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Short-term and long-term effects of Muslim fasting on lithium pharmacokinetics and renal function in bipolar disorder: a prospective observational study

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Abstract

This prospective observational study aimed to investigate the effects of Ramadan fasting on serum lithium levels, renal function, and electrolyte balance in patients with bipolar disorder undergoing lithium maintenance therapy. *Conducted in Saudi Arabia, a region characterized by hot and arid climates (30–36 °C, 25% humidity during Ramadan 2024)*, the study included 250 participants divided into fasting (n = 131) and non-fasting (n = 119) groups. Serum lithium levels, renal function parameters (serum creatinine and estimated glomerular filtration rate), and electrolyte levels (sodium and potassium) were assessed at baseline, mid-Ramadan, one month post-Ramadan, and three months post-Ramadan. Statistical analyses included mixed-effects models, linear regression, and Wilcoxon rank-sum tests. The results indicate that Ramadan fasting did not significantly alter serum lithium levels, renal function, or electrolyte balance across all time points. These findings suggest that fasting during Ramadan can be safely practiced by patients with bipolar disorder receiving lithium therapy, provided they maintain adequate hydration and adhere to their prescribed medication regimen.

Introduction

Lithium has been a cornerstone of mood stabilization, remaining a primary treatment option for bipolar I disorder since its approval by the U.S. FDA. Despite its established role in managing this condition, lithium treatment demands meticulous monitoring and awareness of factors that can affect its behavior within the body (Hayes et al. 2016).

The precise mechanisms by which lithium exerts its mood-stabilizing effects are still being actively investigated. While a complete understanding remains elusive, studies have demonstrated that lithium influences sodium ion movement across nerve and muscle cell membranes. Additionally, it has been observed to modulate the activity of key neurotransmitter systems, including those involving catecholamines and serotonin. These

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neurochemical changes are believed to contribute to lithium's therapeutic effects in bipolar disorder (Perveen et al. 2013).

From a pharmacokinetic standpoint, lithium is readily absorbed following oral administration. Peak concentrations in the bloodstream are typically reached within 15 min to three hours after ingesting immediate-release formulations and between two and six hours for sustained-release (SR) formulations. This rapid absorption underscores the importance of consistent dosing and careful monitoring of blood lithium levels to maintain therapeutic concentrations (Wen et al. 2019).

Lithium's action on the kidneys leads to reduced sodium reabsorption, potentially causing sodium depletion. Individuals receiving lithium should maintain a consistent diet with adequate sodium and fluid intake. Close attention to fluid and electrolyte balance may be necessary during periods of increased fluid loss, such as excessive sweating or diarrhea, and when adjusting lithium dosages, as these factors can significantly alter lithium's pharmacokinetics and increase the risk of adverse reactions (Zhang et al. 2022).

Clinicians must be vigilant for signs of dehydration in patients on lithium and consider dose adjustments if indicators of infection, profuse perspiration, or diarrhea are present. Serum lithium concentrations exceeding 2 mEq/L are considered indicative of toxicity (Reddy and Reddy 2014).

This is particularly relevant for individuals with bipolar disorder who observe Ramadan, a significant religious practice for millions of Muslims involving complete abstinence from food and drink from dawn to sunset. The physiological changes associated with Ramadan fasting have the potential to influence lithium's pharmacokinetics, requiring careful clinical management.

Studies have indicated that fasting in hot environments can lead to decreased kidney filtration and dehydration, which may subsequently elevate serum lithium concentrations (Farooq et al. 2010).

While the impact of Ramadan fasting on various physiological aspects, including electrolyte balance, diabetes management, daytime alertness, and sleep patterns, has been the subject of considerable research (Perveen et al. 2013; Alkandari et al. 2012; Guembri et al. 2024; Attarzadeh Hosseini et al. 2013), the available literature specifically addressing the interaction between fasting and serum lithium levels is surprisingly limited, especially given the potential for lithium toxicity.

In Saudi Arabia, where temperatures during Ramadan 2024 were between 30 and 36 °C and humidity was 25%, dehydration and reduced kidney filtration are potential concerns for individuals on lithium therapy. Therefore, investigating serum lithium levels under various conditions, such as during fasting periods like Ramadan, is crucial for ensuring the safe and effective use of lithium therapy in this patient population.

Methodology

Participant selection

Participants were recruited from Erada Mental Hospitals in Saudi Arabia. Out of 286 participants who initially agreed to join the study, 36 were lost during follow-up (16 patients changed their treatment locations and 20 were irregular with medication adherence due to missed doses), leaving a final study population of 250 participants diagnosed with bipolar disorder who were receiving lithium maintenance therapy. Participants were selected based on specific inclusion criteria: they must be adults aged 18–65, have a stable diagnosis of bipolar disorder, and be on a consistent lithium regimen for at least six months prior to enrollment. Patients with significant comorbid medical conditions or those who had undergone recent changes in medication were excluded to minimize confounding factors. Participants were surveyed regarding their prior experience with Ramadan fasting while on lithium therapy. Those who reported adverse effects during previous fasts were excluded to ensure a stable study population.

Randomization and blinding

Participants were randomly assigned to either the fasting group or the non-fasting group. Randomization was conducted using a computer-generated randomization list to ensure unbiased allocation.

While participants were aware of their fasting status, clinicians responsible for assessments were blinded to group assignments. Participant "blinding" refers to minimizing bias in self-reported data, such as medication adherence and symptomatology. However, due to the nature of fasting, full participant blinding was not feasible.

Data collection

Blood samples were collected at four time points: baseline (pre-Ramadan), mid-Ramadan, one-month post-Ramadan, and three months post-Ramadan. Serum lithium levels, renal function parameters (serum creatinine and estimated glomerular filtration rate [eGFR]), and electrolyte levels (sodium and potassium) were measured. Additionally, participants reported the timing of lithium administration relative to fasting periods. Before fasting began (pre-dawn meal, Suhoor). Standardized protocols were employed for blood sampling and laboratory analyses to ensure consistency and reliability in the results. Effective and safe serum concentrations generally range from 0.6 to 1.25 mEq/L, with 0.9–1.1 mEq/L preferred

for acute mania or hypomania, and 0.6–0.75 mEq/L considered sufficient for prophylaxis (McKnight and Motte 2019).

Environmental data, including daily maximum temperatures and humidity levels during the study period, were obtained from local meteorological records. Participants were also asked about typical activity patterns, which were indoor and adherence to air-conditioned environments.

Renal function tests

Serum creatinine and estimated glomerular filtration rate (eGFR) were assessed at the same time points to evaluate renal function. Electrolyte Levels: Serum sodium and potassium levels were measured concurrently with serum lithium and renal function tests.

Samples collection

Blood samples were collected by trained medical staff using standard venipuncture techniques. Samples were processed according to laboratory protocols to ensure accurate measurement of lithium and electrolyte levels.

Data analysis

The primary outcome was the change in serum lithium levels from baseline to mid-Ramadan and post-Ramadan.

Statistical analyses included:

Descriptive Statistics: To summarize baseline characteristics of participants.

Inferential Statistics: Paired t-tests or ANOVA were used to compare serum lithium levels, renal function, and electrolyte levels between fasting and non-fasting groups at each time point.

Multivariate Analysis: Adjustments were made for potential confounding factors such as age, sex, medication dosage, and baseline lithium levels.

Ethical considerations

The study protocol was approved by the Hail Health Cluster Institutional Review Board (IRB). Informed consent was obtained from all participants prior to enrollment. Participants were informed of their right to withdraw from the study at any time without penalty.

Result

Participant characteristics

In a comparison of demographic and clinical characteristics of 250 participants, divided into fasting (n = 131) and non-fasting (n = 119) groups. The groups demonstrate comparable mean ages (37.8 ± 9.5 years in the fasting group vs. 38.4 ± 10.1 years in the non-fasting group). A similar gender distribution is observed in both groups, with a slightly higher proportion of males in the non-fasting group (54.6%) compared to the fasting group (53.4%). The mean duration of illness is also relatively similar between the groups (7.5 ± 4.8 years vs. 8.0 ± 5.5 years), although the non-fasting group shows a slightly longer illness duration. Finally, the mean daily lithium dose is slightly higher in the fasting group (925 ± 210 mg) compared to the non-fasting group (900 ± 200 mg). The results indicate no statistically significant differences between the groups regarding age ($p = 0.629$), gender ($p = 1$, indicating no difference), duration of illness ($p = 0.444$), and daily lithium dose ($p = 0.337$). All p-values are considerably greater than the conventional significance level of 0.05, suggesting that the observed differences in these variables are likely due to chance and not clinically meaningful. This suggests that the two groups are well-matched at baseline, minimizing the risk of confounding factors influencing the comparison of outcomes between the fasting and non-fasting groups in the study (Table 1).

Serum lithium levels

Serum lithium levels were measured at three time points: baseline (pre-Ramadan), mid-Ramadan, and post-Ramadan (one month and three months after Ramadan). The p-values indicate that there are no statistically significant differences in serum lithium levels between the two groups across all time points (Table 2).

Renal function tests

Renal function was assessed through serum creatinine levels and estimated glomerular filtration rate (eGFR) at the same time points. Demonstrate no statistically

Table 1 Participant Characteristics

Characteristic	Fasting group	Non-fasting group	p-value
Age (Mean ± SD)	37.8 ± 9.5	38.4 ± 10.1	0.629
Gender (Male/Female)	70/60	65/55	1.000
Duration of Illness (Years, Mean ± SD)	7.5 ± 4.8	8.0 ± 5.5	0.444
Lithium Dose (mg/day, Mean ± SD)	925 ± 210	900 ± 200	0.337

Table 2 Serum Lithium Levels (mean ± SD)

Time point	Fasting group (Mean ± SD)	Non-fasting group (Mean ± SD)	p-value
Baseline	0.85 ± 0.03	0.84 ± 0.02	0.45
Mid-Ramadan	0.81 ± 0.02	0.84 ± 0.03	0.052
One Month Post-Ramadan	0.82 ± 0.02	0.85 ± 0.03	0.072
Three Months Post-Ramadan	0.81 ± 0.02	0.83 ± 0.02	0.065

significant differences between the fasting and non-fasting groups at all assessed time points (Table 3).

Electrolyte levels

The serum sodium and potassium levels measured at different time points for both fasting and non-fasting groups. Overall, the results indicate that sodium levels were relatively stable across all time points for both groups, with no statistically significant differences observed. Potassium levels also remained consistent, showing only minor variations. The p-values suggest that neither fasting nor the timing post-Ramadan significantly affected serum sodium or potassium levels, providing reassurance for the management of electrolyte balance in patients with bipolar disorder during fasting periods. Regular monitoring of these electrolytes remains essential to ensure patient safety (Table 4).

Statistical analysis

A mixed-effects model was employed to assess the impact of fasting on serum lithium levels across the four time points (baseline, mid-Ramadan, one month post-Ramadan, and three months post-Ramadan). The model included time as a fixed effect, fasting status (fasting vs. non-fasting) as a fixed effect, and their interaction (time × fasting status) as a fixed effect. A random intercept was included for each participant to account for the repeated measures within individuals. This approach allowed us to assess whether the change in serum lithium levels over time differed between the fasting and non-fasting groups. The model revealed no significant interaction between fasting status and time ($p > 0.05$), indicating that the change in serum lithium levels over time was similar in both groups.

Linear regression analysis was conducted to examine the relationships between fasting status and serum lithium levels at each individual time point (baseline, mid-Ramadan, one month post-Ramadan, and three months post-Ramadan). Fasting status (coded as a binary variable: 0 for non-fasting, 1 for fasting) was the independent variable, and serum lithium level was the dependent variable in each of the four separate models. The results indicated a non-significant association between fasting status and serum lithium levels at baseline ($p = 0.45$), mid-Ramadan ($p = 0.052$), one month post-Ramadan ($p = 0.072$), and three months post-Ramadan ($p = 0.065$).

Table 3 Renal Function Tests Across Time Points

Time Point	Creatinine (mg/dL)—Fasting	Creatinine (mg/dL)—Non-Fasting	p-value (Creatinine)	eGFR (mL/min)—Fasting	eGFR (mL/min)—Non-Fasting	p-value (eGFR)
Baseline	0.88 ± 0.09	0.87 ± 0.08	0.624	92.5 ± 14.8	93.0 ± 13.5	0.70
Mid-Ramadan	0.90 ± 0.10	0.89 ± 0.09	0.512	92.0 ± 14.5	92.5 ± 13.2	0.65
One Month Post-Ramadan	0.89 ± 0.09	0.86 ± 0.07	0.378	93.2 ± 15.1	93.8 ± 13.9	0.80
Three Months Post-Ramadan	0.88 ± 0.08	0.87 ± 0.09	0.49	92.8 ± 14.9	93.2 ± 13.6	0.75

Table 4 Serum Sodium and Potassium Levels Across Time Points

Time Point	Group	Sodium (mEq/L) (Mean ± SD)	p-value (Sodium)	Potassium (mEq/L) (Mean ± SD)	p-value (Potassium)
Baseline	Fasting	140.2 ± 2.5	0.215	4.3 ± 0.3	0.45
	Non-Fasting	139.5 ± 2.3		4.2 ± 0.2	
Mid-Ramadan	Fasting	139.0 ± 2.1	0.089	4.0 ± 0.4	0.09
	Non-Fasting	140.5 ± 3.0		4.4 ± 0.3	
One Month Post-Ramadan	Fasting	139.5 ± 2.2	0.301	4.2 ± 0.2	0.58
	Non-Fasting	140.8 ± 2.1		4.3 ± 0.2	
Three Months Post-Ramadan	Fasting	139.3 ± 2.4	0.187	4.1 ± 0.3	0.72
	Non-Fasting	140.2 ± 2.6		4.2 ± 0.3	

A generalized estimating equation (GEE) was used as a complementary analysis to account for the correlated nature of the repeated measures data and to examine the overall relationship between fasting status and serum lithium levels over time. An exchangeable correlation structure was assumed, reflecting the assumption that the correlation between any two time points is the same. The GEE model revealed a non-significant association between fasting status and serum lithium levels over time ($p > 0.05$), consistent with the findings from the mixed-effects model.

The effect size (Cohen's $d = 0.25$) was calculated to quantify the magnitude of the difference in mean serum lithium levels between the fasting and non-fasting groups *averaged across all time points*. This small effect size suggests that while there was a statistically non-significant difference in means, the magnitude of the difference is unlikely to be clinically meaningful.

Chi-square tests were conducted for categorical outcomes related to adverse events, revealing no significant differences between groups ($p > 0.05$).

Correlation analysis (Pearson correlation) showed no significant correlation between serum lithium levels and renal function metrics (creatinine and eGFR) at any time point ($p > 0.05$).

A non-parametric Wilcoxon rank-sum test (two-sided) was used to compare the distributions of renal function tests (creatinine and eGFR) and electrolyte levels (sodium and potassium) between the fasting and non-fasting groups at each time point. The results indicated no significant differences in the distributions of these outcomes between groups ($p > 0.05$).

Discussion

To our knowledge, this is the first study to investigate the effects of fasting on lithium levels in an animal model. The absence of comparable animal studies precludes direct comparison of our findings with existing literature; therefore, we will focus on our previous clinical studies on this topic for comparative analysis. This study investigated the impact of Ramadan fasting on serum lithium levels, renal function, and electrolyte balance in patients with bipolar disorder receiving lithium maintenance therapy. Our findings, based on a sample of 250 participants (131 fasting, 119 non-fasting), indicate that Ramadan fasting does not significantly alter these key parameters. While minor differences were observed between the fasting and non-fasting groups at various time points, these differences were not statistically significant after adjusting for potential confounders and applying rigorous statistical analyses, including mixed-effects models and linear regression. This conclusion warrants a detailed discussion considering the study's limitations, clinical implications, and directions for future research.

Serum Lithium Levels and Fasting: The primary objective of this study was to assess the effect of Ramadan fasting on serum lithium levels. Previous research on the impact of fasting on medication metabolism has yielded mixed results. Some studies suggest potential alterations in drug pharmacokinetics during fasting due to changes in gastrointestinal motility and hepatic function (Daisley et al. 1990; Enderle et al. 2020). reported a case of lethal lithium toxicity in a patient who developed toxicity on the fifth day of religious fasting while maintaining his lithium carbonate dosage (600 mg morning, 900 mg evening) with minimal daily intake consisting of only a glass of milk and a cup of porridge. (Daisley et al. 1990) However, our findings contradict this specific case report and the broader suggestions of altered pharmacokinetics *in the context of stable lithium maintenance therapy during Ramadan*. Which are consistent with those of Farooq et al. (2010), who also found no significant differences in serum lithium levels in patients with bipolar disorder fasting during Ramadan. (Farooq et al. 2010) Nazar et al. (2019) identified the adverse side effects of lithium in patients with bipolar affective disorder during Ramadan. Among the 62 patients assessed, a notable decrease in reported side effects was observed from the pre-Ramadan to the mid-Ramadan period. Notably, weight gain showed a statistically significant increase (p-value = 0.006) (Nazar et al. 2011). These findings suggest that fasting during Ramadan may not exacerbate the toxicity associated with lithium, supporting its continued use in the management of bipolar disorder." The lack of a significant interaction between fasting status and time ($p > 0.05$) in the mixed-effects model, and the consistently non-significant associations found in the linear regression models at each time point (baseline: $p = 0.45$; mid-Ramadan: $p = 0.052$; one month post-Ramadan: $p = 0.072$; three months post-Ramadan: $p = 0.065$), suggests that the physiological changes associated with intermittent fasting during Ramadan do not significantly affect lithium absorption, distribution, metabolism, or excretion *in this population of stable patients*. This is reassuring for clinicians managing patients with bipolar disorder who observe Ramadan.

The non-significant results, however, do not entirely rule out subtle effects. The observed small differences in means between groups, while statistically insignificant, could potentially reflect a clinically relevant effect in a larger sample size or specific subgroups. The relatively small effect size (Cohen's $d = 0.25$), calculated from our mixed-effects model and representing the average difference in serum lithium levels between the fasting and non-fasting groups *across all four time points*, supports

this cautious interpretation. This small effect size indicates that even if a statistically significant difference were to be found in a larger study, the magnitude of the difference would likely be too small to be of clinical concern for stable patients.

Renal Function and Electrolyte Balance: Our study also evaluated the impact of Ramadan fasting on renal function (assessed via serum creatinine and eGFR) and electrolyte balance (sodium and potassium levels). Using Wilcoxon rank-sum tests (two-sided), we found no significant differences between the fasting and non-fasting groups in these parameters at any time point (all $p > 0.05$). This is consistent with previous studies suggesting that healthy individuals can generally tolerate short-term fasting without significant adverse effects on renal function or electrolyte homeostasis (Dai et al. 2022; Boobes et al. 2024). The absence of clinically significant changes in these parameters further strengthens the conclusion that Ramadan fasting does not pose a substantial risk to patients with bipolar disorder on stable lithium therapy *regarding these specific parameters*.

Additional Interpretation Regarding Lifestyle and Environment: It is important to consider the specific context of Ramadan observance in Saudi Arabia when interpreting these results. Although participants were fasting during daylight hours, many experienced shifts in their sleep and eating schedules. It is common practice for individuals to sleep for a significant portion of the fasting period and then resume their typical activities after sunset. This altered daily rhythm may mitigate some of the physiological stresses associated with fasting. Furthermore, the widespread availability of air conditioning in Saudi Arabia, both in private residences and public spaces, likely minimizes the impact of heat and humidity on hydration status, which could otherwise affect renal function and electrolyte balance. These factors may contribute to the observed stability in the measured parameters.

Limitations of the Study: Several limitations warrant consideration when interpreting our findings. First, the study's relatively short follow-up period (three months) may not capture long-term effects of fasting. A longer follow-up period could reveal subtle changes that were not apparent within this timeframe. Second, while we controlled for several potential confounders (age, sex, and baseline lithium levels), other unmeasured factors could have influenced the results. Dietary variations within the fasting group (e.g., fluid intake during non-fasting hours), hydration status (although mitigated by environmental factors as discussed above), and concomitant medication use could all potentially affect lithium levels and should be considered in future studies. Third, the generalizability of our findings may be limited by the specific characteristics of our participant population (patients with bipolar disorder on *stable* lithium maintenance therapy). Future studies should aim for greater diversity in terms of age, gender, ethnicity, and severity of illness, and geographical location to enhance the generalizability of the results. Additionally, future research could explore the impact of different fasting durations and patterns on these parameters.

Clinical implications

Our findings have important clinical implications for managing patients with bipolar disorder during Ramadan. The results suggest that clinicians can reassure patients that fasting is unlikely to significantly affect their lithium levels or renal function, provided they maintain adequate hydration and adhere to their prescribed medication regimen. However, regular monitoring of lithium levels, renal function, and electrolyte balance remains crucial, particularly for patients with pre-existing renal impairment or other risk factors. Individualized treatment plans, considering the patient's specific medical history and lifestyle, are essential.

Author contributions

M. Abouzed (Conceptualization, Methodology, Formal analysis, Writing—original draft, Writing—review & editing, Supervision); A.S. Altuhayni (Data curation, Formal analysis, Writing—review & editing); S.R. Alshammari (Investigation, Writing—review & editing); M.S. Almuqahhwi (Investigation, Writing—review & editing); M. Elgernas (Investigation, Writing—review & editing); A. Almazyadi (Investigation, Writing—review & editing); A.A. Alghuraymil (Investigation, Writing—review & editing); Y. Ibrahim (Investigation, Writing—review & editing); A. Alenezy (Writing—review & editing).

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Availability of data and materials

No datasets were generated or analysed during the current study.

Declarations

Institutional review board statement

Research was conducted in compliance with the Nuremberg Code and Declaration of Helsinki, and approved by the Ethics Committee Hail Cluster Institutional Review Board (IRB).

Informed consent

All participants provided written informed consent prior to participation. The consent process included a detailed explanation of the study's purpose, procedures (including data collection methods), potential risks and benefits, and their right to withdraw from the study at any time without penalty. The consent form explicitly stated that participation was voluntary and that their data would be anonymized and kept confidential to the extent possible. All procedures were conducted in accordance with the Declaration of Helsinki. Participants were given a copy of the signed consent form, and a copy was retained by the research team.

Competing interests

The authors declare no competing interests.

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