Using the transtheoretical model's stages of change to predict medication adherence in patients with type 2 diabetes mellitus in a primary health care setting

Yara Arafat¹ · Mohamed Izham Mohamed Ibrahim¹ · Ahmed Awaisu¹ · Stephen Colagiuri² · Yaw Owusu¹ · Donald E. Morisky³ · Mudather AlHafiz⁴ · Ahmed Yousif⁵

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Abstract

Background Qatar is currently experiencing a worrying increase in the prevalence of diabetes mellitus (DM). One of the most common reasons for uncontrolled DM is non-adherence to medications. The socio-behavioral intervention has proven effective in some chronic illnesses.

Objectives To assess the stages of change (SOC) and medication adherence scores of type 2 diabetes mellitus (T2DM) patients visiting primary healthcare institutions in Qatar, and to evaluate the cause and effect relationship between SOC and adherence to antidiabetic medications.

Methods The 8-item Morisky Medication Adherence Scale (MMAS-8) was used to assess medication adherence, and a 2-item SOC questionnaire was utilized to classify the SOC. The analysis to determine if the SOC could predict medication adherence while controlling for demographic characteristics, total number of prescribed medications and disease duration was done using hierarchical multiple regression.

Results The final analysis included 387 patients. In relation to medication adherence, majority of the patients were in the maintenance stage (76.7%), followed by the preparation stage (14.7%), the action stage (3.9%), the contemplation stage (3.4%) and the precontemplation stage (1.3%). Most of the patients were in high adherence towards antidiabetic medications (50.3%) followed by low level (26.4%) and medium level (23.3%). SOC was significant and positively predicted medication adherence, which accounted for around 58 to 60% ($p < 0.001$) while controlling for covariates.

Conclusions SOC was significant and positively predicted medication adherence. The study recommends that the SOC questionnaire could potentially be used to identify patients at risk for low adherence.

Keywords Stages of change · Transtheoretical model · Diabetes mellitus · Medication adherence · Primary care

✉ Mohamed Izham Mohamed Ibrahim
mohamedizham@qu.edu.qa

Yara Arafat
arafatyara@gmail.com

Ahmed Awaisu
aawaisu@qu.edu.qa

Stephen Colagiuri
stephen.colagiuri@sydney.edu.au

Yaw Owusu
yowusu@qu.edu.qa

Donald E. Morisky
dmorisky@ucla.edu

Mudather AlHafiz
mudather111@yahoo.com

Ahmed Yousif
ayousif@phcc.gov.qa

¹ Clinical Pharmacy and Practice Section, College of Pharmacy, Qatar University, PO Box 2713, Doha, Qatar

² Boden Institute, University of Sydney, Sydney, NSW, Australia

³ Department of Community Health Sciences, UCLA Fielding School of Public Health, Los Angeles, CA, USA

⁴ Pharmacy Department, Mesameer Healthcare Center, Doha, Qatar

⁵ Pharmacy Department, Westbay Healthcare Center, Doha, Qatar

Introduction

In the past 20 years, the prevalence of diabetes mellitus (DM) has greatly increased globally and become a serious public health problem [1]. The worldwide prevalence of DM in 2014 in adults was estimated to be 8.5% [2]. In the Middle East and North Africa, 37 million people have type 2 DM (T2DM), a figure expected to rise to 68 million by 2035 [3]. Specifically, Qatar is currently experiencing a worrying increase in the prevalence of T2DM, with 239,100 recorded cases (i.e., 13.5% of the adult population aged 20–79 years) in 2015 [4].

It is estimated that the annual cost per person with diabetes in Qatar to be around USD 2868. Immense DM-related spending currently imposes a substantial burden on the global economy as a result of increased direct and indirect medical costs [5, 6]. Therefore, the ability to self-manage T2DM is of paramount importance in improving the health-related quality of life (HR-QOL) in patients with T2DM. To self-manage, patients with diabetes must follow a healthy diet, exercise regularly, and adhere to medications to achieve optimum glycemic control.

Some diabetic care guidelines incorporate diabetes education to encourage self-management. The World Health Organization (WHO) guideline for a national program for diabetes emphasized the importance of educating patients with T2DM for them to attain a healthy quality of life and delay disease progression in addition to preventing the development of further complications [7]. However, there still seems to be a gap between care that is expected and care that is provided by diabetic care teams. The only approach to narrow this gap is to apply multidisciplinary interventions to improve HR-QOL [8]. Poor clinical outcomes in patients with diabetes are largely the result of the dependence of health care professionals on the biomedical model, which assumes that patients are the passive recipients of doctors' instructions to treat chronic conditions [9, 10]. Clinicians who apply this model believe that the problems regarding medication non-adherence are due to certain patient characteristics [11]. However, the WHO defines health as “a state of complete physical, mental, and social well-being, and not merely the absence of disease or infirmity” [12]. Since the biomedical model mainly focuses on improving physical well-being and not the remaining aspects of health, interventions have begun to incorporate socio-behavioral models along with the biomedical model to holistically improve personal health in alignment with the WHO's perspective.

The transtheoretical model (TTM), also known as the stages of change (SOC) model, is a socio-behavioral model that is commonly used in research and clinical practice. This model was first developed in the 1980s by Prochaska and DiClemente to understand how people intentionally modify certain behaviors [13]. The TTM consists of the following five SOC [14]: precontemplation, contemplation, preparation, action, and maintenance. To progress through the SOC,

individuals apply 10 processes of change, with some processes being more relevant to specific SOC than others.

One of the most common reasons for uncontrolled DM is non-adherence to medications. Good health-related outcomes cannot occur if patients do not take their medications consistently as prescribed [15]. Since the biomedical model has failed, and non-adherence to medications is considered a behavioral problem, health care professionals have started applying the principles of the TTM to improve medication adherence. The TTM has previously been used to measure the SOC regarding medication adherence in patients receiving antihypertensive medications [16]. Another study suggested that patients with hypertension who received a TTM-intervention had a higher rate of adherence to their antihypertensive medications than patients who received standard care [17]. TTM-based interventions have also been shown to improve adherence in individuals taking lipid-lowering drugs [18]. Furthermore, two studies were conducted to evaluate the effectiveness of TTM on medication adherence in patients with HIV/AIDS who were actively taking antiretroviral therapy (ART) [19, 20]. One of these studies reported an association between TTM and medication adherence [19] while the other study suggested that incorporation of the social, behavioral, and cognitive aspects of TTM was necessary for an intervention to enhance medication adherence in patients taking highly active antiretroviral therapy (HAART) [20]. To our knowledge, the ability of a TTM intervention to enhance medication adherence has never been previously evaluated in patients with T2DM. However, studies have shown that TTM interventions have helped patients with T2DM move forward through the SOC as it pertained to exercise [21–23] and encouraged patients to follow a healthier diet [22–26], which led to a reduction in glycated hemoglobin (HbA1c) [21, 22, 24, 27].

The objective of this study was to determine the SOC and medication adherence scores of patients with T2DM who attended the Primary Health Care Corporation (PHCC) clinics in Qatar and to determine whether the SOC could predict T2DM medication adherence.

Methods

This cross-sectional prospective study involved patients with T2DM who attended PHCC clinics in Qatar. The study was approved by the Institutional Review Boards of PHCC and Qatar University. After verbally agreeing to participate, patients were asked to sign an informed consent form; the participants were allowed to withdraw from the study at any time if they desired. Mesaimeer and Westbay Health Care Centers were used as the study sites. Recruitment of participants began on February 7, 2016 and ended on April 28, 2016. All eligible participants were recruited during their regularly scheduled visits at the non-communicable diseases (NCD) clinic, and no follow-ups were required. The inclusion criteria for

participants were as follows: (i) confirmed T2DM diagnosis (HbA1c $\geq 6.5\%$, fasting plasma glucose (FPG) ≥ 126 mg/dL, and/or a 2 h plasma glucose ≥ 200 mg/dL); (ii) prescription for oral antidiabetic medications and/or insulin; and (iii) the presence or absence of other comorbidities. Participants were excluded if they were (i) age < 18 years, (ii) pregnant women (because of the possibility of gestational diabetes), (iii) mentally incompetent, and (iv) treatment with only lifestyle modifications.

The main outcomes of interest were the participants' SOC and medication adherence scores. Medication adherence was measured using the 8-item Morisky Medication Adherence Scale (MMAS-8), which provides scores ranging from 0 to 8 and classifies participants into low, medium, and high medication adherence categories [28–30]. The SOC were determined using the 2-item SOC questionnaire. The first item placed participants in precontemplation, contemplation, preparation, or action and maintenance stages. The second item differentiated between individuals at action and maintenance. Other variables that were considered confounding factors were also recorded during the study to control for their effect on SOC and medication adherence. The potential confounding factors recorded were demographic characteristics, the total number of prescribed medications and disease duration. Patients attending NCD clinics at the study centers were requested to answer the SOC and the MMAS-8 questionnaires, which were available in both English and Arabic languages. Other required data were extracted from the electronic and paper-based medical records at each respective clinic.

The data were analyzed using SPSS version 22 (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.), and the α priori level of significance was $p < 0.05$. Descriptive analyses were conducted to determine the patients' SOC and medication adherence scores. Categorical data are presented as frequencies (%), while continuous data are presented as the mean $\pm$ sd. Chi-square test of association was conducted to examine the relationships between different baseline characteristics and SOC and level of medication adherence, while Spearman's rho correlation was conducted to determine the initial correlation between SOC and medication adherence. Finally, hierarchical multiple regression was conducted to determine if SOC could predict medication adherence while controlling for confounding factors (with some using dummy variables).

Results

Out of 387 patients included in the study sample, 63% of whom were male. The mean age of participants was 54.3 ± 10.2 years. Additionally, there were more Arab participants than either Asian or other ethnicities (around 52%, 44%, and 4%, respectively). Non-Qatari participants

comprised 85% of the study sample. Table 1 shows the demographic characteristics of participants in greater detail. Chi-square test of association was conducted to examine the relationships between different baseline characteristics and SOC. Only marital status was significantly associated with the SOC ($p = 0.04$). In another analysis, Chi-square test indicated significant association between level of medication adherence and marital status ($p = 0.04$) and latest educational attainment of participants ($p < 0.001$).

More than three-fourth of the participants were in the maintenance stage of change, while more than half of them self-reported high adherence to their antidiabetic medication regimens. Additionally, the mean adherence score obtained from the MMAS-8 was 6.88 ± 1.62 , indicating medium medication adherence. Table 2 shows the SOC and medication adherence scores of the study participants in detail.

Table 1 Demographic characteristics of study participants ($n = 387$)

Characteristic	Frequency (%)	Mean $\pm$ SD
Age (years), mean $\pm$ SD		54.29 $\pm$ 10.20
Age (years)		
Less than 45	69 (17.8)	
45–54	117 (30.2)	
55–65	153 (39.5)	
Above 65	48 (12.4)	
Sex		
Male	244 (63)	
Female	143 (37)	
Nationality		
Qatari	59 (15.2)	
Non-Qatari	328 (84.8)	
Race		
Arab	201 (51.9)	
Asian	171 (44.2)	
Others	15 (3.9)	
Marital status		
Single	13 (3.4)	
Married	366 (94.6)	
Divorced	1 (0.3)	
Widowed	7 (1.7)	
Educational attainment		
Postgraduate	15 (3.9)	
Bachelor	193 (49.9)	
Less than Bachelor	179 (46.3)	
Occupation		
Professional	88 (22.7)	
Managerial	32 (8.3)	
Assistants and helpers	142 (36.7)	
Unemployed	100 (25.8)	
Retired	25 (6.5)	

Table 2 Stages of Change and Morisky medication adherence scores of participants

Variable	Frequency (%)	Mean $\pm$ SD
Stages of change		
Precontemplation	5 (1.3)	
Contemplation	13 (3.4)	
Preparation	57 (14.7)	
Action	15 (3.9)	
Maintenance	297 (76.7)	
Morisky medication adherence score		
Low adherence	94 (24.3)	
Medium adherence	69 (17.9)	
High adherence	224 (57.8)	
Mean adherence score $\pm$ SD		6.88 $\pm$ 1.62

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There was a significant and positive correlation between the SOC and medication adherence ($r = 0.73$, $p < 0.001$). Table 3 displays the correlations between confounding factors and SOC and with medication adherence. The confounding factors significantly associated with SOC were age, nationality, occupation, disease duration, and the total number of prescribed medications. Factors that were associated significantly with medication adherence were age, nationality, marital

status, education, occupation, disease duration, and the total number of prescribed medications. Thus, all measured confounding factors were controlled for during the hierarchical regression analysis.

Not all of the confounding factors were placed in the same model because multicollinearity, which is a violation of the assumption of hierarchical regression, was present between some of them. Thus, two independent hierarchical regressions were performed to determine whether SOC could predict medication adherence. The first regression model controlled for age, disease duration, and occupation, while the second model controlled for the total number of prescribed medications, education, and nationality; this separation avoided multicollinearity violations between confounding factors. SOC significantly predicted medication adherence when age, disease duration, and occupation were controlled ($\beta = 0.79$, $t = 25.132$, $p < 0.001$). The first model significantly predicted medication adherence and explained 7.5% of the variance [$R = 0.27$, $R^2 = 0.08$, $F(4, 382) = 7.74$, $p < 0.001$]. In the second model, SOC alone predicted 57.5% of the variance in medication adherence. Including all the variables in the second model significantly improved the R^2 value, which predicted 65.2% of the variance in medication adherence [$R = 0.81$, $R^2 = 0.65$, $F(5, 381) = 142.73$, $p < 0.001$].

The second hierarchical regression analysis determined whether the total number of prescribed medications, education, nationality, and SOC could predict medication adherence. As in the first model, the total number of prescribed

Table 3 Correlation of confounding factors with SOC and medication adherence

Characteristic	SOC	Medication adherence
Demographic characteristics		
Age	$r = 0.28$ $p = 0.01^{**}$	$r = 0.22$ $p = 0.01^{**}$
Gender	$r = 0.06$ $p = 0.21$	$r = 0.09$ $p = 0.09$
Nationality	$r = -0.13$ $p = 0.01^{**}$	$r = -0.13$ $p = 0.01^{**}$
Ethnicity	$r = 0.03$ $p = 0.48$	$r = 0.03$ $p = 0.58$
Marital status	$r = 0.09$ $p = 0.07$	$r = 0.10$ $p = 0.04^*$
Education	$r = -0.09$ $p = 0.06$	$r = -0.20$ $p = 0.01^{**}$
Occupation	$r = -0.16$ $p = 0.01^{**}$	$r = -0.19$ $p = 0.01^{**}$
Disease duration	$r = 0.17$ $p = 0.001^{**}$	$r = 0.15$ $p = 0.003^{**}$
Number of prescribed medications	$r = 0.21$ $p = 0.01^{**}$	$r = 0.17$ $p = 0.001^{**}$

* $p < 0.05$

** $p < 0.01$

medications, education, and nationality significantly predicted medication adherence [$(\beta = 0.136, t = 2.613, p < 0.05)$ and $(\beta = -0.172, t = -3.436, p < 0.001)$, respectively]. The first model significantly predicted medication adherence and explained 6.0% of the variance [$R = 0.25, R^2 = 0.06, F(3, 383) = 8.23, p < 0.001$]. In the second model, SOC alone predicted 59.9% of the variance in medication adherence, whereas the entire second model predicted 65% [$R = 0.81, R^2 = 0.65, F(4, 382) = 184.75, p < 0.001$]. Table 4 presents the results of both hierarchical regression analyses.

Discussion

This study examined the causality relationship between SOC and medication adherence in patients with T2DM. Age, nationality, marital status, education, and occupation, which were controlled while determining whether SOC significantly predicted medication adherence were the only demographic characteristics significantly correlated with SOC or medication adherence. These findings are consistent with past researches performed in similar areas. Congruent with the findings of our study, previous studies observed significant relationships between age and medication adherence in several populations,

suggesting that medication adherence increases with age [31–34]. The literature also suggested that ethnic group affects medication adherence, where Caucasians generally had better adherence than African Americans, Hispanics, and other minority ethnic groups [35–37]. Though the literature recommends that nationality could affect medication adherence, most of those studies were carried out with different nationalities or ethnicities than the ones represented in this study, making it difficult to compare our results with other findings. It was worthwhile to include the nationality factor into the analysis because in Qatar with around 2.7 million population, the local i.e. Qatar (Arab) nationals make up less than 15% of the total population. Further, marital status strongly influences medication adherence, and several studies suggested that being married could positively influence medication adherence [38–40]. Surprisingly, educational attainment negatively affected medication adherence in the current study, as patients with lower educational attainment had a higher medication adherence rate than those with bachelor's or postgraduate degrees. These results were contradicted with other studies; they suggested that educational attainment was positively associated with medication adherence and that educated patients had better knowledge of their disease and prescribed medications [41–44]. However, two previous studies have supported our findings, which

Table 4 Hierarchical regression analysis of prediction of medication adherence by stages of change, controlling for confounding factors

Variables	Model 1			Model 2		
	B	T	Sig.	B	T	P value
First hierarchical regression						
Age	0.17	3.20	0.001 **	−0.01	−0.09	0.93
Disease duration	0.08	1.54	0.12	0.05	1.39	0.17
Occupation	−0.12	−2.25	0.02 *	−0.05	−1.627	0.10
Marital status	0.02	0.35	0.73	0.02	0.51	0.61
SOC				0.79	25.13	0.01 **
R	0.27			0.81		
R ²	0.08			0.65		
R ² for change	0.08			0.58		
F	7.74			142.73		
Sig. F change	0.00**			0.00**		
Second hierarchical regression						
Total prescribed medications	0.14	2.61	0.009**	−0.01	−0.19	0.84
Education	−0.17	−3.44	0.001**	−0.12	−3.83	0.01 **
Nationality	−0.04	−0.79	0.43	0.01	0.13	0.89
SOC				0.79	25.9	0.01 **
R	0.25			0.81		
R ²	0.06			0.65		
R ² for change	0.06			0.59		
F	8.23			184.75		
Sig. F change	0.00**			0.00**		

* $p < 0.05$

** $p < 0.01$

showed that patients with lower education levels had better medication compliance [33, 34]. This high rate of compliance is probably because patients with lower educational levels trusted the advice given to them by their health care professionals more than their highly educated counterparts. Occupation also negatively affected medication adherence, where the results demonstrated that the higher the classification of occupation, the lower the patient's medication adherence. This finding contradicts the results of a previous study that stated unemployed patients had poorer medication adherence rates [45]. However, that trend was not observed in all studies particularly since results were likely to differ according to health care system and national practice [46]. Moreover, disease duration and the total number of prescribed medications were both significantly correlated with SOC and medication adherence. Therefore, those variables were chosen as covariates in the hierarchical regression analysis to ensure the study's internal validity. A few studies agreed with our findings and indicated that there were associations between disease duration and medication adherence particularly when the length of the chronic disease diagnosis was positively associated with medication adherence [47–49]. As the total number of prescribed medications increased, medication adherence also increased, which suggests that physicians should not be restricted to prescribing a limited number of medications as supported by Richard et al. (2003), who pointed out that patients with T2DM had high medication adherence rates regardless of the number of total prescribed medications [50]. In addition, our study demonstrates that some demographic characteristics affect SOC and medication adherence in patients with chronic conditions, contradicting the previous finding that demographic characteristics did not influence SOC or medication adherence in patients with HIV [19]. The 34 to 35% of the unexplained variance in the hierarchical regression model was likely caused by other covariates that were not included in the model, such as health literacy, patient knowledge, and the patient–prescriber relationship. Health literacy is defined as the ability to read, understand, and remember medication instructions and to act on health information [51]. Patients with lower health literacy are usually less adherent to therapy [52], whereas patients with higher health literacy (who can read and understand drug labels) are more adherent [53, 54]. Patient knowledge is also thought to influence medication adherence, as patients without an adequate level of knowledge of their disease or prescribed medications do not show consistent adherence [55]. Other patients lack an understanding of the importance and value of regular clinic visits. Observations in both clinics indicated that several patients with T2DM did not attend their scheduled NCD clinic appointments which might influence medication adherence because patients who do not attend do not understand the importance of these visits. Finally, the patient–prescriber relationship could partially explain the unexplained variance, approximately 34 to 35%. Several studies have

concluded that the patient–prescriber relationship is an important factor that affects medication adherence [43, 56, 57]; good adherence occurs when doctors are emotionally supportive, give reassurance or respect, and treat patients as equal partners [56, 58]. Moreover, approximately 10% of patients with medium–low adherence stated that their nonadherence was unintentional (i.e., they forget to take their medications when they are busy with work or family but otherwise take them regularly). Another reason for medium–low adherence among patients who were prescribed metformin was that physicians told patients to take the drug with meals. Thus, when patients skipped meals, they did not take their medication, indicating that patients were not informed that they should never skip a dose and that the right thing to do in such situations is to eat a small amount of food with metformin. Institutional policies in Qatar create more resistance to research related to practitioners and health care providers than to research related to patient care, making it difficult to measure these covariates. However, it is important to consider the impact of these factors, as they could influence the medication adherence scores of patients with T2DM.

The results of our study found that SOC predicts approximately 58 to 60% of the variance in medication adherence when controlling for demographic and clinical characteristics that impacted medication adherence. To the authors' knowledge, only one previous study has been conducted to determine whether TTM could enhance medication adherence in addition to encouraging patients to exercise regularly and follow healthier diets [21]. This study's results showed that SOC encouraged patients to exercise more and maintain healthier diets, which reduced HbA1c; however, there was little change in medication adherence. This was the only study conducted to determine if TTM could enhance medication adherence in patients with T2DM. However, a study among patients with HIV that sought to determine the relationship between SOC and medication adherence produced similar results to our study [19]. The HIV adherence study observed a positive relationship between SOC and adherence to ART and showed that patients with HIV in the precontemplation, contemplation, or preparation stages had medication adherence scores that were approximately 10% lower than those scores that were obtained from patients at the action or maintenance stages. However, in contrast to our results, that study found that demographic characteristics poorly predicted adherence. A previous attempt was made to understand several factors associated with nonadherence with antidepressant medications in a setting similar to our study [59]. That study found that low medication adherence was associated with lower SOC. Patient SOC were significant predictors of adherence to antidepressants ($p = 0.047$) and were the strongest predictors of medication adherence of any variable tested in the study, including the patients' satisfaction with their physician and the type of depression they suffered.

Several issues affected the interpretation of the present data. One criticism of the SOC model is that it does not capture changes in the many behavioral facets and dimensions required for complex behavioral change [60]. For instance, adhering to a certain medication regimen requires many behaviors beyond simply swallowing a pill: provider visit retention, filling prescriptions, and consistently taking doses [61]. It is unclear how these many behaviors are targeted by the SOC. Instead, the SOC model is related to overall medication adherence according to questions on the MMAS-8. Further, this study may be subject to social desirability bias which results in the misreporting of responses related to the SOC and medication adherence. Such a bias would lead to an underestimation of those metrics in early SOC and among those patients with low medication adherence. In other words, patients tend to overestimate their personal stage of change as well as their level of medication adherence.

Another limitation is that the SOC determinations only regarded the taking of antidiabetic medications as prescribed. SOC related to following a healthy diet or exercising were not determined, even though those factors both contribute to self-management of T2DM.

Further interventions applying TTM to SOC-relevant change processes are needed to determine the ability of TTM to describe impacts on medication adherence usefully in populations with T2DM. Without further research, no clear recommendations can be provided regarding the effectiveness of TTM in improving the rates of medication adherence. We also encourage educating patients with T2DM because that is very important for the enhancement of medication adherence. It is crucial that each patient understands the pathology of DM, how their prescribed medications work, and the diet they need to maintain.

Conclusions

The study findings concluded that SOC predicted approximately 58 to 60% of the variance contributed to medication adherence while controlling for confounding factors. Further findings recommend that the two-item SOC is useful to identify patients at risk of low adherence and when to conduct interventions using TTM. These interventions could move those patients to the action or maintenance stages and improve their medication adherence. This change could improve clinical outcomes such as HbA1c reduction, and eventually, enhance patient's HR-QOL.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Dr. Morisky is the developer/owner of the copyrighted and trademarked protected Morisky Medication Adherence Scale and sells MMAS licenses and consulting services through MMAS Research LLC, 14725 NE 20th St., Bellevue, Washington 98,007. Dr. Morisky was not involved in the data collection or analysis.

Ethical approval The study was approved by the Institutional Review Boards of Primary Health Care Corporation and Qatar University.

Informed consent Informed consent was obtained from all individual participants included in the study.

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