

Clinical implication of fasting glucose and systolic/diastolic blood pressure on the prevalence of periodontitis in non-diabetic and non-hypertensive adults using nationally representative data

KYUNGDO HAN¹ and JUN-BEOM PARK²

Departments of ¹Biostatistics and ²Periodontics, College of Medicine,
The Catholic University of Korea, Seoul 06591, Republic of Korea

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Abstract. The prevalence of diabetes mellitus and hypertension is increasing worldwide and an association between fasting glucose/blood pressure and periodontitis has been suggested. The present study was performed to assess the association between fasting glucose and systolic/diastolic blood pressure on the prevalence of periodontitis in non-diabetic and non-hypertensive adults using nationally representative data. Subgroup analysis was performed to evaluate the combined effects of obesity/abdominal obesity and impaired fasting glucose. This study involved a cross-sectional analysis using data from the Republic of Korean National Health and Nutrition Examination Survey from 2013 to 2015. A total of 8,341 respondents without diabetes and hypertension over 19 years old without missing values were included in the present study. A significant increase was observed in the prevalence of periodontitis with increasing systolic blood pressure and diastolic blood pressure. The percentage of periodontitis increased with increased glucose levels, with similar trends in glycated hemoglobin. The odds ratios (ORs) and 95% confidence intervals (CIs) for systolic blood pressure of $90 \leq x < 100$, $100 \leq x < 110$, $110 \leq x < 120$, $120 \leq x < 130$ and $130 \leq x < 140$ were 1.116 (0.591-2.107), 1.165 (0.624-2.175), 1.238 (0.673-2.278), 1.008 (0.538-1.888) and 1.042 (0.545-1.993), respectively, when systolic blood pressure < 90 was considered as a reference. The ORs and 95% CIs for glucose of $90 \leq x < 100$, $100 \leq x < 110$ and $110 \leq x < 126$ were 1.074 (0.92-1.253), 1.214 (0.986-1.494) and 1.358 (1.005-1.834), respectively when glucose < 90 was considered as a reference. The association between fasting glucose/blood pressure and periodontitis was confirmed by multiple logistic regression analyses after

adjusting for confounding factors among non-diabetic and non-hypertensive Republic of Korean adults. Subgroup analysis revealed that higher ORs of periodontitis were observed in participants with impaired glucose level and obesity when compared with individuals without impaired glucose level or obesity. The results of the present study suggest that detection of fasting glucose and blood pressure may serve as a risk indicator for periodontal disease.

Introduction

Previous studies have shown that systemic diseases are known to be associated with periodontitis (1). The prevalence of both diabetes mellitus and hypertension is increasing worldwide (2). Diabetes and hypertension are widely studied for possible association with periodontitis (3,4). The rapid increase in the prevalence of diabetes is also seen in Korea (5). The prevalence of diabetes among adults aged ≥ 30 years in 2001, 2005 and 2007-2009 was 8.9, 9.1 and 9.9%, respectively based on the series of Korea National Health and Nutrition Examination Surveys (5). The report with more current results showed that the prevalence of diabetes increased up to 11.0% in 2013 (6). Complication of diabetes includes diabetic retinopathy, diabetic nephropathy, diabetic neuropathy and macrovascular diseases (7). Previous report showed that the prevalence of hypertension was 28.5% in the Korean National Health and Nutrition Examination Survey in 2011 (8). The report indicated that the awareness, treatment, and control rates of the generation population were generally improved. Researchers have shown that a relationship exists between type 2 diabetes mellitus and periodontal disease (9). Glycemic control has been shown to affect periodontal disease and participants having poorly controlled diabetes were associated with severe periodontitis (10). Similarly, a positive association has been reported between hypertension and periodontitis (4). All periodontal measures had significant associations with hypertension (11).

However, the association between impaired fasting glucose or high blood pressure and periodontitis in individuals without diabetes or hypertension is not yet well understood. Thus, this study was performed to assess the relationship between fasting glucose and systolic/diastolic blood

Correspondence to: Professor Jun-Beom Park, Department of Periodontics, College of Medicine, The Catholic University of Korea, 222 Banpo-daero, Seocho-gu, Seoul 06591, Republic of Korea
E-mail: jbasoonis@yahoo.co.kr

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pressure on the prevalence of periodontitis in non-diabetic and non-hypertensive adults using nationally representative data. Subgroup analysis was performed to evaluate the combined effects of obesity/abdominal obesity and impaired fasting glucose.

Materials and methods

Survey and subjects. This survey was reviewed and approved by the Institutional Review Board of the Korean Centers for Disease Control and Prevention, and all participants provided written informed consent. This study is a secondary data analysis of data collected during the Korean National Health and Nutrition Examination Survey (KNHANES) from 2013 to 2015. The Institutional Review Board at the Catholic University of Korea approved of this study (KC16EISI0713). This study is a human observational study and the authors have conformed to the STROBE guidelines.

A total of 22,948 individuals participated in the KNHANES survey. The number of surveys was reduced to 13,401 by excluding participants without periodontal examination, participants with less than 8 h of fasting before examination, and individuals who were younger than 19 years old. The analysis in this study was confined to a total of 8,341 responses that had no missing values for the outcome variables (Fig. 1).

Demographic variables. Sociodemographic and lifestyle variables of participants were evaluated with a self-administered questionnaire regarding education level, household income, smoking, and alcohol intake. Smokers were classified as current smokers or non-smokers. Alcohol consumption was categorized as drinkers [mild to moderate drinkers (1-30 g/day)], and heavy drinkers (>30 g/day), or non-drinkers. Education level was categorized as either entered high school (≥ 10 years) or not. Number of household members was evaluated. Household income was divided into quartiles by number of included family members. The lowest quartile of household income was less than 1,092.40 USD/month.

Anthropometric measurements. Trained staff members performed the measurements of the participants. Health status of each participant was evaluated. Body weight and height were measured with the participants in light indoor clothing without shoes (12). Waist circumference was measured at the narrowest point between the lower border of the rib cage and the iliac crest. Body mass index was calculated by the following formula: weight/height^2 (kg/m^2). Systolic blood pressure and diastolic blood pressure were measured on the right arm using a standard mercury sphygmomanometer (Baumanometer; W.A. Baum Co., Inc., Copiague, NY, USA). Systolic blood pressure and diastolic blood pressure measurements were performed two times with a 5-min interval, and the average of the two measurements was used for the analysis.

After fasting for more than 8 h, blood samples were collected from the antecubital veins. Serum fasting plasma glucose, glycated hemoglobin, the total concentration of cholesterol, low-density lipoprotein, and triglycerides were tested with the Automatic Analyzer 7600 (Hitachi, Tokyo, Japan) using the kits (Daiichi, Tokyo, Japan) (13).

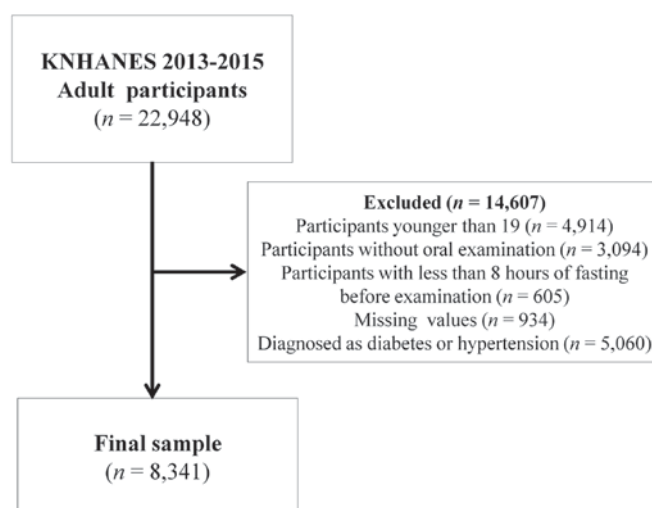


Figure 1. Participant flow chart.

Description of obesity, diabetes mellitus, and hypertension.

Body mass index was categorized by $\geq 25 \text{ kg/m}^2$ or lower. Waist circumference was categorized as $\geq 90 \text{ cm}$ in men and $\geq 80 \text{ cm}$ in women. A body mass index (BMI) $\geq 25 \text{ kg/m}^2$ was defined as the presence of obesity (14), and the cutoffs of abdominal obesity were defined as waist circumference (WC) $\geq 90 \text{ cm}$ in men or $\geq 85 \text{ cm}$ in women (15). Diabetes was diagnosed if fasting blood sugar was $\geq 126 \text{ mg/dl}$, glycated hemoglobin was $\geq 6.5\%$ or the individual was currently using antidiabetic medications (16). Impaired fasting glucose was defined as a level of blood glucose between 100 and 125 mg/dl with no diabetic medication. Hypertension was defined as systolic blood pressure $\geq 140 \text{ mmHg}$ and diastolic blood pressure was $\geq 90 \text{ mmHg}$ or reported use of regular antihypertensive drugs (17). Metabolic syndrome was diagnosed if three or more of the following criteria were fulfilled: waist circumference $\geq 90 \text{ cm}$ in men and $\geq 80 \text{ cm}$ in women; fasting triglycerides $\geq 150 \text{ mg/dl}$ or use of lipid-lowering medication; high-density lipoprotein cholesterol $< 40 \text{ mg/dl}$ in men and $< 50 \text{ mg/dl}$ in women or use of lipid-lowering medication; blood pressure $\geq 130/85 \text{ mmHg}$ or use of antihypertensive medication; and fasting blood glucose $\geq 100 \text{ mg/dl}$ or current use of antidiabetic medication (18).

Oral health behaviors and periodontitis. Periodontal treatment needs were assessed using the Community Periodontal Index (CPI), which the World Health Organization/Federation Dentaire Internationale has defined as an epidemiological screening procedure for rough depiction of periodontal status and treatment needs by trained dental practitioners (19). All teeth of each subject were divided into sextants. A specially designed periodontal probe (PWHO, Osung MND, Seoul, Republic of Korea) with a ball end 0.5 mm in diameter was used. Ten specific index teeth (17, 16, 11, 26, 27, 36, 37, 31, 46 and 47) were examined to evaluate each sextant's score. A sextant was only scanned if two or more teeth were present. If index teeth were absent from a sextant, then all of the remaining teeth were examined to produce the score, and the highest score was recorded as the score for the sextant. Code 3 was used for a shallow pocket with depth of 3.5-5.5 mm and

Table I. Baseline characteristics of study participants according to presence of periodontitis.

Variables	Periodontitis		P-value ^a
	No	Yes	
Total	6,373	1,968	
Age, years	37.94±0.23	49.29±0.37	<0.0001
Male	44.65 (0.66)	56.24 (1.17)	<0.0001
Systolic blood pressure (mmHg)	109.73±0.18	112.91±0.31	<0.0001
Diastolic blood pressure (mmHg)	72.33±0.15	74.01±0.22	<0.0001
Glucose (mg/dl)	91.66±0.15	94.88±0.24	<0.0001
Glycated hemoglobin (%)	5.46±0.01	5.59±0.01	<0.0001
Body mass index (kg/m ²)	22.98±0.05	23.69±0.08	<0.0001
Body mass index ≥25 kg/m ² (%)	23.64 (0.62)	30.92 (1.20)	<0.0001
Waist circumference (cm)	78.33±0.17	81.4±0.24	<0.0001
Waist circumference ≥90 cm in men and ≥80 cm in women (%)	15.37 (0.56)	21.6 (1.11)	<0.0001
Metabolic syndrome (yes)	9.6 (0.43)	18.76 (1.08)	<0.0001
Total cholesterol (mg/dl)	184.57±0.50	193.38±0.88	<0.0001
Low-density lipoprotein (mg/dl)	109.12±0.43	116.9±0.81	<0.0001
Triglycerides ^b	95.07 (93.48-96.69)	116.28 (112.80-119.88)	<0.0001
Smoking, current	16.39 (0.66)	27.52 (1.33)	<0.0001
Drinking, current	61.74 (0.70)	58.78 (1.37)	0.0421
Education-university graduate or higher	45.47 (0.90)	32.61 (1.51)	<0.0001
Income, lowest quartile	9.14 (0.54)	12.52 (0.96)	0.0004
Number of natural teeth	26.6±0.05	24.94±0.13	<0.0001
Frequency of tooth brushing per day			<0.0001
≤1	6.55 (0.37)	9.98 (0.78)	
2	34.09 (0.66)	39.94 (1.36)	
≥3	59.36 (0.72)	50.08 (1.38)	
Use of secondary oral products	56.99 (0.77)	52.18 (1.43)	0.0021
Tooth pain	35.99 (0.87)	44.89 (1.41)	<0.0001

Data are presented as mean ± standard error of the mean or percentages (standard error). ^aP-values were obtained by independent t-test for continuous variables or Chi-square test for categorical variables. ^bGeometric mean (95% confidence of intervals).

code 4 for a deep pocket depth ≥5.5 mm. Moderate periodontal disease was defined if CPI was code 3 and severe periodontitis was defined if CPI was code 4. Presence of periodontitis was defined if CPI was 3 or greater.

The frequency of daily tooth brushing and use of secondary oral products were used for the evaluation of oral health behavior. Secondary oral products included dental floss, mouthwash, interdental brushes, electric toothbrushes, irrigation devices, tongue cleaners, end-tufted brushes, and special devices for dentures. The survey also recorded the participants' tooth pain.

Statistical analysis. All analyses were conducted using SAS version 9.3 (SAS Institute Inc., Cary, NC, USA). The SAS survey procedure was applied to reflect the complex sampling design and the sampling weights of KNHANES and to provide nationally representative prevalence estimates. The data are presented as the mean ± standard error of the mean for continuous variables and as proportions (standard errors) for categorical variables. A Chi-square test for categorical

variables or an independent t-test for continuous variables was performed to assess the differences in characteristics categorized by presence of periodontitis. Logistic regression analysis was used to evaluate the periodontitis in association with impaired fasting glucose categorized by the presence of obesity or abdominal obesity. The model was adjusted for age, sex, smoking, drinking, education, income, body mass index, number of natural teeth, frequency of tooth brushing per day, and use of secondary oral products.

Results

Table I shows the baseline characteristics of study participants according to the presence of periodontitis. Among the 8,341 participants, 1,968 were diagnosed as having periodontitis. The percentage of males was higher in periodontitis group ($P<0.05$). The systolic blood pressure, diastolic blood pressure, glucose level, glycated hemoglobin, body mass index, total cholesterol, low-density lipoprotein, and triglycerides were statistically higher in the periodontitis group ($P<0.05$).

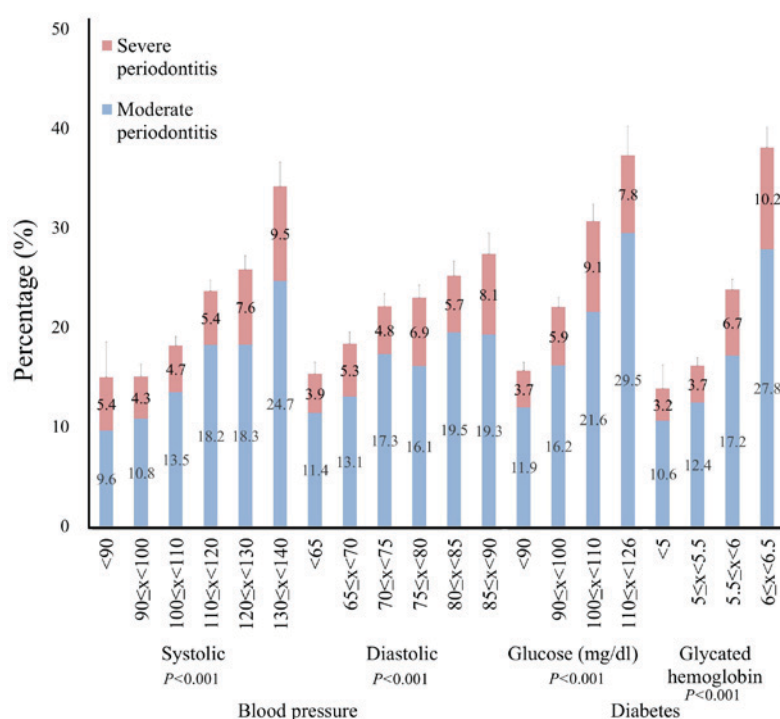


Figure 2. Percentage of moderate and severe periodontitis as categorized by blood pressure and glucose level.

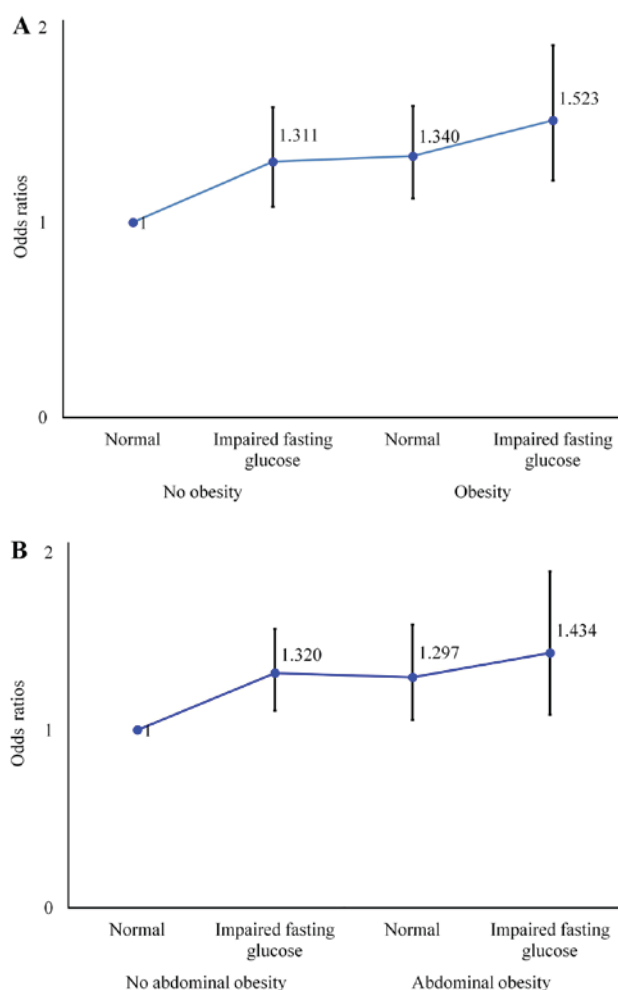


Figure 3. Odds ratios of periodontitis categorized by the (A) presence of obesity and impaired fasting glucose or (B) the presence of abdominal obesity and impaired fasting glucose.

The numbers of current smokers and individuals with lower income or tooth pain were higher in the periodontitis group. However, the percentage of individuals with tooth brushing frequency of three or higher per day and the percentage of individuals using secondary oral products were significantly lower in the periodontitis group ($P < 0.05$).

The percentage of moderate and severe periodontitis categorized by blood pressure and glucose level is shown in Fig. 2. The percentage of periodontitis increased with increasing systolic blood pressure. Similar trends were seen with diastolic blood pressure. The percentage of periodontitis increased with higher glucose level, with similar trends in glycated hemoglobin.

The prevalence of periodontitis in the combination of obesity/abdominal obesity and impaired fasting glucose level is shown in Fig. 3. Fig. 3A shows odds ratios (ORs) of periodontitis categorized by the presence of obesity and impaired fasting glucose. Even for participants without obesity, the ORs increased to 1.311. For participants with obesity having impaired fasting glucose, the ORs of periodontitis increased to 1.523. Similar trends were seen with participants with abdominal obesity (Fig. 3B). ORs for participants without abdominal obesity having impaired glucose, participants with abdominal obesity with normal glucose level, and individuals having combination of abdominal obesity and impaired fasting glucose were 1.320, 1.297 and 1.434, respectively, when a non-abdominally obese individual with normal fasting glucose was considered as reference.

Fig. 4 shows ORs and 95% confidence intervals (CIs) of periodontitis after adjustments for age, sex, smoking, drinking, education, income, body mass index, waist circumference, chronic kidney disease, number of natural teeth, frequency of tooth brushing per day, and use of secondary oral products.

Table II shows the ORs and 95% CIs of periodontitis categorized by systolic blood pressure, diastolic blood pressure,

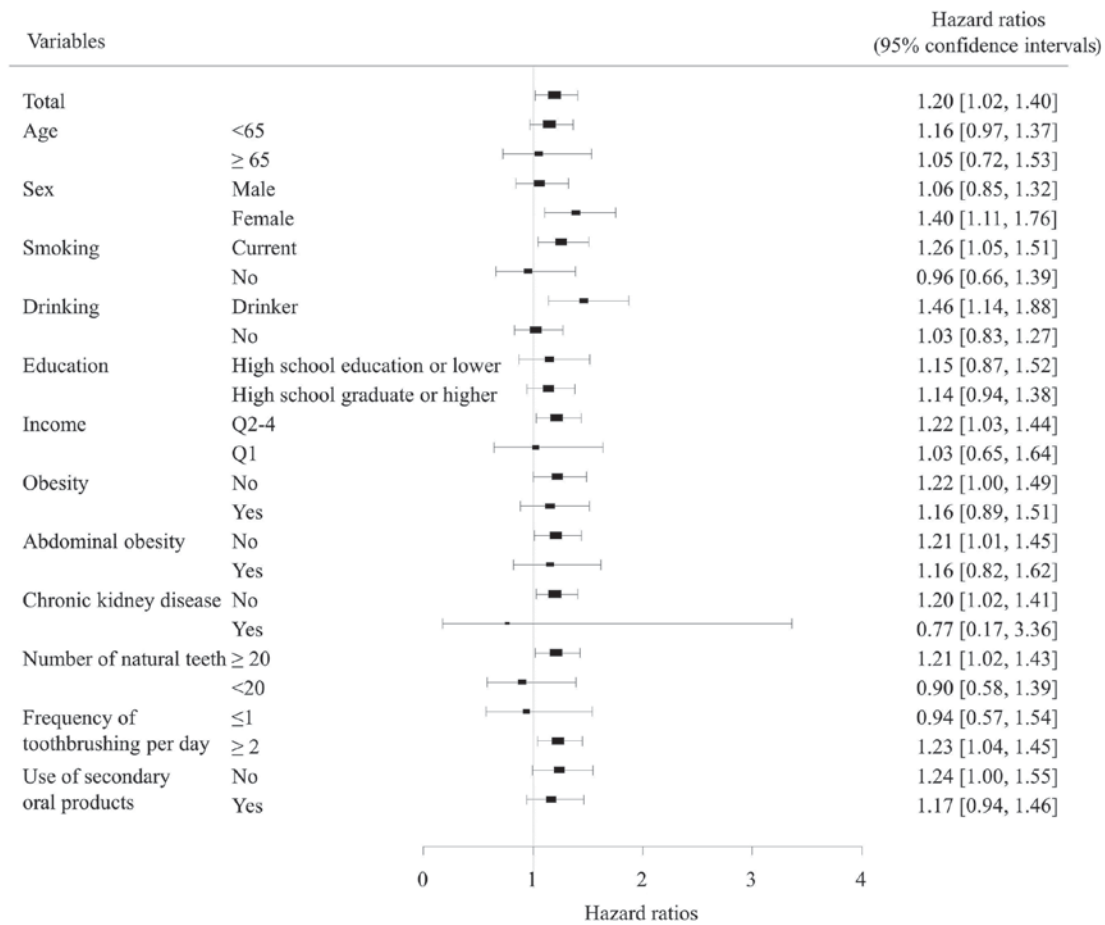


Figure 4. Hazard ratios and 95% confidence intervals of periodontitis in individuals with impaired fasting glucose after adjustments for age, sex, smoking, drinking, education, income, body mass index, waist circumference, chronic kidney disease, number of natural teeth, frequency of tooth brushing per day, use of secondary oral products and duration of sleep.

glucose, and glycated hemoglobin. The ORs and 95% CIs for systolic blood pressure of $90 \leq x < 100$, $100 \leq x < 110$, $110 \leq x < 120$, $120 \leq x < 130$, and $130 \leq x < 140$ were 1.116 (0.591, 2.107), 1.165 (0.624, 2.175), 1.238 (0.673, 2.278), 1.008 (0.538, 1.888), and 1.042 (0.545, 1.993), respectively, when systolic blood pressure < 90 was considered as reference. The ORs and 95% CIs for diastolic blood pressure of $65 \leq x < 70$, $70 \leq x < 75$, $75 \leq x < 80$, $80 \leq x < 85$, and $85 \leq x < 90$ were 1.192 (0.94, 1.511), 1.324 (1.049, 1.67), 1.152 (0.905, 1.467), 1.188 (0.931, 1.516), and 1.263 (0.937, 1.702), respectively, when diastolic blood pressure < 65 was considered as reference. The ORs and 95% CIs for glucose of $90 \leq x < 100$, $100 \leq x < 110$, and $110 \leq x < 126$ were 1.074 (0.92, 1.253), 1.214 (0.986, 1.494), and 1.358 (1.005, 1.834), respectively, when glucose < 90 was considered as reference. The ORs and 95% CIs for glycated hemoglobin $5 \leq x < 5.5$, $5.5 \leq x < 6$, and $6 \leq x < 6.5$ were 0.887 (0.583, 1.348), 0.853 (0.559, 1.301), and 1.021 (0.652, 1.599), respectively, when glycated hemoglobin < 5 was considered as reference.

Discussion

This study showed that both impaired fasting glucose and prehypertension were associated with periodontitis by multiple logistic regression analyses after adjusting for confounding factors among Korean adults. Subgroup analysis revealed that ORs of periodontitis increased in impaired fasting glucose

in both non-obese and obese participants. Highest ORs were seen with the combination of impaired fasting glucose and obesity/abdominal obesity.

Various parameters can be used to determine impaired fasting glucose and prehypertension (17,20-24). Impaired fasting glucose was defined as a level of blood glucose between 100 and 125 mg/dl with no diabetic medication (17). The criteria for the World Health Organization is $110 \leq x < 125$ mg/dl (20). Regarding hypertension, if the participants were ≥ 60 years old, then average blood pressure of 150/90 mmHg or lower was considered as controlled, and the criteria of blood pressure $< 140/90$ mmHg was considered controlled for individuals younger than 60 (21). A previous report recommended lower targets for individuals with diabetes mellitus of 130/80 mmHg (22). In a previous study, prehypertension was defined as systolic blood pressure between 120 and 139 mmHg or diastolic blood pressure between 80 to 89 mmHg (23). In another study, participants with repeated measurements of systolic pressure of 130 to 139 mmHg and diastolic pressure of 89 mmHg or lower, or systolic pressure of 139 mmHg or lower and diastolic pressure of 85 to 89 mmHg, were assigned to the treatment of prehypertension (24). In this study, we classified the glucose level and glycated hemoglobin into four stages according to the severity. Systolic and diastolic blood pressure was categorized into six stages according to the severity.

Table II. Odds ratios and 95% confidence interval for periodontitis categorized by systolic blood pressure, diastolic blood pressure, glucose and glycated hemoglobin.

Variables	Odds ratios (95% confidence interval)		
	Model 1	Model 2	Model 3
Systolic blood pressure (mmHg)			
<90	1 (reference)	1 (reference)	1 (reference)
90≤x<100	1.191 (0.642, 2.21)	1.113 (0.589, 2.101)	1.118 (0.591, 2.114)
100≤x<110	1.247 (0.676, 2.301)	1.156 (0.619, 2.158)	1.169 (0.625, 2.185)
110≤x<120	1.37 (0.754, 2.487)	1.243 (0.676, 2.284)	1.245 (0.676, 2.293)
120≤x<130	1.183 (0.641, 2.184)	1.014 (0.542, 1.899)	1.013 (0.540, 1.900)
130≤x<140	1.259 (0.669, 2.369)	1.072 (0.56, 2.055)	1.044 (0.545, 2.002)
Diastolic blood pressure (mmHg)			
<65	1 (reference)	1 (reference)	1 (reference)
65≤x<70	1.149 (0.912, 1.447)	1.171 (0.927, 1.481)	1.193 (0.941, 1.513)
70≤x<75	1.391 (1.107, 1.747)	1.322 (1.05, 1.665)	1.325 (1.050, 1.672)
75≤x<80	1.227 (0.968, 1.556)	1.156 (0.91, 1.468)	1.156 (0.908, 1.472)
80≤x<85	1.267 (0.995, 1.612)	1.177 (0.924, 1.498)	1.190 (0.933, 1.519)
85≤x<90	1.443 (1.082, 1.925)	1.271 (0.945, 1.711)	1.270 (0.942, 1.711)
Glucose (mg/dl)			
<90	1 (reference)	1 (reference)	1 (reference)
90≤x<100	1.113 (0.959, 1.292)	1.076 (0.923, 1.254)	1.071 (0.918, 1.250)
100≤x<110	1.333 (1.093, 1.627)	1.214 (0.988, 1.492)	1.212 (0.984, 1.492)
110≤x<126	1.542 (1.163, 2.044)	1.364 (1.014, 1.835)	1.355 (1.003, 1.830)
Glycated hemoglobin (%)			
<5	1 (reference)	1 (reference)	1 (reference)
5≤x<5.5	0.958 (0.634, 1.447)	0.893 (0.586, 1.36)	0.887 (0.584, 1.349)
5.5≤x<6	1.027 (0.68, 1.55)	0.864 (0.565, 1.321)	0.853 (0.559, 1.302)
6≤x<6.5	1.354 (0.881, 2.081)	1.072 (0.682, 1.684)	1.018 (0.650, 1.594)

Model 1, Age and sex adjusted; Model 2, Model 1 + smoking, drinking, education, income, and body mass index adjusted; Model 3, Model 2 + number of natural teeth, frequency of tooth brushing per day, use of secondary oral products and duration of sleep adjusted.

A previous report recommended initiating treatment in adults aged 60 years or older with systolic blood pressure persistently at or above 150 mmHg to achieve a target systolic blood pressure of less than 150 mmHg to reduce the risk for mortality, stroke, and cardiac events (25). However, it was noted that evidence was low in quality for achieving a target systolic blood pressure of less than 140 mmHg to reduce the risk of stroke or cardiac events. Similarly, another report showed that more intensive blood pressure-lowering treatment of a group with mean blood pressure level of 133/76 mmHg resulted in no clear effects on total mortality, cardiovascular death, heart failure, or end-stage renal disease (26). Fewer studies have been performed regarding prehypertension and it was shown that prehypertension was considered a precursor of stage 1 hypertension and a predictor of excessive cardiovascular risk (24). Prevalence of periodontitis in the prehypertension group increased from 25.8% for systolic blood pressure of 120≤x<130 mmHg and 34.2% for 130≤x<140 mmHg, respectively. Prevalence of periodontitis in the prehypertension group increased from 25.2 to 27.4% for diastolic blood pressure of 80≤x<85 and 85≤x<90 mmHg, respectively.

A previous report showed pre-diabetes related to impaired fasting glucose was positively associated with periodontitis (27). Research has also shown that periodontitis showed an association with decreased β -cell function and increased prevalence of impaired fasting glucose before onset of diabetes (28). It was also shown that chronic periodontitis measured by clinical attachment loss and pocket depth was positively associated in a linear relation with impaired fasting glucose (28). This study also showed that the percentage of periodontitis increased from 22.0% for fasting glucose level of 90≤x<100 mg/dl, 30.7% for fasting glucose level of 100≤x<110 mg/dl, and 37.3% for fasting glucose level of 110≤x<126 mg/dl. ORs of periodontitis increased with impaired fasting glucose and combination of obesity and impaired fasting glucose showed the highest ORs of 1.523. The relative increase of ORs of impaired fasting glucose for periodontitis was 1.311 for no obesity but 1.137 for the obesity group. Similar trends were seen regarding abdominal obesity. The relative increase of ORs of impaired fasting glucose for periodontitis was 1.320 for no abdominal obesity but 1.106 for the abdominal obesity group. It should also be considered that

more care may be given to prehypertensive individuals with impaired fasting glucose (23).

This study emphasized the importance of evaluation and treatment of periodontitis in individuals with prediabetes and prehypertension. This study has great strength because the conclusion was derived from nationally representative data (29). The design of this study is based on a stratified, multistage, probability-cluster survey of the population of institutionalized civilians (30). Oral health was evaluated using periodontal index from index teeth using probing depth (31). A multiple regression analysis was used to evaluate periodontitis in relation to impaired fasting glucose and blood pressure after adjustment for various confounding factors including age, sex, smoking, drinking, socioeconomic factors, oral health behavior, and systemic diseases (32). However, it should be noted that the causal direction of the associations between prediabetes/prehypertension and periodontitis cannot be ascertained due to the design of this study being cross-sectional (33).

The association between fasting glucose/blood pressure and periodontitis was proven by multiple logistic regression analyses after adjusting for confounding factors among non-diabetic and non-hypertensive Korean adults. Subgroup analysis showed that higher ORs of periodontitis were noted in participants having both impaired glucose level and obesity when compared with individuals without impaired glucose level or obesity. Further prospective studies with a larger sample size of individuals over a longer period of time are required to evaluate the cause-and-effect association. The results of the present study suggest that detection of fasting glucose and blood pressure may serve as a risk indicator for periodontal disease.

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Availability of data and materials

All data generated or analyzed during this study are included in this published article.

Authors' contributions

KH and JP collaborated to design the study; KH and JP were responsible for data access and analysis; KH and JP wrote the manuscript; both authors reviewed the manuscript.

Ethics approval and consent to participate

The Institutional Review Board at the Catholic University of Korea approved this study (approval no. KC16EISI0713).

Patient consent for publication

Not applicable.

Competing interests

The authors confirm that they have no competing interests.

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