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Positive impact of pre-Ramadan education on glycemic control and reducing risk of hypoglycemia in type 2 diabetic elderly patients during COVID 19 pandemic

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ABSTRACT
Background: Elderly patients have higher risks for complications during Ramadan fasting. Educating patients is essential for fasting safely.
Aim: To evaluate the impact of pre-Ramadan education in reducing risk of hypoglycemia and achieving glycemic control in elderly.
Methods: A prospective study carried out in outpatients clinics of Internal Medicine department in Assiut university hospital. It included 316 type 2 diabetic patients who intended to fast. They were grouped into 2 groups; < 65 years and ≥ 65 years patients. The patients received pre-Ramadan individual education sessions. A semi-structured questionnaire was used to collect the data to stratify the risk of fasting. The study was carried out in 3 phases. Assessment of hypoglycemia and biochemical parameters after the education was the primary outcome.
Results: Fasting blood glucose decreased during and after Ramadan in elderly significantly (p = 0.0001). The patients who achieved fasting blood glucose less than 8 mmol/L increased from 29.3% to 46.6% after Ramadan in elderly patients. HbA1c decreased significantly after Ramadan (p = 0.001). The main cause of breaking fast was hypoglycemia in both groups; 9% vs. 7.7% in patients < 65 and ≥ 65 years respectively. The waist circumference showed significant decrease in patient with 65 years old or more (p = 0.05). Total cholesterol and LDL increased with no statistical significance in patients ≥ 65 years (p = 0.512, 0.470). Both groups showed improvement of HDL cholesterol during and after Ramadan (P = 0.0001).
Conclusion: Pre-fasting education had positive impact on decreasing the risk of symptomatic hypoglycemia in elderly diabetic patients.

1. Introduction
Ramadan fasting is mandatory for all adult healthy Muslims. Diabetic patients can be excluded from fasting Muslims as other sick people, however most of patients insist to fast. Hypoglycemia, hyperglycemia, dehydration and thrombosis are risks of fasting in diabetic patients [1]. This leads to the important role of pre-Ramadan evaluation for risk stratification and education of diabetic patients for safe fasting. International diabetes federation-Diabetes and Ramadan (IDF-DAR) 2021 established guidelines for doctors to categorize patients who intend to fast during Ramadan based on status of glycemic control, hypoglycemia risk, glycemic lowering medications, diabetes related complications and comorbidities. Individuals in the moderate and high risk categories for developing complications related to fasting should be advised against fasting [2].

Elderly people have higher rates of diabetes-related complications and co-morbidities, longer duration of disease and risk for frailty and cognitive impairment. These factors place most elderly patients in the high risk category for fasting and development of complications during Ramadan [2]. Ramadan fasting in 2021 occurred during COVID 19 pandemic. Diabetes is recognized as an important risk factors for severity of COVID 19, admission to intensive care, increasing risks for complications and mortality causing more challenge to fasting patients [3]. However, the DAR 2020 Global survey found that most of the patients decided to fast. It also showed that COVID 19 infection did not increase with fasting and fasting results were positive with few adverse
outcomes [4]. In our previous study that included 320 patients, we conclude the significant impact of pre-Ramadan educational program on reduction of hypoglycemia and other acute complications especially in high and very high risk patients during Ramadan fasting [5]. However, to the best of our knowledge there in no published data about the impact of pre-Ramadan education with consideration of the age of patients. In this study we aimed to evaluate the impact of pre Ramadan education in elderly for fasting safely comparing between those < 65 years and ≥ 65 years.

2. Methods

The study was carried out in the outpatient clinics of Internal medicine department at Assiut university hospital. Patients were selected from daily follow-up in the clinics using the convenience sampling technique during the three months before Ramadan 2021. Patients were informed about the study and their consents were obtained.

Inclusion criteria were Muslim diabetic patients with type 2 diabetes who intended to fast in Ramadan. They were grouped according to their age; the first group included patients < 65 years while patients ≥ 65 years represented the second group.

Exclusion criteria were patients who did not intend to fast, patients with serious comorbidities such as recent acute coronary syndrome or severe hepatic/renal disease, patients with recent hospitalization for diabetic ketoacidosis or severe hyperglycemia or hypoglycemia a month prior to start of Ramadan.

Design: A before-after intervention study was done. Risk evaluation of patients before Ramadan according to IDF-DAR 2021 risk categories [2] was estimated. IDF-DAR 2021 risk categories were shown in supplementary figure 1. The high risk patients were advised against fasting. The patients received educational program before Ramadan (6weeks) in individual sessions focusing on advising patient’s about dietary habits, encouraging patients to continue their daily physical activities, confirming the benefit of frequent blood sugar measurement during the fasting day, medication adjustment coping with the recommendation.

Data: Data of the patients were gathered through a semi-structured questionnaire, which included: age, sex, duration of diabetes, current treatment and medical complication of diabetes, history of hyperglycemia, diabetic ketoacidosis or hypoglycemia in the 3 months before the start of Ramadan and history of fasting during the previous Ramadan.

Anthropometric measures including (Body weight, waist circumference and Body mass index), blood pressure and laboratory investigation including (Fasting blood glucose, Complete blood count, Serum creatinine and blood urea, Serum uric acid level and Lipid profile) were collected in three periods; the first (2–3 weeks before Ramadan), the second period (the third week of Ramadan), and the third one (4 weeks after Ramadan). HbA1c were measured in first period and third period of the study. At the end of fasting, number of fasting days (either <15 days, ≥15 days but not the whole month or the whole month) and causes of breaking the fast were reported. Hypoglycemia was defined as blood glucose below 70 mg/dL. Hypoglycemia was classified into symptomatic hypoglycemia and biochemical hypoglycemia (blood glucose level ≥ 54 –70 mg/dL without symptoms). Severe hypoglycemia was considered in presence of severe cognitive impairment requiring external assistance for recovery.

2.1. Sample size

Sample size was calculated using EPI info 2000 statistical package. The calculation was done depend on previous studies that show that expected frequency of hypoglycemia during fasting among intervention group ( receiving educational program before Ramadan) is 4% and expected frequency among control group ( not receiving educational program before Ramadan) is 19.5%. The sample size at 95% confidence interval required per group is 79.

2.2. Statistical analysis

Data was collected and analyzed using SPSS (Statistical Package for the Social Science, version 20, IBM, and Armonk, New York). Continuous data was expressed in the form of mean ± SD while nominal data was expressed in the form of frequency (percentage). Chi²-test was used to compare the nominal data of different groups in the study while student t-test was used to compare mean of different two groups and ANOVA test for more than two groups. Multivariate regression analysis was used to determine the independent risk factors for HbA1C % of patients and fasting blood sugar.

3. Results

The study included 316 patients with T2D. They were divided into two groups according to their age. The first group included patients less than 65 years (200 patients), while the second group included patients with 65 years old or more (116). Patients in both groups received focused pre-Ramadan education program. The demographic and clinical data of patients in both groups were described in Table 1.

The majority of patients were females (76%, 60.3% in group 1 and 2 respectively). Micro vascular complications were found in 55% in patients < 65 years vs. 60.3% in patients with ≥ 65 years with no statistically significant difference (p = 0.733).

Risk evaluation of patients before Ramadan according to IDF-DAR 2021 risk categories [2] was estimated. Most of patients with 65 years or more were in moderate and high risk group (43.10% and 37.9% respectively). 14% of patients < 65 years were in high risk group as shown in Fig. 1. 67% of patients in first group and 51.7% of patients in second group were obese with no statistically significant difference (p = 0.154). 60.3% of elderly patients used oral hypoglycemic with no significant difference between the two groups. The mean HbA1c value was 9.69 ± 2.0 in patients with less than 65 years vs. 8.95 ± 1.74 in patients with 65 years or more (P = 0.02).

Table 2 showed the effect of pre-Ramadan educational program on physical and biochemical parameters of patients in both groups.

As regard the weight of the patients, there wasn’t significant change during the study in both groups. The waist circumference showed significant decrease in patient with 65 years old or more (p = 0.05). Systolic blood pressure increased in both groups during and after Ramadan with statistical significant difference (p = 0.0001) while diastolic blood pressure increased in patients less than 65 years (p = 0.004).

HB level and platelets count did not significantly change during the study in both groups. Total cholesterol decreased in patients less than 65 years during Ramadan and these changes continued after Ramadan (p = 0.039). Total cholesterol and LDL increased with no statistically significant in patients 65 years or more (p = 0.512, 0.470). Both groups showed improvement of HDL cholesterol during and after Ramadan (P = 0.0001).

3.1. Impact of pre-Ramadan education on glycaemic parameters

The frequency of self-measuring of blood glucose increased in both groups compared with the frequency before Ramadan; 77% and 58.6% in patients ≥ 65 and < 65 years respectively.

Fasting blood glucose (FBG) decreased during and after Ramadan in both groups significantly (p = 0.0001). The patients who achieved FBG less than 8 mmol/L increased from 29.3% before Ramadan to 46.6% after Ramadan in elderly patients. HbA1c decreased significantly in both groups after Ramadan (p = 0.0001 in group 1 and 0.001 in group 2). Number of patients with HbA1c ≤ 7% increased in both groups after Ramadan. Table 3.

3.2. Ramadan fasting in patients less than 65 years

The main cause of breaking fast was hypoglycaemia in both groups.
Of 200 patients in first group, 9% broke their fast because of symptomatic hypoglycaemia; 10 patients of them (55.6%) were on pre-mixed insulin and 8 (44.4%) patients were treated by oral hypoglycaemic drug. 6% of patients broke fast because of hyperglycaemia; two patients broke fast daily during Ramadan because of hyperglycaemias and dehydration. Two patients (1%) developed DKA. Fig. 2.

55% of the patients fast the whole month while 42% fast more than 15 days as shown in supplementary figure 2.

3.3. Ramadan fasting in patients 65 years or more

Of 116 patients, 9 patients (7.7%) broke their fast because of hypoglycaemia. 4 Patients had symptomatic hypoglycaemia while the others detected hypoglycaemia during blood glucose self-measuring. No one had severe hypoglycaemia that required hospital admission. 6 patients (66.7%) were treated by oral hypoglycaemic drugs; sulphonylurea. 5.2% (6 patients) broke their fast because of hyperglycaemia. Dehydration was less frequent (3.4%) as a cause of breaking fast in this group compared to the other group (12%). Two patients (1.7%) developed DKA as shown in Fig. 2.

Rates of hypoglycaemia and hyperglycaemia decreased in both groups in comparison to previous Ramadan as shown in Fig. 3.

As Ramadan fasting this year occurred during COVID 19 pandemic, 8 patients less than 65 years and 6 patients more than 65 years got infected during Ramadan. Two of the elderly had DKA and needed hospital admission. The other patients had mild infections and broke their fast for few days till fever subsided.

Table 4 shows multivariate linear regression analysis of the significant factors predicting HbA1c and fasting blood glucose after adjusting for all correlates. Age was a significant predictor for HbA1c. Age, disease duration and complications were the significant predictors for fasting blood glucose.

4. Discussion

Ramadan fasting has a religious value for all Muslims especially the elderly who insist to fast regardless their health state. During the past few years, educational programs were applied to help diabetic patients to fast safely without risk. However the effect of these programs was not evaluated in elderly. Elderly who fasted this year for about 16 h in hot
climate and during the lockdown of COVID-19 pandemic had higher risk for hypoglycaemia and hyperglycaemia. We aimed to study the effect of education in reducing hypoglycaemic risk and achieving glycaemic control in elderly.

In the study which included 316 patients, the majority of the patients had either micro-vascular or macro-vascular complications referring to the high prevalence of complications among our patients. The presence of the complications classified these patients as high risk for fasting and increased risk for hypoglycaemia. This could be considered as a limitation in order to the generalization of the conclusions; however this was not the only parameter to determine the risk according to IDF-DAR which included the age, treatment and glycaemic state before fasting. Also, there was no difference between younger and elderly patients despite the noticed difference in the disease duration. This confirmed the presence of complications at early stages of disease and the importance of assessment of vascular complication of diabetes regularly for early detection. In a global study to assess the prevalence of vascular complications among patients with type 2 diabetes, it showed that 22.2% and 9.9% at early stages of disease had micro and macro-vascular complications in Egypt [6]. Also, younger patients had more chances to ask for medical advices for early diagnosis of complications and other comorbidities than elderly.

Obesity was founded in 61.4% of the study patients. This refers to the high prevalence of obesity in Egypt particularly among women as shown in a recent study [7]. Central obesity was found in 24.1% of Egyptian adults as shown in another study [8]. Also, a study showed that 14.2% of Egyptian primary school student were obese [9]. There is a strong link between obesity and diabetes and insulin resistance [10]. Sedentary life and bad nutritional habits of our patients that contains high amount of rice and bread and less fresh vegetables and fruits especially in low socio-economic state increase the risk for obesity and diabetes. The Egyptian primary school student were obese [9] . There is a strong link between obesity and diabetes and insulin resistance [10]. Sedentary life and bad nutritional habits of our patients that contains high amount of rice and bread and less fresh vegetables and fruits especially in low socio-economic state increase the risk for obesity and diabetes. The prevalence of obesity among patients with type 2 diabetes, it showed that 22.2% and 9.9% at early stages of disease had micro and macro-vascular complications in Egypt [6]. Also, younger patients had more chances to ask for medical advices for early diagnosis of complications and other comorbidities than elderly.

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### Table 2

Impact of pre-Ramadan education program on clinical characteristics during the study phases in the young and elderly groups.

| Variable                  | Pre-Ramadan Mean ± SD | During Ramadan Mean ± SD | After Ramadan Mean ± SD | P-value* |
|---------------------------|-----------------------|--------------------------|-------------------------|----------|
| Body Weight(Kg) Age < 65 | 80.48 ± 13.943        | 80.00 ± 15.457          | 80.55 ± 13.679          | = 0.443  |
| P-value **                | = 0.024 **            | = 0.008 **              | = 0.015 **              |          |
| Age ≥ 65                 | 75.45 ± 12.339        | 75.00 ± 12.628          | 75.21 ± 12.149          | = 0.05   |
| Waist(cm) Age < 65       | 80.48 ± 13.943        | 80.00 ± 15.457          | 80.55 ± 13.679          | = 0.443  |
| P-value **                | = 0.024 **            | = 0.008 **              | = 0.015 **              |          |
| Age ≥ 65                 | 75.45 ± 12.339        | 75.00 ± 12.628          | 75.21 ± 12.149          | = 0.05   |
| Systolic BP(mmHg) Age < 65 | 116.20 ± 10.326      | 119.80 ± 10.916         | 125.70 ± 10.076         | = 0.0001 |
| P-value **                | = 0.114               | = 0.002 **              | = 0.110                 |          |
| Age ≥ 65                 | 119.31 ± 14.125       | 126.21 ± 13.743         | 128.28 ± 9.010          | = 0.0001 |
| Diastolic BP(mmHg) Age < 65 | 72.00 ± 6.431        | 72.30 ± 5.515           | 74.60 ± 5.932           | = 0.004  |
| P-value **                | = 0.0001              | = 0.122                 | = 0.568                 |          |
| Age ≥ 65                 | 76.55 ± 7.621         | 75.00 ± 8.219           | 75.17 ± 6.280           | = 0.295  |
| SBP level(G/dL) Age < 65 | 12.9 ± 1.48           | 12.9 ± 1.48             | 13.26 ± 6.99            | = 0.616  |
| P-value **                | = 0.286               | = 0.286                 | = 0.461                 |          |
| Age ≥ 65                 | 12.6 ± 1.93           | 12.6 ± 1.93             | 12.6 ± 1.93             | = 0.322  |
| Platelet10^12 / dL Age < 65 | 229.41 ± 78.885     | 229.41 ± 78.885         | 229.41 ± 78.885         | = 0.370  |
| P-value **                | = 0.750               | = 0.750                 | = 0.750                 |          |
| Age ≥ 65                 | 225.43 ± 68.836       | 225.43 ± 68.836         | 225.43 ± 68.836         | = 0.097  |
| Cholesterol(mg/dL) Age < 65 | 202.00 ± 51.852      | 196.76 ± 47.88           | 195.5900 ± 40.44         | = 0.039  |
| P-value **                | = 0.451               | = 0.890                 | = 0.940                 |          |
| Age ≥ 65                 | 203.30 ± 67.93        | 206.1724 ± 67.79        | 201.33 ± 56.61          | = 0.512  |
| Triglycerides (mg/dL) Age < 65 | 158.09 ± 68.239     | 167.39 ± 81.26          | 165.46 ± 83.36          | = 0.07   |
| P-value **                | = 0.627               | = 0.661                 | = 0.986                 |          |
| Age ≥ 65                 | 151.98 ± 68.69        | 160.31 ± 83.86          | 164.72 ± 87.63          | = 0.07   |
| LDL(mg/dL) Age < 65       | 144.05 ± 58.82        | 140.57 ± 56.33          | 138.61 ± 49.18          | = 0.128  |
| P-value **                | = 0.798               | = 0.526                 | = 0.344                 |          |
| Age ≥ 65                 | 152.27 ± 71.87        | 152.27 ± 71.87          | 152.27 ± 68.12          | = 0.470  |
| HDL(mg/dL) Age < 65       | 40.42 ± 12.744        | 43.83 ± 9.88            | 46.43 ± 9.244           | = 0.0001 |
| P-value **                | = 0.909               | = 0.594                 | = 0.646                 |          |
| Age ≥ 65                 | 40.16 ± 11.23         | 45.50 ± 12.19           | 46.88 ± 8.87            | = 0.0001 |

* T-test analysis was used to compare the mean difference between the two groups
  * * Chi-square Test analysis was used to compare the difference in proportions
  * ** Mann-Whitney U test was used to compare the median difference between the two groups
  
  Significance level is considered when p value < 0.05

Abbreviations: BMI, body mass index; BP, blood pressure; HDL, high-density lipoprotein; LDL, low-density lipoprotein; SD, standard deviation.
The majority of patients (61%) used oral hypoglycaemic drugs. Sulphonylurea ± metformin were the most common prescribed drugs probably related to financial aspect and patient’s refusal to change to new drugs. The second common drugs were DDP4 inhibitors and the least drugs were SGLT2 inhibitors which represented the most recent and expensive class of drugs for the patients. According to results of many studies [12], IDF-DAR 2021 considered the DDP4, SGLT2 and sulphonylurea including gliclazide and glimipride as low risk drugs for fasting than glibenclamide and insulin [2]. The percentage of patients older than 65 years who depend completely on multiple insulin injections was higher than in younger group. This can be attributed to the longer duration of illness and probably less response to oral drugs. Age itself may be considered a risk factor for fasting. As elderly patients have more associated comorbidities, longer duration of diabetes and it complications and higher risk for cognitive dysfunction, they are classified in moderate and high risk group for fasting. According to (IDF-DAR) 2021 risk categories [2], only 19% of elderly patients were in low risk category who are able to fast while 37.9% were in high risk group who must not fast because of risks associated with fasting. Despite the IDF-DAR recommendations against fasting in high risk group, these patients insisted to fast [2]. Unfortunately, the majority of patients in younger and older groups were in moderate risk group who should advised against fasting. This confirms the importance of diabetes education and glycaemic control achievement for diabetic patients who want to fast [5,13,14].

Only 17.2% of the elderly patients had HbA1c ≤ 7% before Ramadan. Also 3.4% and 12.1% of patients experienced symptomatic severe hypoglycaemia and hyperglycaemia respectively in the 3 months before Ramadan that required medical consultation. This indicated the poor glycaemic control before the start of fasting and categorize patient
in high risk group for fasting. Pre-Ramadan education decrease blood glucose significantly in elderly patients during and after Ramadan. This coincides with the results of previous studies [5,13,14]. Surprisingly, the number of patients who achieved glycaemic control less than 8 mmol/L increased significantly after Ramadan in elderly in comparison to younger. This can be explained by their adherence to the given instructions and their dietary habits that depended on small amount of food during Iftar and Suhoor time. Also, they maintain physical activity in Tarweeh pray. They avoided outdoor activities during fasting hours because of hot weather and quarantine of COVID 19. They maintained following the program’s instructions during Ramadan for longer duration than the younger. This can explain also the decrease in waist circumference of the patients during fasting.

Reduction of the risk of hypoglycaemia in both groups was the result of the pre-Ramadan education. Hypoglycaemia is considered the great problem especially in elderly during fasting hours. Educating elderly decreased the hypoglycaemic frequency from 13.8% in previous Ramadan to 7.7% in current Ramadan. All episodes of hypoglycaemia were mild and self-corrected by the patients who broke their fast. Awareness of the patients with hypoglycaemia manifestations and frequent self-measuring blood glucose helped elderly to detect more asymptomatic hypoglycaemia and manage the episode early. The frequency of glucose self-measuring increased to 77% in elderly compared to before Ramadan. This detected more asymptomatic hypoglycaemia and explained the higher recorded frequency of hypoglycaemia during Ramadan than the three months before Ramadan (7.7% vs.3.4% respectively). On opposite to what is expected and founded in a previous study [2], hypoglycaemia was higher in younger than elderly (9% vs.7.7%) which can be explained with the higher frequency of activities during fasting hours. Also the elderly were commitment to the instructions and maintained blood glucose monitoring throughout Ramadan not only in the first two weeks as in younger. Most of the hypoglycaemic episodes were reported in the midday followed by after 3 pm till Iftar time referring to the impact of pre-Suhoor dose of insulin or oral hypoglycaemic drugs or the morning physical activities.

In our patients, there was no significant difference in the frequency of hypoglycaemia in relation to treatment either insulin or oral hypoglycaemic drugs in younger group (10 vs. 8 patients respectively). The dose of the drug, the amount of the meal at suhoor and the degree of exertion during fasting hours are probably the main risk factors for hypoglycaemia rather than type of therapy. These results coincide with results of a previous study [6]. In the elderly, hypoglycaemia was recorded with oral hypoglycaemic drugs more than with insulin (twice the frequency). This can be explained by their use to long acting sulphonylurea and modifying the insulin dose according to the blood glucose level.

Pre-Ramadan education decreased risk of other acute complications. Although hyperglycaemia was reported in 20% of patients but a lot of them refused to break the fast. They also did not consult medical advice avoiding exposure to infection during COVID 19 pandemic. They managed themselves by increasing dose of therapy and frequent monitoring of blood glucose. The reported incidence of hyperglycaemia in previous studies was 16.3% [2] and 11.6% [15]. DAR global survey 2021 showed that 79.1% who experienced hyperglycaemia did not break fast [2]. However, the frequency of hyperglycaemia was significantly less in comparison to the previous Ramadan (6% vs 10% in younger group and 5.2% vs 13.3% in elderly group) due to good adherence to the items of education.

The ongoing Covid-19 pandemic did not influence the decision to fast in our patients. 4 elderly patients got infected with COVID19 with mild severity that needed home isolation. They broke their fast for average 3–10 days till improvement of general condition and fever subsided. The other 2 elderly patients had DKA and needed hospital admission.

The current study showed insignificant change in cholesterol, Low density lipoproteins and triglycerides in both groups while high density lipoproteins increased mildly in both groups. A previous studies showed insignificant changes in total cholesterol and triglycerides [5,13]. However, a positive result of education program on lipid profile was reported in another study [17]. While the impact of education is positive in reducing the acute complications and achieving glycaemic control, it needs patients’ restriction to the program for longer duration to evaluate its impact on body weight and lipid profile. Many studies in EGYPT, Saudi Arabia and UAE showed that there was no beneficial impact on body weight [5,16,17].

At the end of fasting, elderly patients confirmed that they felt safe and comfortable with fasting especially with their fear and anxiety about COVID 19 infection. They used to measure their blood glucose and reduce their physical activities during fasting hours to avoid hyperglycaemia. Although many patients did not break their fast when blood glucose was < 70 mg/dl or > 300 mg/dl as they instructed, they modified their physical activities and diets according to blood glucose. 70.7% of elderly fast the whole month in comparison to 55% of younger patients. This probably explained by dehydration which caused 12% of younger to break the fast with hot weather and outdoor activities. Also breaking fast due to menstrual cycle in younger which is a religious permission to stop fasting.

5. Conclusion

Educating elderly diabetic patients before fasting had a positive impact on decreasing the risk of hypoglycaemia and other acute complications. Safe fasting in elderly can be achieved with dietary modifications, drug dose adjustment and regular glucose self-monitoring. Frequent blood measuring during fasting hours especially midday hours helps to detect asymptomatic hypoglycaemia. Longer duration is needed to detect the outcome for pre-Ramadan education programs on body weight and lipid profile.

Declaration of Competing Interest

The authors declare they have no conflicts of interest and all the authors have read and approved the final submitted version.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.pcd.2022.03.014.

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