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Is the Performance of a Periodontal Prediction Model for Identification of Diabetes affected by Participants' Characteristics?

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Objective: To evaluate whether the diagnostic accuracy of a novel periodontal prediction model (PPM) for identification of adults with diabetes varies according to participants' characteristics. ***Basic Research Design***: The study was carried out among 250 adults attending primary care clinics in Riyadh (Saudi Arabia). The study adopted a case-control approach, where diabetes status was first ascertained, and data collection carried out afterwards using questionnaires and periodontal examinations. Variations in the performance of the PPM by demographic (sex and age), socioeconomic (education) and behavioural factors (smoking status and last dental visit) were evaluated using receiver-operating characteristic (ROC) regression. ***Results***: The PPM including 3 periodontal parameters (missing teeth, percentage of sites with pocket depth ≥6mm and mean pocket depth) had an area under the ROC curve (AUC) of 0.69 (95% Confidence Interval: 0.61-0.78), which dropped to 0.64 (95% CI: 0.53-0.75) after adjustment for covariates. Larger variations in performance were found by participants' sex, age and education, but not by smoking status or last dental visit. The PPM performed better among male (adjusted AUC: 0.76; 95% CI: 0.53 to 0.99), younger (0.67; 95% CI: 0.50 to 0.84) and less educated participants (0.76; 95% CI: 0.60, 0.92). ***Conclusions***: The diagnostic accuracy of a novel periodontal prediction model to identify individuals with diabetes varied according to participants' characteristics. This study highlights the importance of adjusting for covariates on studies of diagnostic accuracy.

Keywords: *Periodontitis, Diabetes Mellitus, Statistical regression, ROC analysis, Confounding Factors*

Introduction

Diabetes is a public health problem that requires intersectoral action to tackle its substantial burden on people, societies and healthcare systems (Ricci-Cabello *et al*., 2010). Early identification of unrecognised diabetes can improve disease management and prevent costly complications (Kyrou *et al*., 2020). Several studies have evaluated predictors and risk factors for undiagnosed diabetes and developed prediction models (Collins *et al*., 2011). However, such models have limited predictive ability, resulting in a large proportion of the population being misclassified (Collins *et al*., 2011). Researchers thus continue to search for new predictors to improve identification of diabetes. A few promising studies have shown the potential of using periodontal measurements to identify individuals with diabetes (Borrell *et al*., 2007; Lalla *et al*., 2011, 2013). Despite methodological differences between studies, a combination of missing teeth and sites with probing pocket depth (PPD) consistently had the greatest diagnostic accuracy, with an area under the curve (AUC) ranging from 0.58 to 0.65 (Borrell *et al*., 2007; Lalla *et al*., 2011, 2013).

A typical approach in diagnostic research is to report the performance of a novel test (or prediction model) in all included participants, often using the receiver-operating characteristic (ROC) curve pooled across all participants (Cohen *et al*., 2016; Collins *et al*., 2015). However, many factors, such as participants' characteristics, features of the test or the severity of the condition (among cases only) can affect diagnostic accuracy (Janes *et al*., 2009; Janes and Pepe, 2008). It is thus necessary to account for these covariates as the performance of the test might be less than optional in certain groups. When evaluating a test to classify individuals, if observations depend on a covariate, the test should be calibrated to account for this covariate (Janes and Pepe, 2008) to reflect the most relevant test performance as closely as possible (Janes *et al*., 2009). More importantly, it allows generalisability of the test to other population groups. Despite these recommendations, only one previous study has assessed the performance of a prediction model based on periodontal measurements among different groups. Borrell and colleagues (2007) found that their preferred prediction model performed better in identifying American adults with undiagnosed diabetes among African-American, male and older participants.

A periodontal prediction model (PPM) for identification of diabetes was recently developed among adults visiting primary care clinics in Riyadh (Saudi Arabia). The PPM was based on three periodontal measures (number of missing teeth, proportion of sites with PPD≥6mm and mean PPD), had an AUC of 0.694 (95% CI: 0.612-0.776) and correctly classified 62.4% of participants (Talakey *et al*., 2020). Consequently, this study aimed to evaluate whether the diagnostic accuracy of this novel PPM

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varies according to participants' sociodemographic and behavioural factors. When looking for relevant covariates, one should focus on factors that confound the association between the test and the outcome (periodontal disease and diabetes in the current scenario) among the controls (Janes and Pepe, 2008). Demographic factors, socioeconomic measures and smoking habits are all associated with both periodontal disease, on one side (Johnson and Guthmiller, 2007; Leite *et al*., 2018; Schuch *et al*., 2017), and diabetes, on the other side (Chang, 2012; Kyrou *et al*., 2020; Ricci-Cabello *et al*., 2010).

Materials and methods

The study adopted a case-control design, where cases were defined as individuals diagnosed with diabetes while controls were defined as non-diabetic individuals. The study protocol was approved by the ethics boards of King's College London (HR-17/18-8281) and King Saud University (E-18-3386). All participants signed a written informed consent.

A total of 250 participants (53 diabetic and 197 controls) were recruited from the primary care clinics at King Khalid University Hospital (KKUH), King Saud University (Riyadh, Saudi Arabia) between December 2018 and June 2019. Participants' diabetic status was confirmed from medical records and defined as fasting plasma glucose of ≥126mg/dL or haemoglobin A1c (HbA1c) ≥6.5% according to the American Diabetics Association guidelines that are followed in the hospital (ADA, 2018). A minimum sample size of 208 participants (52 cases and 156 controls) was required to reject the hypothesis of no difference between an AUC of 0.65 for the PPM and the null value of 0.50, assuming 95% confidence level, 90% statistical power and a case-to-control ratio of 1-to-3 (Hanley and McNeil, 1982).

Participants were included if they were Saudi and aged 30 years or older. Cases should have been diagnosed with type 2 diabetes during the past 12 months (incident), while controls were free from the condition. Participants were excluded if they had type 1 or gestational diabetes, were edentulous, wore fixed orthodontic appliances or had any contraindications to carry out a periodontal examination (congenital heart disease, congenital heart murmurs, bacterial endocarditis, valvular heart disease, pacemaker or prosthetic valve replacement or going through surgery in the next 6 months for pacemaker implantation or valve replacements).

Data collection

Data were collected using questionnaires and periodontal examinations, all undertaken at the dental clinics of the College of Dentistry, King Saud University. Participants completed a questionnaire to provide information on demographic, socioeconomic and behavioural factors. Four covariates (sex, age, education and smoking status) were selected for analysis because they are associated with both periodontal disease and diabetes (Chang, 2012; Johnson and Guthmiller, 2007; Kyrou *et al*., 2020; Leite *et al*., 2018; Ricci-Cabello *et al*., 2010; Schuch *et al*., 2017), and could therefore affect the performance of the PPM. Information about participants' education was collected in 5 categories (no education, some high school, high school, some college or university education, university degree or higher) and classified as less than high school, high school and more than high school. Smoking status was collected with 3 questions. Smokers were those who reported smoking daily or less than daily (currently or in the past). All others were considered non-smokers. We also included last dental visit as a covariate to assess whether the performance of the PPM was higher among those who had visited the dentist more recently; assuming that a dental visit would be a good opportunity for diabetes screening (Strauss *et al*., 2010). Time since participants' last dental visit was determined using 5 options (within the last 6 months, more than 6 month but less than a year ago, more than a year but less than 2 years ago, more than 2 years ago and never visited the dentist) and classified as within the past year or more than a year ago.

Periodontal examinations were carried out by two trained and calibrated dentists who were blinded to the case/control status of participants and supported by a dental assistant. A full-mouth periodontal assessment was conducted, including PPD, clinical attachment loss (CAL) and bleeding on probing (BoP) at 6 sites (mesio-buccal, mid-buccal, disto-buccal, disto-lingual, mid-lingual, mesio-lingual) per tooth, excluding third molars using the William's probe. Measurements rounded to the lowest whole millimetre. Duplicate examinations in 10% of the participants (one random quadrant) were conducted to assess intra- and inter-examiner reliability. The intra-examiner reliability values (intra-class correlation coefficients) were 0.77 (BoP), 0.87 (PPD) and 0.91 (CAL) for dentist 1 and 0.80 (BoP), 0.89 (PPD) and 0.94 (CAL) for dentist 2. The inter-examiner reliability values were 0.87, 0.89 and 0.93 for BoP, PPD and CAL, respectively. The following clinical periodontal measures were derived: number of missing teeth, proportion of sites with BoP, PPD (cut offs: ≥4mm, ≥6mm) and CAL (cut offs: ≥3mm, ≥5mm), mean PPD and mean CAL which are the current standards for reporting periodontal disease in epidemiology surveys (Holtfreter *et al*., 2015). The development and internal validation of the PPM, based on the number of missing teeth, the proportion of sites with PPD≥6mm and mean PPD, has been reported elsewhere (Talakey *et al*., 2020).

Data analysis

All analyses were run in Stata 15 (Stata Corp., College Station, TX, USA). First, cases and controls were compared in terms of their sociodemographic characteristics (sex, age and education) and behavioural factors (smoking status and last dental visit) using the Chi-squared test for categorical variables and Student's t-test for numerical variables.

The performance of the PPM was reported using the AUC pooled across all participants (reference value), before adjusting for sex, age (continuous), education, smoking status and last dental visit. The influence of covariates on the diagnostic performance of the PPM was assessed using parametric ROC regression (Alonzo and Pepe, 2002; Pepe, 2000), which was implemented in Stata with the *rocreg* command (Janes *et al*., 2009).

In ROC regression, the ROC curve is modelled as a function of covariates common to cases and controls, covariates specific to cases (if any) and a function that defines the location (intercept, α_1) and shape (slope, α_2) of the curve (Alonzo and Pepe, 2002; Pepe, 2000). This is the preferred approach since it specifies a parametric model but does not assume distributions for the PPM results (Janes *et al*., 2009; Janes and Pepe, 2008; Medeiros *et al*., 2006). Under this framework, we tested whether the PPM results in adults with diabetes were greater than specific quantiles of the PPM distribution in adults without diabetes but with the same characteristics (Janes *et al*., 2009). Parameters were estimated using generalised probit regression (Alonzo and Pepe, 2002). No interaction terms were included in the model. Bias-corrected standard errors and 95% confidence intervals (95% CI) were estimated using a bootstrap resampling procedure with 1000 replications (Janes *et al*., 2009; Janes and Pepe, 2008). To aid interpretation, we reported the area under the curve (AUC) for each group of categorical variables and at 4 values for continuous age (35, 45, 55 and 65 years).

Results

A total of 2093 patients visited the primary care clinics during the recruitment period, of whom, 333 were considered eligible and 250 (75%) agreed to participate (Recruitment Profile available at https://kclpure.kcl.ac.uk/portal/files/131483305/Supplemental_figure_1.pdf). The composition of the study sample is shown in Table 1. Participants with diabetes were more likely to be older and less educated than those without diabetes. However, no significant differences were found between cases and controls in terms of behavioural factors.

The results from the ROC regression model are shown in Table 2. After adjustment for covariates, the AUC of the PPM dropped to 0.639 (95% CI: 0.527, 0.753). The performance of the PPM was lower among female, older, more educated, smoking participants and among those who visited the dentist more than a year ago, as indicated by the negative coefficient associated with these categories in the ROC regression model (Table 2). However, large differences in performance were only observed between sex, age and education groups (Table 3). The adjusted AUC was 0.76 (95% CI: 0.54, 0.99) and 0.61 (95% CI: 0.50, 0.73) for men and women, respectively; 0.68 (95% CI: 0.50, 0.85), 0.65 (95% CI: 0.54, 0.76), 0.62 (95% CI: 0.49, 0.76) and 0.60 (95% CI: 0.38, 0.81) at ages 35, 45, 55 and 65 years, respectively; and 0.76 (95% CI: 0.60, 0.93), 0.67 (95% CI: 0.55, 0.78) and 0.56 (95% CI: 0.42, 0.69) for participants with less than high school, high school and more than high school, respectively (Table 3 and Figure 1). As shown in Figure 1, the separation in ROC curves between smokers and non-smokers as well as between those who visited the dentist within the past year and more than a year ago was minimal.

Discussion

This study showed that certain participants' characteristics could affect the performance of a novel PPM to identify Saudi adults with diabetes. The performance of the PPM, as assessed by the AUC, dropped slightly after adjustment for five covariates. Large differences in the performance of the PPM were noted between sex, age and education groups. Conversely, minimal differences were found between smoking status and dental visit groups.

We found that the PPM performed better among men, younger and less educated participants. These three covariates are conventional risk factors included in widely used questionnaires for diabetes screening, such as the Finnish Diabetes Risk Score (FINDRISC) and the Canadian Diabetes Risk Score (CANRISK). Periodontal disease and diabetes are more common among men and less educated adults (Kyrou *et al*., 2020; Schuch *et al*., 2017). However, while the prevalence of diabetes increases with age, the prevalence of severe periodontitis peaks at around the fourth decade of life (Kassebaum *et al*., 2014). In our sample, the prevalence of moderate-to-severe periodontitis, defined

Table 1. Comparison of sociodemographic characteristics by diabetes status (n=250)

	Control Group (n=197)		*Diabetic Group (n=53)*		*p value*[a]
Sex, n %					0.946
Male	29	14.7	8	15.1	
Female	168	85.3	45	84.9	
Mean age ± SD, years	41.9 ± 9.8		49.9 ± 8.5		<0.001
Education, n %					0.007
Less than high school	32	10.7	14	26.4	
High school	21	16.2	12	22.6	
More than high school	144	73.1	27	50.9	
Smoking status, n %					0.390
Non-smoker	174	88.3	49	92.5	
Smoker	23	11.7	4	7.5	
Last dental visit, n %					0.448
Within the past year	130	66.0	32	60.4	
More than a year ago	67	34.0	21	39.6	

[a] Chi-square test used to compare proportions and Student's t-test to compare means

Table 2. Effect of participants' characteristics on the ROC curve of the periodontal prediction model for identification of adults with diabetes (n=250)

Model parameters	*Coef.*[a]	*[95%CI]*[b]
Sex		
Male	0.00	[Reference]
Female	-1.64	[-6.31, 0.75]
Age, in years	-0.03	[-0.07, 0.06]
Education		
Less than high school	0.00	[Reference]
High school	0.08	[-1.30, 1.80]
More than high school	-0.78	[-1.71, 0.37]
Smoking status		
Non-smoker	0.00	[Reference]
Smoker	-1.71	[-6.98, 0.62]
Last dental visit		
Within the past year	0.00	[Reference]
More than a year ago	-0.07	[-1.00, 0.72]
Intercept (α_1)	5.65	[-1.23, 14.94]
Slope (α_2)	0.89	[0.56, 1.13]

[a] Parametric ROC regression was fitted, and regression coefficients reported. The coefficient represents how greater or smaller the performance of the PPM is in one group compared to the reference category, holding all other variables in the table constant.
[b] Bias-corrected 95% confidence intervals (95% CI) were estimated using a bootstrap resampling procedure with 1000 replications.

Table 3. Performance of the periodontal prediction model (PPM) across covariate groups

Covariates	*AUC*[a]	*[95%CI]*
Sex		
Male	0.764	[0.536, 0.993]
Female	0.614	[0.496, 0.731]
Age in years		
At 35 years	0.677	[0.504, 0.849]
At 45 years	0.650	[0.537, 0.764]
At 55 years	0.623	[0.491, 0.755]
At 65 years	0.596	[0.379, 0.812]
Education		
Less than high school	0.764	[0.602, 0.925]
High school	0.666	[0.550, 0.782]
More than high school	0.555	[0.417, 0.692]
Smoking status		
Non-smokers	0.639	[0.528, 0.749]
Smokers	0.610	[0.255, 0.965]
Last dental visit		
Within the past year	0.633	[0.505, 0.761]
More than a year ago	0.642	[0.478, 0.806]

[a] Separate ROC curves and areas under the curve (AUC) were derived for each covariate group based on parametric ROC regression including only one covariate at a time. Bias-corrected 95% confidence intervals (95% CI) were estimated using a bootstrap resampling procedure with 1000 replications.

according to the case definition for population-based surveillance, was slightly higher among 35-44-year-olds than other age groups. Although our finding of greater performance among younger participants disagrees with that of a US study where performance was better with increased age among adults (Borrell *et al*., 2007), that earlier study did not report estimates for adults below 45 years (i.e. estimates were reported at ages 45, 50, 55 and 60 years only). As such, the studies are not directly comparable.

Surprisingly, we did not find differences in the performance of the PPM between smokers and non-smokers. A recent study showed that smoking habits affect the performance of salivary biomarkers in identifying individuals with periodontitis, with better diagnostic accuracy of all biomarkers among smokers than non-smokers (Lahdentausta *et al*., 2019). However, the performance of matrix metalloproteinase (MMP-8) was mainly affected by amount of consumption (pack years) whereas the performance of MMP-9, tissue inhibitor of metalloproteinase-1 and myeloperoxidase was influenced by time since cessation. Therefore, it is possible that the performance of the PPM could depend on other aspects of the smoking habit such as intensity, duration and time since cessation (Lahdentausta *et al*., 2019). This is an area that requires further exploration.

Nor did we find differences in the performance of the PPM according to participants' last dental visit. A US study showed that many adults with periodontitis at risk of diabetes had visited the dentist recently (33% in the past 6 months and 60% in past 2 years), and would benefit from diabetes screening using periodontal parameters in dental settings (Strauss *et al*., 2010). Our findings suggest that the PPM could perform equally well in identifying adults with diabetes among regular and non-regular dental attenders. This finding is encouraging as it implies that the use of the PPM could benefit everybody not only regular dental attenders.

The study findings highlight the fact that the PPM might be more accurate among specific groups, such as male, younger and less educated individuals, to identify diabetes in Saudi Arabia. Therefore, the PPM could be an efficient tool for diabetes risk assessment among dental patients with these sociodemographic characteristics. This approach is in line with the previous use of prediction models among patients with known risk factors for diabetes (Lalla *et al*., 2011, 2013). On the other hand, one way to increase the generalisability of the PPM would be to either expand it to include these covariates as predictors, or better yet, to evaluate the incremental value of the PPM when added to conventional diabetes screening tools (FINDRISC and CANRISK already include these sociodemographic factors). As for research, further studies should use stronger (prospective) designs and evaluate other covariates that might affect the performance of prediction models, either in this area or other areas of dentistry. One should pay attention to factors that alter the relationship between exposure and outcome (periodontal disease and diabetes in the present study) among controls. In epidemiological

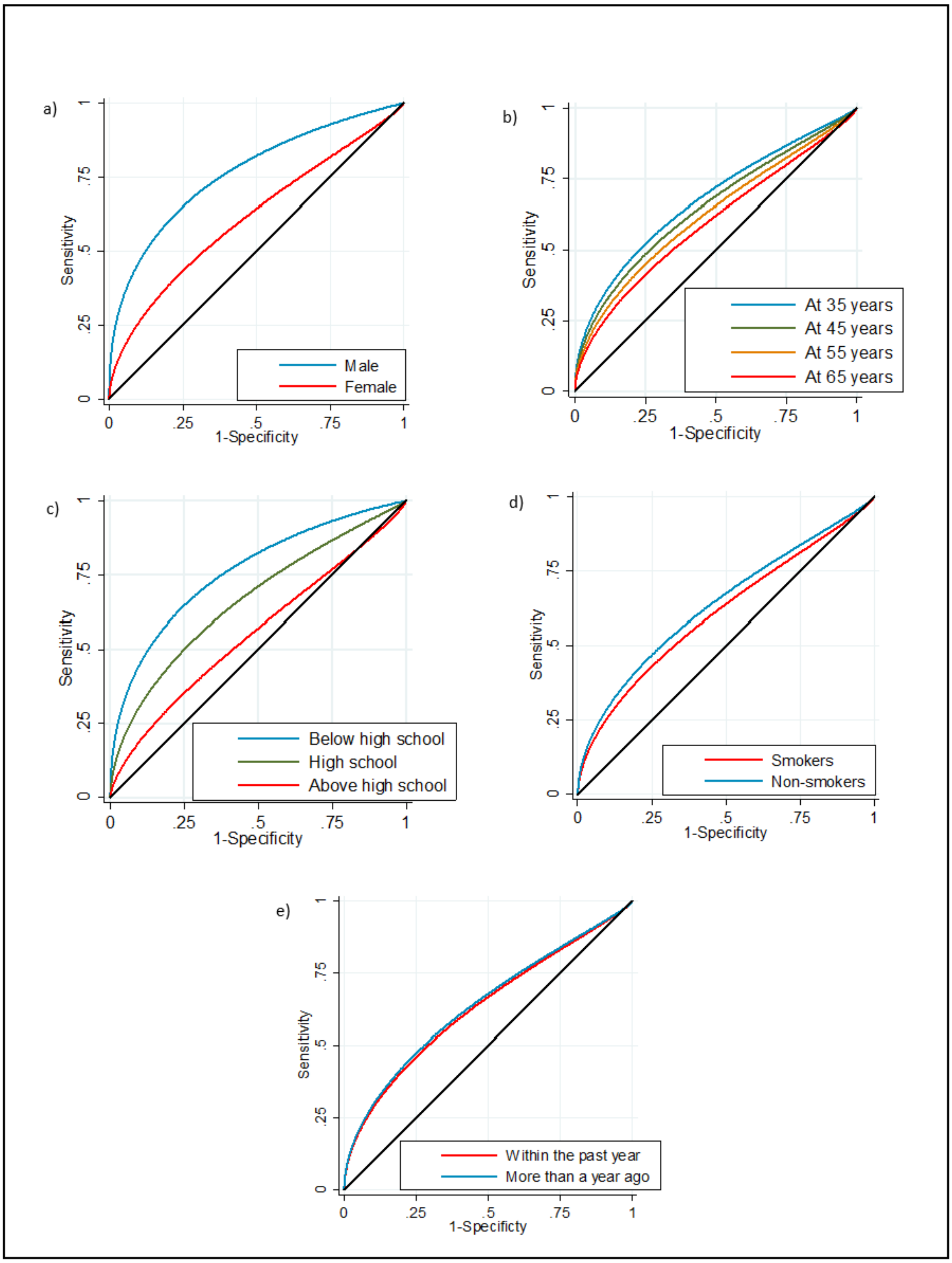

Figure 1. Adjusted ROC curves of the periodontal prediction model by gender, age, education, smoking and dental visiting. 1a) Gender. AUCs for males (AUC) and females =0.764 and 0.614 respectively 1b) Age. AUCs for those aged 35, 45, 55 and 65 years = 0.677, 0.650, 0.623 and 0.596 1c) Education. AUCs for below high school, at and above high school = 0.764, 0.666 and 0.555 1d) Smoking. AUCs for non-smokers and smokers = 0.639 and 0.610) 1e) Dental visiting. AUCs for visited in the past year and more than a year ago = 0.633 and 0.642.

terms, one should be looking for effect modifiers rather than just confounders.

We acknowledge that this study has some limitations. First, the study adopted a case-control design where a prospective cohort design is considered the optimal approach to estimate diagnostic accuracy of prediction models. However, the cross-sectional design is preferable when building a body of evidence before using a more costly design (Moons *et al*., 2012). Second, we recruited participants from a single site in Saudi Arabia, which is not representative of the entire Saudi population. Therefore, the results cannot be generalised beyond the study sample. Finally, assessing the external validity of the present findings in external samples is recommended (Collins *et al*., 2015).

Conclusion

The diagnostic accuracy of a novel periodontal prediction model to identify individuals with diabetes can vary according to participants' characteristics. The prediction model performed better among male, younger and less educated individuals. This study highlights the importance of adjusting for covariates on studies evaluating the diagnostic accuracy of novel tests, prediction models or biomarkers.

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