observation, it might be prudent to make a small dose increment in LT4 dose during Ramadan but we do not recommend this until it is justified from more research evidence. Similarly, the timing of intake of LT4 can be left to patient discretion as we did not observe any impact of interval of LT4 from meal or the quality of meal on thyroid status. More studies are needed to assess the impact of Ramadan fasting on patients with primary hypothyroidism from different geographical locations and with different duration of fasting especially with longer fasting hours than ours.

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Figure legends:

Figure 1: Pre and post Ramadan TSH levels for study participants

Figure 2: Changes in TSH levels pre and post Ramadan fasting

Figure 3: Mean TSH levels pre and post Ramadan fasting with respect to compliance with intervals between meals and Levo-thyroxine intake