


# Comments on “Anthropometric, Psychosocial, Physiological, and Postural Observances During Ramadan in Men With Chronic Obstructive Pulmonary Disease”

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## Keywords

chronic respiratory condition, deficiency, fasting, incapacity, social disadvantage, statistical issues

Dear Editor,

I read with great interest the Tunisian study of Mekki et al. (2022) aiming to evaluate the effects of Ramadan intermittent fasting (RIF) on deficiency (*eg*; anthropometric and postural data), incapacity (6-minute walk test [6MWT] data), and social disadvantage (quality of life [QoL] items) stages of patients with chronic obstructive pulmonary disease (COPD). Such experimental studies are very encouraged for at least four reasons. *First*, while patients with chronic conditions are exempted from fasting because of ongoing disease conditions (Athar, 1990), numerous ones refuse this exemption and insist on fasting during Ramadan (Adeli et al., 2015; Askari et al., 2016; Aydin et al., 2014; Bener et al., 2006; Ben Saad, 2019; Erkekol et al., 2006; Nematy et al., 2015; Norouzy et al., 2013). Though the association amid faith rituals and health (*eg*; effects of RIF on chronic conditions) is a remarkable issue for doctors nearly for 40 years, this topic was undertaken in a scarce studies presenting debated results (Adeli et al., 2015; Askari et al., 2016; Aydin et al., 2014; Bener et al., 2006; Ben Saad, 2019; Erkekol et al., 2006; Latiri et al., 2017; Mrad et al., 2019; Nematy et al., 2015; Norouzy et al., 2013; Rejeb et al., 2018; Singha Roy & Bandyopadhyay, 2018; Soori et al., 2016; Subhan, 2008; Subhan et al., 2006; Zouari et al., 2018). *Second*, RIF implicates precise dietary and lifestyle changes, such as abrupt changes in sleep cycle, physical activities, and eating agendas (Barkia et al., 2011; Faris et al., 2019; Ramadan, 2002). These changes may unpleasantly mark the COPD patients' health if not addressed correctly (Abolaban & Al-Moujahed, 2017). The above-mentioned lifestyle changes can cause clinical

situation to deteriorate due to a persistent gap between up-to-date professional information and conclusive strong evidence concerning the pathophysiologic and metabolic changes of fasting (Rejeb et al., 2018). *Third*, the 2022 Global Initiative for Chronic Obstructive Lung Disease (GOLD, 2022) have not addressed the effects of religious beliefs and behaviors, and no recommendation has been advanced for COPD patients who prefer fasting during Ramadan. *Fourth*, since personal beliefs influence patients' health behaviors and adherence to treatments, health-care providers need to learn how RIF can affect the health of their COPD Muslim patients, and how to help them fast safely (Abolaban & Al-Moujahed, 2017). However, in the study of Mekki et al. (2022), a few clarifications related to six methodological points, are needed.

*The first point* is related to the diagnosis of COPD. Mekki et al. (2022) omitted to report the exact applied criteria to retain the COPD diagnosis, *eg*; a post bronchodilator ratio between forced expiratory volume in one second (FEV<sub>1</sub>) and forced vital capacity < 0.70 or < lower limit of normal (Ben Saad et al., 2014). The authors have simply reported the following vague

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sentence “clinically stable individuals with a functional diagnosis of COPD according to the GOLD guideline were selected (Singh et al., 2019).” On the one hand, how is it possible to apply the 2019-GOLD guideline for a study performed in 2015? On the other hand, while the COPD diagnosis requires obligatory the practice of a bronchodilator (Singh et al., 2019), in the subsection “spirometry” of Mekki et al. (2022) paper’s, it “appears” that no bronchodilator test was performed. Therefore, it is possible that some retained patients were asthmatics or have both asthma and COPD (Ben Saad, 2020). Moreover, Mekki et al. (2022) included only COPD patients GOLD II and III, without informing readers how these two stages were determined (*eg*; based on post bronchodilator  $FEV_1$  [%] (Anane et al., 2020; Kammoun et al., 2018)). The omission of the applied criteria related to the COPD diagnosis and classification is a “serious” element that makes the reproduction of this study somewhat questionable (Ben Saad et al., 2014).

**The second point** concerns the 6MWT. First, Mekki et al. (2022) omitted to add as non-inclusion or exclusion criteria, the 6MWT contraindications (Singh et al., 2014) (*ie*; signs of unstable angina or myocardial infarction during the previous month, resting heart  $\geq 120$  bpm, systolic blood pressure  $\geq 180$  mmHg, diastolic blood pressure  $\geq 100$  mmHg). Second, Mekki et al. (2022) expressed the 6-minute walk distance (6MWD) as an absolute value (in meter). This method is quite problematic and, as done for spirometric data, it was better to standardize the 6MWD and to express it as a percentage of predicted normal values (Ben Saad et al., 2009; Daami et al., 2017; Masmoudi et al., 2008). It is worth noting that Tunisia has validated 6MWD norms for healthy adults (Ben Saad et al., 2009; Masmoudi et al., 2008), and that Tunisian 6MWD is significantly correlated with age, weight, height, and body mass index (Ben Saad et al., 2009; Daami et al., 2017; Masmoudi et al., 2008). The method opting for a standardization of the 6MWD according to predicted normal values was applied in a study, which was published in the *Am J Mens Health*, and aiming to raise the effects of RIF on healthy boys’ cardiorespiratory capacity (Miladi et al., 2020).

**The third point** is related to the use of a French version of a QoL questionnaire (namely the VQ11 (Ninot et al., 2013)). It is true that the VQ11 is a valid questionnaire that provides a reliable measure of COPD health related QOL (Ninot et al., 2013). Nevertheless, the use of the French version to evaluate the QoL of Arab patients having a low schooling level (40% in the study of Mekki et al. (2022)) is debatable. On the one hand, it was more appropriate to discuss the aforementioned point (*ie*; use of a non-validated version of VQ11) as an additional study limitation as previously done in a Tunisian study

(Rejeb et al., 2018). On the other hand, since the Arabic version of VQ11 is applicable in Tunisian COPD patients with reliable results (Knaz et al., 2020), the author is wondering why it was not applied (Knaz et al., 2020).

**The fourth point** is related to a statistical flaw. Mekki et al. (2022) setted the level of significance at  $P < .05$ . This choice is “problematic” (Bland & Altman, 1995). In practice, when numerous data are compared at a time, it is probable by fortuitous alone that some of them will be statistically significant (Bland & Altman, 1995; Subhan, 2008). Consequently, stricter criteria should be applied than the usual 0.05 threshold, as previously done by Siddiqui et al. (Siddiqui et al., 2005). For example, when comparing the VQ11 components ( $n = 4$ ), for any component to reach a statistical significance, data must have a p-value equal to  $0.05/(\text{number of data}) = 0.0125$ . Should this statistical approach been applied, possibly the results would have changed.

**The fifth point** concerns the statistical approach adopted by Mekki et al. (2022). The latter opted for the “statistical” significance approach with a “P-value”  $< .05$  was considered as “significant.” Nowadays, this approach is discouraged, and it was better to opt for the “clinical” significance approach (Alsoufi, 2018), by applying, for example, the minimal clinical important difference (MCID) for the 6MWD (Holland et al., 2014). For example, it is true that the 6MWD mean value measured during the fourth week of Ramadan was significantly lower than the one measured before Ramadan ( $502.1 \pm 50.3$  vs.  $521.6 \pm 44.7$  m,  $p < .01$ ), but the mean difference between the two sessions (estimated at 21 m) doesn’t exceed the MCID of 30 m (Holland et al., 2014). According to Holland et al. (2014), the available evidence suggests a MCID between 25 and 33 m ( $M = 30$  m) for adult patients with chronic respiratory disease. In Mekki et al. (2022), the application of the aforementioned specific approach (*ie*; MCID approach) shall surely change the conclusion related to the effects of RIF on 6MWD of COPD patients. It is interesting to note that the “clinical” significance approach was applied in a study, which was published in the *Am J Mens Health*, and aiming to raise the effects of RIF on healthy boys’ 6MWD (Miladi et al., 2020).

**The sixth point** is related to a striking form of publication (bibliographical) bias (Bahadoran et al., 2020). The following statement advanced by Mekki et al. (2022) “to 2015, only one study has examined the effects of RIF in patients with COPD (Aydin et al., 2014)” is a striking form of publication/citation and can induce readers in error. It is true that the study was performed in 2015, however; since the paper was sent to the *Am J Mens Health* on November 2021, Mekki et al. (2022) were asked to update their references. This is an important issue, because between 2015 and 2021, at least three

Tunisian pilot studies, related to the previous topic, were published in the *Am J Mens Health* (Mrad et al., 2019; Rejeb et al., 2018; Zouari et al., 2018). These three studies, which included stable COPD male patients, were published in 2018 and 2019 (Mrad et al., 2019; Rejeb et al., 2018; Zouari et al., 2018), and aimed to evaluate the effects of RIF on spirometric data (Zouari et al., 2018), on inflammatory and hematological indices (Rejeb et al., 2018), and on oxidant/antioxidant stress biomarkers (Mrad et al., 2019). The “omission” to quote these three articles (Mrad et al., 2019; Rejeb et al., 2018; Zouari et al., 2018) in Mekki et al. (2022) references’ list is a citation bias (Bahadoran et al., 2020). Citation, which is the act of correctly referring to others’ concepts, thoughts, or ideas, is a critical practice in medical scientific writing (Bahadoran et al., 2020). Citation is used to recognize others’ work, and to direct readers to sources of information (Bahadoran et al., 2020). Outside technical skills, the citation requests an exhaustive knowledge of the field and should follow elementary guidelines, including the selection of pertinent and valid sources, and referring to others’ work truthfully and ethically (Bahadoran et al., 2020).

To conclude, the evaluation of the effects of RIF on human physiology has clinically applicable implications (Ben Saad, 2018, 2019). For that reason, future studies aiming to evaluate the effects of RIF on deficiency, incapacity and social disadvantages of patients with chronic conditions, such as COPD, should be conducted and reported more rigorously by taking into account the various factors discussed above.

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### Data Availability Statement

The data used to support the findings of this study are included within the article.

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