

# Responses to the Letter

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Dear Editor,

## General Responses

The six points raised by the author are known; he added nothing to the scientific literature. However, I would like to clarify that there is no consensus about fast or not fast for COPD population; this depends on the health state and also on the motivation and beliefs of the patient. As mentioned in many studies, Ramadan fasting is mainly related to changes on life mode and circadian rhythms (e.g., sleep cycle and hours of food); some adaptations to fasting could occur in COPD patients, such as the medication time.

Few studies have examined the effects of Ramadan Observances (RO) in patients with COPD. Aydin et al. (2014) focused almost exclusively on changes in medication use during RO. Rejeb et al. (2018) evaluated only the effects of Ramadan fasting on inflammatory and hematological indices of COPD male patients. In addition, little is known about the clinical, psychosocial, and physiological effects of such fasting in COPD. Therefore, the aim of our original study was to analyze the effects of RO on anthropometric, psychosocial, physiological, and postural characteristics in patients with COPD. Participants of our study were male volunteers with COPD (Stages II and III), who gave their written and informed consent to take part in a study approved by the local committee for ethics. Smokers, those with cardiovascular or neurological disease, lower extremely musculoskeletal problems, and visual or other health problems were excluded from the study by our medical staff. No health problems were observed in all our stable COPD Muslim patients who observed Ramadan fasting. We also confirm that Global Initiative for Chronic Obstructive Lung Disease published in 2022 has not presented any recommendations for the patients who prefer fasting during Ramadan.

## Specific Responses

Responses related to the six points raised by the author. First of all, we would like to be precise that we used original and pertinent references. In each point, the author mentioned his own reference (Ben saad, 2019, 2020; Ben saad et al., 2014; etc.) or the references of his team (Daami et al., 2017; Rejeb et al., 2018). In our paper, the

choice of references is mainly based on scientific criteria, such as the reference should be pertinent and presenting original results.

1. The criteria related to the COPD diagnosis are mentioned in the “Method” section (subsection “Sample”), according to the GOLD guidelines (D. Singh et al., 2019). As Reviewer 2 recommended to supplement the relevant literature in the last 5 years, we modified some references. Stages II and III were selected based on the post-bronchodilator FEV<sub>1</sub> (Celli et al., 2016; GOLD, 2015; D. Singh et al., 2019). The ratio between FEV<sub>1</sub>/FVC < 0.70 or lower limit of normal was also performed in our study. We used the GOLD guidelines, which are well known in the scientific community. In our study, these GOLD guidelines constituted our methodological basis to diagnosis and to classify COPD patients.
2. We reported exclusion criteria in the “Method” section (subsection “Sample”): Smokers, those with cardiovascular or neurological disease, lower extremely musculoskeletal problems, and visual or other health problems were excluded from the study by our medical staff. This sentence includes cardiovascular problems (hypertension and tachycardia), which are transposable to the 6-minute walking test (6MWT) contraindications. In addition, we expressed the performance in the 6-minute walking test distance (6MWT) in meters (m), which is the common unit used in many publications (Acheche et al., 2020; ATS, 2002; Celli et al., 2016; Mekki et al., 2019; Holland et al., 2014; S. J. Singh et al., 2014). The distance walked in meters has similar capacity to predict mortality as the values corrected by using reference equations (Polkey et al., 2013; Puhan et al., 2008; S. J. Singh et al., 2014), so the 6MWT) is reported in meters. Hence, Celli et al. (2016) demonstrated that 6MWT) in meters (i.e., less than 350 m progressively increases the risk of death and hospitalization) can be used to stratify patients with COPD for clinical trials and interventions. We compared the patient with himself during three periods (before Ramadan, second week of fasting,



and fourth week of Ramadan fasting) to verify the impact of fasting on the selected parameters. The expression of the performance in percentage of predicted normal values could be also valuable for clinical aims.

3. We used the validated French version of the quality of life questionnaire (VQ11). It is important to notify that our patients are francophone and most of them have a sufficient schooling level to understand the French version. Nevertheless, when a word was not understood by a patient, it was fully explained by the investigator. In addition, the studies mentioned by the author of the letter to the Editor related to the VQ11 were published after 2015 and our study was conducted in 2015 and this is why we had used the validated French version in that time (the time between the end of our study and its publication in *AJMH*).
4. We disagree with the author's use of the Bland and Altman's (1995) method. The statistical analysis according to Bland and Altman (1995) is a method of data plotting used in analyzing the agreement between two different assays. Our data were analyzed in three different periods for the same group. In our study, the statistical method used is more appropriate. This method was used by the research team of the author's letter to the Editor (Latiri et al., 2017 in *AJMH*, and Zouari et al., 2018 in *AJMH*). Our data were analyzed using a one-way repeated measures analysis of variance (ANOVA; three testing periods) and the two-way ANOVA (for the VQ11; three periods  $\times$  four components of the questionnaire). A post hoc Tukey test was performed to compare the results. In addition, effect sizes for one-way ANOVA were calculated as eta squared, and for two-way ANOVA to assess the practical significance of our findings (Lakens, 2013). This method is used by several studies.
5. First, the conventional cutoff for the "*p*" value to be considered statistically significant is of .05 (or 5%). What a *p* < .05 implies is that the possibility of the results in a study being due to chance is <5%. Clinical significance, on the contrary, refers to the magnitude of the actual treatment effect (also known as the "effect size"), which will determine whether the results of the trial are likely to affect current medical practice (Ranganathan et al., 2015). The effect size was used in our study. However, in the revised version of our manuscript, the reviewer recommended us to remove all the *F* values and solely report means  $\pm$  *SD* and *p* values that make it easier to follow. Minimal clinical important difference

(MCID) could be of interest. In fact, in our study the 6MWT mean value measured during the second week of Ramadan was significantly lower than the one measured before Ramadan ( $485 \pm 55.1$  vs.  $521.3 \pm 44.7$ , *p* < .001) and the mean difference between the two sessions (estimated 37 m) does exceed the MCID of 30 m (Holland et al., 2014).

6. The sentence is clear: "To 2015, only one study has examined the effects of RIF in patients with COPD." The author mentioned that we omitted some studies. These studies were published after 2015 and assessed only spirometric data, inflammatory and hematological indices, and oxidant/antioxidant biomarkers during Ramadan fasting. However, in our study we assessed other parameters, such as anthropometric, psychosocial, physiological, and postural parameters during Ramadan in men with COPD. We cannot cite references that are not directly linked to the objective of the study.

Finally, I would like once again to sincerely thank you for the special attention you have given to this matter and express my deep conviction that this letter to the Editor you received will not have any impact on the trust governing the relation between our institutions.

Sincerely, yours

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