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# Prevalence of Prolonged QTc Interval and Associated Factors among Type Two Diabetic Patients at Kilimanjaro Christian Medical Centre, in North-Eastern Tanzania

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## Abstract

**Objective:** Diabetes Mellitus (DM) is steadily increasing globally; whereas Cardiac Autonomic Neuropathy (CAN) is one of the well-established complications of diabetes mellitus that is long standing and poorly controlled. Alteration in cardiac sympathetic innervations may result in QTc interval prolongation and predispose to arrthymias and sudden death. QTc interval prolongation in ECG is rapid, non-invasive and specific method in detecting CAN among type two diabetic patients. This study aimed to determine the prevalence of prolonged QTc interval among Type 2 DM (T2DM) patients at Kilimanjaro Christian Medical Center, Moshi Tanzania. This cross-sectional hospital-based study was carried out from October 2016 to March 2017 among 310 type 2 diabetic patients.

**Results:** The prevalence of prolonged QTc interval among T2DM was found to be 32%. Poor glycaemic control (OR: 2.55, P=<0.0001), Being Hypertensive (OR: 1.73, P=0.037), High Total cholesterol (OR: 1.52, P=0.001), High LDL-c (OR: 1.28, P=0.005), High Triglycerides (OR: 1.64, P=0.001), Fasting plasma glucose (OR: 1.08, P=0.017), Diabetes duration (OR: 1.09, P=<0.0001), Insulin regimen (OR: 2.14, P=0.011), Combined regimen (Oral hypoglycemic and Insulin) (OR: 4.55, P=0.015), High BMI (P=0.008) were significant factors. Multivariate logistic regression showed that poor glycaemic control, fasting plasma glucose, insulin regimen and combined regimen (insulin and oral hypoglycemic) were determinants for QTc prolongation among T2DM patients in this study.

**Conclusion:** This study revealed a high prevalence of prolonged QTc interval. Modifiable factors such as poor glycaemic control, dyslipidemia, hypertension, fasting plasma glucose and treatment modalities were associated with the QTc prolongation. Furthermore, longer diabetes duration was also associated with QTc prolongation. Thus there is need of having a tightly glycaemic control, screening and management of dyslipidemia as well as regular ECG check up to high risk group.

**Keywords:** QTc prolongation • Type 2 diabetes mellitus • Moshi

**Abbreviations**: BMI: Body Mass Index; CAN: Cardiac Autonomic Neuropathy; CVD: Cardiovascular Diseases; CI: Confident Interval; DM: Diabetes Mellitus; ECG: Electrocardiogram; HbA1c: Glycosylated Hemoglobin; HDL-c: High Density Lipoprotein Cholesterol; HTN: Hypertension; LDL-c: Low Density Lipoprotein Cholesterol; T2DM: Type 2 Diabetes Mellitus; TC: Total Cholesterol; TG: Triglyceride; OR: Odds Ratio

## Introduction

Diabetes Mellitus (DM) is a major health problem globally [1]. The global prevalence of DM is 8.8% among adults and this is projected to raise to 10.4% by 2040 [2]. Diabetes mellitus is one of the major risk factors for Cardiovascular Diseases (CVD) and is significantly associated with doubling the morbidity and mortality [1,3]. Type 2 diabetes (T2DM) accounts for 90–95% of all diagnosed cases of diabetes, with higher prevalence among older adults [4]. The conversional risk factors like hypertension, dyslipidemia, smoking habit, and alcohol intake; after being addressed, the ventricular instability may still be one of the important mechanisms, which could account for the increased cardiovascular risks among diabetes [5,6]. Cardiovascular mortality

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among DM patients account for 70% of which, 50% are due to Sudden Cardiac Deaths (SCDs) [7]. Ventricular tachyarrhythmia account for the majority of SCDs [8]. American Heart Association (AHA) and American College of Cardiology Foundation (ACCF) has recommended the use of Electrocardiogram (ECG) which is a simple noninvasive diagnostic test to screen for CVD risks in diabetes and hypertensive patients [9]. Various ECG makers have been of clinical important in clinical practices [10]. Moreover, QTc prolongation has been found to be the predictor of cardiovascular mortality in both healthy population and diabetic patients [11,12]. Hence, prolongation of the corrected QT interval (QTc) has been demonstrated to be a specific easier indicator for detection of Cardiac Autonomic Neuropathy (CAN) among diabetes population in most studies [11,13].

CAN is a common complication of diabetes and is associated with resting tachycardia, Postural Hypotension, painless myocardial ischemia or infarction, arrhythmias and sudden cardiac death. Thus, QTc prolongation can be utilized as a rapid method to target the people at high risk of cardiovascular events. Little is known concerning the magnitude of the problem in these low income countries. The purpose of this study was to determine the prevalence of prolonged QTc interval and the associated factors among T2DM patients attending Diabetes clinic.

## Materials and Methods

The study was conducted from October 2016 to March 2017 at Kilimanjaro Christian Medical Centre (KCMC), which is the tertiary referral hospital in north-eastern part of Tanzania. The study enrolled 318 T2DM diabetic patients, who were consecutively recruited at outpatient diabetes clinic during the clinic days. In 310 of the enrolled study participants had completed the data set and were available for analysis. Patients with Known end- stage renal disease, history of chronic atrial fibrillation on ECG, Patients on medications that prolong QTc interval Congestive Heart Failure (CHF) New York Heart Association (NYHA) classes 3-4 were excluded.

Informed written consent was obtained and a standardized questionnaire was used to collect information on demographics, clinical and laboratory characteristics. With the subjects wearing light clothing and no shoes, the principal investigator carried out anthropometric measurements such body weight; height and waist circumference were measured. Body Mass Index (kg/m$^2$) was calculated as weight (kilograms) divided by squared height in (meters). A standardized mercury sphygmomanometer was used to measure Blood pressure. Two readings were taken after least 5 minutes of patient rested. Under aseptic technique, by using Glucoplus™ meter (GlucoplusInc, Saint-Laurent, QC H4S 1S3, Canada) Fasting Plasma Glucose was measured. Capillary blood from a finger prick was put on glucoplus strip and the readout was done using the Glucoplus meter. Results were used for the patients' care and ideal management. An overnight fasting blood sample for at least 8 hours was taken for lipid profile analysis (LDL-c, HDL-c, TG and TC).

By using chemical analyzer COBAS INTEGRA 400 Plus serial NO 397672 the sample was analysed. Serum creatinine and HbA1c was also anlysed.

The ECG machine was calibrated according to the protocol and manual. A trained nurse after explained the procedure conducted ECG on the study participants. Using Hewlett Packard M1771A Page writer 200 ECG/EKG machine serial number CNB0307869.The ECG nurse attached 12 electrodes to the skin on the chest, arms, and legs. As the person lies still for a few minutes, the electrodes pick up electrical signals from the heart and relay them to a machine that records these signals, on the ECG graph paper, after which the electrodes were removed. Tracings were performed at paper speed of 25 mm/s and voltage calibration of 10 mm/mV. The ECG was performed and a printout is given. The Principal investigator and a Physician independently for accuracy calculated QTc interval. The mean duration of all QTc intervals was measured. RR and QT intervals were measured with a ruler and magnifying glass on the resting ECG tracing. The QT interval was measured from the beginning of QRS complex to the down slope of the T wave. QT interval measured in seconds. The R-R interval measured in Small Square then multiplied by 0.04 to be changed to milliseconds. Lead II was considered for consistence of readings. By using Bazett's Formula (QTc=QT/(RR)), QTc was obtained. QTc of >440 ms for males and >460ms for females was considered abnormally prolonged.

### Statistical analysis

All data were analyzed using SPSS statistical version 20.0. Data were examined for distribution, and outliers through univariable analysis. Continuous variables were summarized using mean and Standard Deviation (SD). Categorical variables were summarized using frequency and percentages. Student t-test was used to determine mean difference of the continuous variables. The Chi-squared test ($\chi^2$) was used to determine association among categorical variables. A multivariate logistic regression was used to analyze association between QTc prolongation and independent associated factors. Measures of association Odds Ratio (OR) with 95% Confidence Intervals (CIs) for the factors associated with prolonged QTc were used. P-value of <0.05 was considered statistically significant. Informed written consent (by signature or thumbprint) was obtained from all participants. Ethical clearance (No 959) was sought and granted by the Institution Review Board at KCMU-College and Ethical Committee, as well as permission was obtained from Internal Medicine head of department and diabetic clinic in charge before commencing the study.

## Results

A total of 318 patients met the inclusion criteria, 8 patients were dropped out as they had incomplete investigations hence, 310 patients were included in the analysis. A total of 310 T2DM patients were studied. The mean (SD) age of study participants was 57.68 (8.88) years. Majority (57.10%) were between 45-60 years.

There was high proportion (70.32%) of diabetic women. Almost half of the study participants came from urban area. Majority (76.13%) of study participants were married. About half of the diabetic patients were employed and at leastall the study participants had attained formal education.

Majority (62.26%) were hypertensive. About one third of T2DM patients had normal weight. High proportion (63.55%) of patients had good glycaemic control with HbA1c of <7% (Table 1).

**Table 1.** Characteristics of T2DM patients attending diabetes clinic at KCMC, Moshi Tanzania (n=310).

| Characteristics | N (%) |
|---|---|
| **Age (years)** | |
| Mean (SD) | 57.68 (8.88) |
| 35-45 | 18 (5.81) |
| 45-60 | 177 (57.10) |
| >60 | 115 (37.10) |
| **Sex** | |
| Females | 218 (70.32) |
| Males | 92 (29.68) |
| **Residence** | |
| Rural | 147 (47.42) |
| Urban | 163 (52.58) |
| **Marital status** | |
| Married | 236 (76.13) |
| Unmarried | 74 (23.87) |
| **Occupation** | |
| Employed | 156 (50.32) |
| Unemployed | 154 (49.58) |
| **Education level** | |
| Primary | 113 (36.45) |
| Secondary | 94 (30.32) |
| Tertiary | 103 (33.23) |
| **Hypertension** | |
| Yes | 193 (62.26) |
| No | 117 (37.74) |

| | |
|---|---|
| **BMI** | |
| Underweight | 14 (4.52) |
| Normal | 106 (34.19) |
| Overweight | 94 (30.32) |
| Obese | 96 (30.97) |
| **Glycemic control (HbA1c)** | |
| Good glycaemic control | 197 (63.55) |
| Poor glycaemic control | 113 (36.45) |

The mean systolic blood pressure of the study participants was 134.39 mmHg SD (19.83) while the mean diastolic blood pressure was 79.44 mmHg SD (11.53). Total cholesterol had a mean of 5.14mmol/l SD (1.01) with the range of 3.05-7.4 mmol/L. The mean LDL-c was 2.55 mmol/L SD (1.39) and the mean HDL-c was 1.84 mmo/L SD (4.43) while the mean triglycerides were 1.44 mmol/L SD (0.83). Mean HbA1c was 6.73% SD (1.79) 3.66-12.92%. The mean BMI was 27.71 (kg/m$^2$), SD (5.24).

The mean serum creatinine was 74.44 µmol/L SD (13.50). Prevalence of prolonged QTc interval was found to be 32%. Prevalence of severe prolonged QTc interval was found to be 7%.The following factors namely: high BMI, poor glycaemic control, being hypertensive, total cholesterol, LDL-c, triglycerides, fasting plasma glucose and longer diabetes had shown significance association with prolonged QTc interval among type two diabetic patients (Table 2).

**Table 2.** Clinical and laboratory characteristics of T2DM patients attending diabetes clinic at KCMC, Moshi Tanzania (n=310).

| Characteristics | Mean | Standard Deviation | Range |
|---|---|---|---|
| Systolic Blood Pressure (mmHg) | 134.4 | 19.83 | 90-200 |
| Diastolic Blood Pressure (mmHg) | 79.44 | 11.53 | 60-120 |
| Total cholesterol (mmol/l) | 5.14 | 1.01 | 3.05-7.4 |
| LDL-c (mmol/L) | 2.55 | 1.39 | 0.16-6.41 |
| HDL-c (mmol/L) | 1.84 | 4.43 | 0.13-7.9 |
| Triglycerides (mmol/L) | 1.44 | 0.83 | 0.12-5.12 |
| HbA1c (%) | 6.73 | 1.79 | 3.66-12.92 |
| BMI (kg/m$^2$) | 27.71 | 5.24 | 15-39 |
| Waist circumference (cm) | 96.81 | 11.63 | 67-123 |
| Fasting Plasma Glucose (mmol/L) | 7.9 | 3.77 | 3.9-26.2 |
| Duration of diabetes (years) | 9.02 | 6.53 | 1-30 |
| Creatinine (µmol/L) | 74.44 | 13.5 | 42-120 |

By using multivariate logistic regression: patients, who had poor glycaemic control, had 2.09 higher odds of having prolonged QTc interval than those with good glycaemic control (OR: 2.09; 95% CI (1.12-3.92)). An increase in one unit of fasting plasma glucose was associated with 11% higher odds of having prolonged QTc interval. (OR: 1.11(1.03-1.19)).

Being on insulin regimen had 2.29 higher chance of developing QTc prolongation as compare to those who were not on insulin regimen (OR: 2.29; 95% CI (1.05-4.99)). The use of both oral hypoglycemic drugs and insulin has 6.93 higher risk of developing QTc interval prolongation (OR: 6.93; 95% CI (1.54-31)) (Table 3).

**Table 3.** Crude and adjusted logistic regression of QTc prolongation and independent variables among T2DM patients.

| Characteristics | Crude OR 95% (CI) | P-Value | Adjusted OR 95%(CI) | P-Value |
|---|---|---|---|---|
| **Age (years)** | | | | |
| 35-45 | 1 | | | |
| 45-60 | 2.37 (0.66-8.53) | 0.186 | - | |
| >60 | 2.56 (0.70-9.36) | 0.155 | - | |
| **Sex** | | | | |
| Female | 1 | | | |
| Male | 0.97 (0.58-1.64) | 0.919 | - | |
| **(Glycemic control) HbA1c** | | | | |
| Good glycaemic control | 1 | | 1 | |
| Poor glycaemic control | 2.55 (1.56- 4.18) | <0.0001 | 2.09 (1.12-3.92) | 0.002 |
| **Hypertension** | | | | |
| No | 1 | | 1 | |
| Yes | 1.73 (1.03-2.88) | 0.037 | 1.13 (0.61-2.09) | 0.693 |
| Systolic blood pressure | 1.01 (0.99- 1.02) | 0.27 | - | |
| Diastolic blood pressure | 1.01 (0.99-1.04) | 0.167 | - | |
| Total cholesterol | 1.52 (1.19-1.94) | 0.001 | 1.24 (0.88-1.75) | 0.223 |
| LDL-c | 1.28 (1.08-1.51) | 0.005 | 1.09 (0.87-1.37) | 0.444 |
| HDL-c | 1.37 (0.91-2.07) | 0.129 | | |
| Triglycerides | 1.64 (1.23-2.19) | 0.001 | 1.17 (0.79-1.73) | 0.428 |
| **BMI** | | | | |
| Normal | 1 | | 1 | |
| Underweight | 0.37 (0.08-1.74) | 0.208 | 0.49 (0.08-2.88) | 0.427 |

| | | | | |
|---|---|---|---|---|
| Overweight | 0.68 (0.36-1.27) | 0.223 | 0.49 (0.24-0.99) | 0.048 |
| Obese | 1.72 (0.97-3.06) | 0.065 | 1.06 (0.54-2.07) | 0.874 |
| Waist circumference | 0.99 (0.97-1.01) | 0.403 | - | |
| Fasting Plasma glucose | 1.08 (1.01- 1.15) | 0.017 | 1.11 (1.03-1.19) | 0.006 |
| Duration of diabetes | 1.09 (1.05-1.13) | <0.0001 | 1.04 (0.99-1.09) | 0.123 |
| **Diet control** | | | | |
| Diet only | 1 | | | |
| Diet+OHG | 2.67 (0.58-12.27) | 0.208 | - | |
| **Insulin** | | | | |
| No | 1 | | | |
| Yes | 2.14 (1.19-3.88) | 0.011 | 2.29 (1.05-4.99) | 0.037 |
| **Combined (OHG+Insulin)** | | | | |
| No | 1 | | 1 | |
| Yes | 4.55 (1.34-15) | 0.015 | 6.93 (1.54-31) | 0.012 |

## Discussion

The prevalence of QTc prolongation was found to be one third of the study participants. Factors, which were found to be associated with QTc prolongation among T2DM patients, were: poor glycaemic control, being hypertensive, dyslipidemia (high total cholesterol, high LDL-c, elevated triglycerides), high BMI, DM duration, fasting plasma glucose, treatment with insulin and combined regimen (oral hypoglycemic and insulin). The prevalence of QTc prolongation in study was 32%. Almost a third of T2DM patients in the center are at risk of having sudden cardiac death, due to CAN. Factors like advanced age could account for this as the mean age in this study was 57.6 years. Patients with more than 60 years of age had higher prevalence as compared to the other age group. Longer DM duration as mean age was 11.7 years. The current trend towards urbanization and adoption to the western lifestyle and diet could be the contributing factor, as 52.58% of the study participants were residing in the urban area. The presence of HTN among the study participants could be the contributing factor as 62.26% were hypertensive. Within African settings, some studies had almost similar prevalence of QTc prolongation among diabetic patients, in Egypt the prevalence was 33.6% [14].

This could be explained by the high prevalence of T2DM in Egypt 15.6%, with the associated factors like obesity, dietary pattern and poor adherence to medication [15]. Other studies had shown almost similar prevalence in China which was 30.1%, and Baghdad 32.5% [16,17]. Similar factors as advanced age and longer DM durations could account for these. However, Low prevalence of QTc prolongation was seen in Cameroon, Nigeria and Turkey 10.2%, 25.5% and 21% respectively [18-20]. Low mean DM duration could explain this. Studies in Macedonia, United Kingdom (UK) and USA had revealed high prevalence of prolonged QTc 37.5%, 44.1% and 51.3% respectively [21-23]. The presence of comorbid diseases HTN and DM among all the study participants could explain this high prevalence, as hypertension is among the factor associated with QTc prolongation. The prevalence of severe prolonged QTc interval more than 500 ms was 7%. However in UK the prevalence was 2% [24].

Advanced age accounted for QTc prolongation, 60 years and above is more likely to have prolongation of QTc; this could be due to the risk of atherosclerosis, secondary hypertension and other comorbid diseases among this age group. In this study 57.68 years was the mean age, which was almost similar to previous studies 58.4 years, 54.9 years and 56.45 years respectively [20,21,24]. In the study, 33.88% of the study participant with more than 60 years had prolonged QTc interval. Previous studies have shown association

between advance age and QTc prolongation, In UK advanced age (more than 60 years) was associated with QTc prolongation (P-value <0.002) [22]. Though age was not statistically significant as majority of the study participants were between 45-60 years 57.10%.

Among the 310 patients, female 70% (n=218) out of which 27.52% (n=60) had prolonged QTc interval. Males accounted for 29.68% (n=92) out of which 40.22% (n=37) had prolonged QTc interval. This finding correlates with a study that was done in Nigeria [19]. This is due to high proportion 40.22% of males with prolonged QTc had poor glycaemic control as compare to females 34.86% with prolonged QTc. However, other studies showed female had high proportion of having prolonged QTc interval. In UK 55% of females as well as in china had QTc prolongation as compare to males [16,22]. These could be explained by the reasons that, females have prolonged QTc duration as compared to adult males. The presence of sex hormones; endogenous testosterone and progesterone hormones shortens the action potential whereas the estrogen hormone prolongs the QTc interval [26].

High BMI was associated with QTc prolongation, in the current study almost twenty-nine and forty two percent respectively of study participant had prolonged QTc. Obese patients had 1.72 times higher risk of having QTc prolongation as compare to other BMI categories. In UK, BMI was found to be associated with QTc prolongation [26]. In China, Japan and Egypt did not show statistical significance between QTc prolongation and BMI [14,16,24].

In this study, dyslipidemia constitutes to the QTc prolongation among T2DM patients. Patients with high total cholesterol had 52% high risk of having prolonged QTc interval, as well as those with LDL-c had 28% higher risk and the high triglycerides had 64% higher chance of developing QTc interval prolongation. The presence of high prevalence of dyslipidemia among DM patients at our center could account for this. A study by Chamba et al, shown high prevalence of dyslipidemia (83%) with high LDL-c 64.4% among DM patients [25].Thus, patients with deranged lipid parameters had high chances of developing QTc prolongation in this study. Similar results were reported previously in T2DM in Egypt and China [14,16]. Whereas, in UK, triglycerides alone was found to statistically significant associated with QTc prolongation [22]. In study the HDL-c levels were not associated with QTc interval prolongation likewise in Egypt [14]. In multivariate analysis none of these parameters were found to be statistically significant.

Furthermore, hypertension is associated with QTc prolongation. In our study, 62.26% were hypertensive of which 34.2% had prolonged QTc interval. Being hypertensive, there is 73% more chance of developing QTc prolongation. Though the association between Hypertension and prolonged QTc was not statistically significant. In this study, the presence of systolic or diastolic blood pressure did not show significant association with Prolonged QTc interval. However, other studies in China had shown systolic and diastolic blood pressure to be associated with prolonged QTc interval [16].

In the present study, poor glycemic control is an independent predictor of QTc prolongation. (36.45%) of the study participants with prolonged QTc had poor glycemic control, whereby, patients with poor glycemic control had 2.55 times high chances of developing QTc prolongation as compare to the good glycemic control patients (OR=2.55; P=<0.0001). Even after adjusting for the confounders those patients who had poor glycaemic control, had 2.09 times higher odds of having prolonged QTc interval, as compared to those with good glycaemic control (OR: 2.09; 95% CI (1.12-3.92)). The high prevalence of dyslipidemia (83%) among DM seen by Chamba and colleagues could be among the reason [25]. Similarly, poor glycemic control was observed in China and UK [16,22]. However, study in Egypt did not show statistical significance [14]. In our study, mean fasting plasma glucose was 8.86 mmol/L among patients with prolonged QTc interval. Results show that there is 8% higher chance of developing QTc prolongation as compared to those with normal fasting plasma glucose. UK and Macedonia had found significant association between QTc prolongation and fasting plasma glucose [21,22]. In this study, patients with longer DM duration had 9% higher chance of developing QTc prolongation as compare to those with less than 10 years of DM duration. This similar finding was seen in previous studies in Egypt, China and UK [14,16,22].

In this study, Insulin therapy was associated with higher chance of risk of QTc prolongation as well as the drug combination (insulin and oral hypoglycemic) with (OR: 2.14; 95%CI (1.19-3.88)) and (OR: 4.55; (1.34-15)), respectively. 26.26% of those who uses insulin regimen had prolonged QTc. 8% and 2% of those who were on combined regimen (insulin and OHG) and had prolonged QTc interval. The reason as could be most of the time T2DM patients are on oral medications but when they are switched to insulin regimen means there is poor glycemic control of which has lead to resistance. Those on the diet control are still in the acceptable glycemic range. Previous studies mean HbA1c were Egypt (7.56%), Japan (7.9%) and Turkey (8%) of which have reported the association between insulin therapy and QTc prolongation with the P- value of <0.05 [14,20,24]. However, in Turkey 52.3% of the study participants were on insulin regimen, these tallies with their mean poor glycemic control of 8% [20].

## Study limitation

Kilimanjaro Christian Medical Centre is zonal tertiary referral hospital, majority of the cases might had an intervention at the lower health facilities thus there might be referral bias. Recall bias as some of the medications do cause QTc prolongation which cannot be remembered by patients. Majority of our patients had co-morbidities such as HTN, which might be one of the confounding factors.

## Conclusion

The prevalence of prolonged QTc interval among T2DM patients is high. However, there are some of the modifiable factors like dyslipidemia, poor glycemic control, being hypertensive, fasting plasma glucose and treatment modality have accounted for this burden. These findings have clinical relevance T2DM with QTc prolonged have CVD risk. Prompt addressing these factors will help to reduce the magnitude of the QTc prolongation hence reduce mortality. Regular ECG checkup for the high risk patients will enable for early intervention of the QTc prolongation.

## Data Availability

The data used to support the findings of this study are available from the corresponding author upon request.

## Disclosure

None to declare.

## Conflicts of Interest

The authors declare that they have no conflicts of interest.

## Authors' Contributions

FGR, AH, NC and KGK were involved in idea development, designing the study, data collection, analysis and writing up the first version of this manuscript.

IAL participated in proposal development and interpretation of results. ERS, NGC and CT reviewed and re-analyzed the dataset and reviewed the manuscript and references to get the final version. All authors read and approved the final format of the manuscript for publication.

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## Competing Interests

The authors declare that they have no competing interests.

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