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ORIGINAL RESEARCH

Association Between Glycated Hemoglobin and Diabetic Retinopathy in Individuals with Diabetes: A Focus on the Modifying Effect of Ambulatory Blood Pressure

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Background: Suboptimal glycemic control in individuals with diabetes is one of the major contributors to the development of diabetic retinopathy (DR). However, the role of ambulatory blood pressure (ABP) in this association remains unclear. The purpose of this research was to assess the associations among ABP, glycosylated hemoglobin (HbA1c), and DR in a diabetic population, with an emphasis on individuals exhibiting suboptimal glycemic and BP control.

Methods: This study included 498 diabetic patients with comprehensive ABP data. The assessment of diabetes is based on the criteria of the American Diabetes Association (ADA). We adopted Least Absolute Shrinkage and Selection Operator (Lasso) regression to identify key variables and used logistic regression to investigate associations, followed by subgroup analyses.

Results: After adjustment for covariance variables, HbA1c showed a strong correlation with DR (OR: 1.228, 95% CI: 1.010–1.368). Among participants with low ABP, the prevalence of DR rises significantly with higher HbA1c levels (OR: 1.217,95% CI:1.057–1.402), whereas in those with elevated ABP (OR:1.366,95% CI:1.122–1.662), this relationship was markedly stronger, particularly in the context of Awake systolic blood pressure (SBP). Comparable findings were noted in both categorical models, as well as in subgroup analyses. However, heterogeneity was observed in subgroup analyses stratified by age.

Conclusion: ABP may modify the relationship between HbA1c and DR; specifically, suboptimal glycemic management in patients at elevated ABP levels exacerbates the risk of DR. Therefore, it is imperative for diabetic patients to prioritize both BP regulation and glycemic management in their comprehensive disease management strategy.

Keywords: glycosylated hemoglobin, ambulatory blood pressure, diabetic retinopathy, diabetic population

Introduction

The global incidence of diabetes is growing due to rising life expectancy, which will substantially heighten the global health-care burden.[1] DR is a common complication among people with diabetes and is globally recognized as a leading reason for visual damage and blindness.[2] In addition to diminishing patients' quality of living and functional capacity, it is linked to an elevated risk of mortality.[2] According to the European Region of the World Health Organization (WHO), approximately one third of individuals with diabetes are visually impaired or blind due to DR.[3] It is estimated that the amount of people over the age of 40 diagnosed with DR in the United States will increase threefold between 2005 and 2050.[4] DR is a well-established microangiopathic disease, associated with poor diabetes and hypertension control, the duration of diabetes, and elevated levels of HbA1c.[5–8]

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HbA1c reflects long-term glycemic regulation and serves as a crucial marker for evaluating glycemic control in persons with type 2 diabetes (T2DM).[9,10] Several recent reports have surveyed the association between HbA1c and both microvascular and macrovascular complications. A 32 years follow-up of patients with type 1 diabetes mellitus (T1DM) found that weighted mean HbA1c was a robust biomarker for proliferative DR (PDR) and nephropathy, demonstrating that higher levels of HbA1c accelerated the onset of retinopathy.[11]

Similar to the effects of HbA1c, several research have suggested that hypertension is correlated with a poor prognosis in diabetic patients, while controlling BP reduces the incidence and progression of DR. It has been indicated that for every 10 mmHg rise in SBP, a patient's risk of developing early DR increases by 10%.[12] However, some RCTs have reported conflicting findings concerning BP control in T2DM, with certain studies indicating a benefit for DR prevention and others showing no significant effect.[13–15] Typically, in-office BP measurements are used for the diagnosis and evaluation of hypertensive patients. However, BP fluctuates dynamically throughout the day due to circadian rhythms, autonomic nervous system regulation, and daily activities, such as the morning peak phenomenon or dipper, and in-office BP values fail to accurately reflect these circadian variations. In contrast, ABP monitoring (ABPM) can more accurately capture the BP levels experienced at home, at work, and during sleep. As a result, ABPM may offer greater specificity and sensitivity than in-office measurements and has demonstrated strong predictive value for cardiovascular disease, potentially improving the accuracy of BP management in diabetic patients.[16–19] Multiple researches have demonstrated the relationship between DR and 24-hour or nocturnal BP elevations.[20–22] However, to our knowledge, few investigations have extensively explored the association between HbA1c, ABP, and DR.

Although there are a number of studies on BP, HbA1c, and DR, there is limited evidence on ABP. Therefore, we aimed to study the relationship between 24-hour BP (24h BP), daytime BP (Awake BP), nocturnal BP (Asleep BP), and HbA1c and DR in a diabetic population, which could provide insights into minimizing diabetic complications.

Methods

Data Source and Participants

The Metabolic Management Center (MMC) platform is a specialized database established by Yuhuan Second People's Hospital to monitor follow-up visits of diabetic patients. The baseline cohort was established in 2022, with annual enrollment of new patients, who are typically followed up 3 to 4 times annually. Of these, 498 participants were selected with comprehensive ABPM records between September 2022 and May 2024. Diabetes was diagnosed based on the 2016 diagnostic criteria of the ADA.[23] Subsequently, clinical information and laboratory data were collected from all participants. All researchers have received written informed consent and approval from the Medical Ethics Committee of Health Community Group of Yuhuan Second People's Hospital (Project No.1708). This study adhered to the principles of the Declaration of Helsinki.

Clinical Data Collection and ABP Measurement

Demographic, physical examination, laboratory, and clinical information was collected from all participants. Demographic data included age, gender, education level (below high school or senior school and beyond), annual family income (<100,000, 100,000–300,000, and >100,000 yuan), occupation (civil servant, technician, or unemployed), smoking status (yes or no), and alcohol consumption (yes or no). Physical examination data included SBP, diastolic blood pressure (DBP), height, and weight. Laboratory data consisted fasting plasma glucose (FPG), total cholesterol (TC), triglycerides (TG), high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein cholesterol (LDL-C), and HbA1c. Clinical information included medical history, such as hypertension and diabetes.

We monitored participants' ABP for 24 hours using a validated ABP monitor (Model A&D TM-2430, Japan). A cuff of adequate size was placed on the non-dominant arm of each participant. During the 24-hour study period, the equipment was set to measure BP once 30 minutes during the day and once 60 minutes during the bedtime. Daytime readings were defined as occurring from 8:00 a.m. to 6:00 p.m., and bedtime readings were defined as occurring from 10:00 p.m. to 4:00 a.m.[24] The device automatically recorded BP readings, and at the conclusion of the monitoring period, the data were uploaded to the Shuoyun Blood Pressure Analysis Management Platform. Valid records required at least 10

daylight readings and 5 overnight readings to be required for the analysis. In this study, daytime ABP and nighttime ABP were determined by calculating the mean values based on the corresponding BP readings. High Awake BP was defined as a mean Awake SBP of 135 mmHg or greater or Awake DBP of 85 mmHg or greater. High Asleep BP was defined as a mean Asleep SBP of 120 mmHg or greater or a Asleep DBP of 70 mmHg or greater.[25]

Primary Outcome

The primary outcome of the study was the presence or absence of DR. We performed a standardized clinical examination and retinal videography on all study participants. Retinal images were obtained for all participants and subsequently interpreted by two specialized clinical ophthalmologists to assess the presence or absence of DR, with a third specialist providing adjudication in case of disagreement. Upon reviewing the data, we found that, of the 114 individuals with DR, 7 participants had mild DR, 1 participant had severe DR, and the remaining participants had moderate DR. Given that the majority of the subjects had moderate DR, we chose not to differentiate further between DR subtypes in our analyses. Instead, we categorized the results based on the presence or absence of DR.

Exposure of Interest

The primary exposure in this study was the level of HbA1c. To assess the robustness of our results, we analyzed HbA1c as a continuous variable, a dichotomous variable (HbA1c <7% vs HbA1c ≥7%), and a tertiary variable (HbA1c ≤5.6%, HbA1c: 5.7%-6.4%, or HbA1c ≥6.5%), respectively. These categories reflect whether HbA1c control in diabetic patients is considered satisfactory.

Statistical Analysis

We quantified the general characteristics of the research participants through descriptive statistics. We first screened the variables using lasso regression. Lasso regression is a regularization method for linear regression issues that can decreases model complexity, avoids over-fitting, and chooses essential feature variables.[26–28] It constrains the parameter estimates of the model so that many parameters become zero.[26–28] After the contraction process, variables with regression coefficients reduced to zero are dropped from the model, while those with nonzero coefficients are identified as being closely related to the response variable, thereby fulfilling the role of variable selection.[26–28] We then used logistic regression to evaluate the relationship between HbA1c (as continuous, dichotomous, and trichotomous variables) and DR, with the results expressed as odds ratios (OR) and 95% confidence intervals (CI). The ABP variables, selected using Lasso regression, were categorized as dichotomous variables based on threshold values. Stratified analyses were conducted according to low and high ABP levels to determine whether these associations varied based on ABP. We applied two logistic models for different covariates to assess the relationship between HbA1c, ABP, and DR. These were (1) model 1, which was not adjusted for any covariates, and (2) model 2, which was adjusted for sex, age, BMI, smoking, alcohol consumption, and history of hypertension.

In addition, we analyzed subgroups by sex (male or female) and age (<60 or ≥60 year). Both models were adjusted accordingly. Statistical analysis software SPSS 27.0 and RStudio were employed in this study. A p-value of lower than 0.05 was defined as statistically meaningful.

Results

A total of 498 individuals were enrolled in this research, of which 275 (55.2%) were diagnosed with hypertension, defined as physician-diagnosed hypertension. The presence of DR was observed in 114 participants, while 384 participants were without DR. Detailed results of participant characteristics and ABP parameters are shown in Table 1. There was no obvious difference in gender, age, and BMI between participants with as well as without DR. HbA1c levels were 7.361±1.813% in those without DR and 8.148±1.973% in those with DR (P<0.001). ABP measurements revealed that both daytime and nighttime SBP were greater in participants for DR than in those without DR (136.08±16.851 vs 132.94±15.373 mmHg; 126.70±16.293 vs 122.60±8.867 mmHg, respectively; see Table 1).

A total of 14 variables were contained in the lasso regression model: gender, age, BMI, 24h SBP, 24h DBP, Awake SBP, Awake DBP, Asleep SBP, Asleep DBP, history of hypertension, 24h SBP coefficient of variation, 24h DBP

Table 1 General Characteristics of the Population

Characteristics	Total (n=498)	Non-DR (n=384)	DR (n=114)	*p*-Value
Age (years)	58.00±10.972	57.60±11.327	59.37±9.600	0.099
Gender				0.325
Male	295(59.2)	232(60.4)	63(55.3)	
Female	203(40.8)	152(39.6)	51(44.7)	
BMI (kg/m^2)	25.90±3.563	26.04±3.512	25.43±3.707	0.107
Education				0.355
Below high school	457(91.8)	350(91.1)	107(93.9)	
High school and above	41(8.2)	34(8.9)	7(6.1)	
Annual income (yuan)				0.671
<100,000	262(52.6)	203(52.9)	59(51.8)	
100,000–300,000	197(39.6)	149(38.8)	48(42.1)	
>300,000	39(7.8)	32(8.3)	7(6.1)	
Occupation				0.080
Office staff	26(5.2)	18(4.7)	8(7.0)	
Technical staff	237(47.6)	193(50.3)	44(38.6)	
Underemployed	235(47.2)	173(45.1)	62(54.4)	
Smoking				0.593
No	382(76.7)	297(77.3)	85(74.6)	
Yes	116(23.3)	87(22.7)	29(25.4)	
Drinking				0.749
No	331(66.5)	257(66.9)	74(64.9)	
Yes	167(33.5)	127(33.1)	40(35.1)	
History of hypertension				0.385
No	223(44.8)	176(45.8)	47(41.2)	
Yes	275(55.2)	208(54.2)	67(58.8)	
FPG (mol/L)	7.66±2.74	7.45±2.57	8.39±3.17	0.005
TG (mmol/L)	1.68±1.27	1.68±1.29	1.691.20	0.927
TC (mmol/L)	4.78±1.19	4.81±1.18	4.67±1.20	0.276
HbA1c (%)	7.542±1.878	7.361±1.813	8.148±1.973	<0.001
24h ABPM (mmHg)				
24h SBP	133.32±59.607	133.37±67.369	133.16±15.604	0.955
24h DBP	78.80±8.435	79.03±8.529	78.02±8.099	0.259
Awake SBP	133.66±15.762	132.94±15.373	136.08±16.851	0.062
Awake DBP	80.73±8.815	80.97±8.867	79.95±8.627	0.278
Asleep SBP	123.54±16.092	122.60±8.867	126.70±16.293	0.017
Asleep DBP	74.44±9.028	74.65±9.188	73.71±8.463	0.328

coefficient of variation, family income, and occupation. The variable selection process in the lasso regression model is displayed in Figure 1. Among the 14 variables, four variables had non-zero coefficients in the lasso regression model, including BMI, Awake SBP, Asleep SBP and Asleep DBP.

The results of the regression analysis displayed that HbA1c was strongly associated with DR (OR: 1.228, 95% CI: 1.010–1.368). Stratified analysis using ABP variables, selected through lasso regression analysis, revealed that abnormal ABP was correlated with a greater prevalence of DR related to HbA1c compared to those with normal ABP. Specifically, the OR were as follows: Awake SBP: 1.366 (1.122–1.662) vs 1.217 (1.057–1.402); Asleep SBP: 1.234 (1.056–1.442) vs 1.230 (1.052–1.437); and Asleep DBP: 1.285 (1.118–1.477) vs 1.150 (0.956–1.383) (see Table 2 and Figure 2 for details). Similar results were observed in additional analyses, with a more pronounced effect observed in Awake SBP. When HbA1c was categorized as dichotomous or tertiary, with the minimum value as the reference, the prevalence of DR increased significantly with greater levels of HbA1c in the high Awake SBP group, while the relationship became nonsignificant in the low Awake SBP group (see Table 3 Figures 2 and 3 and Supplementary Table 1).

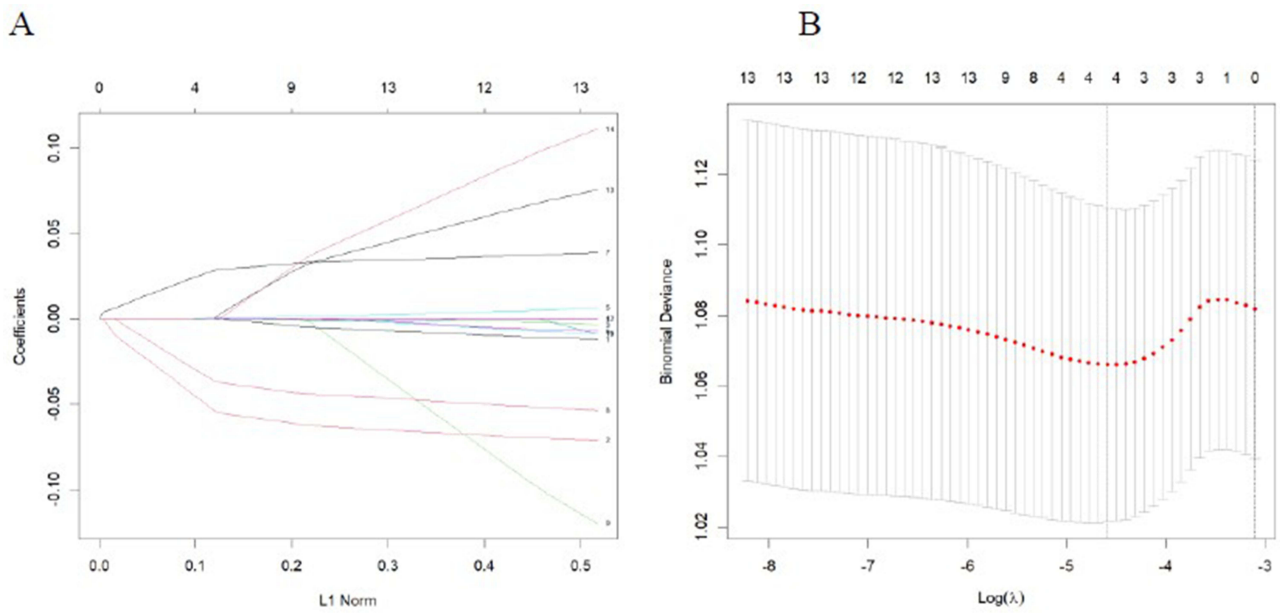

Figure 1 Variable selection for LASSO binary logistic regression model. (**A**) A coefficient profile plot was produced against the L1 Norm sequence . Four variables with nonzero coefficients were selected by optimal L1 Norm penalty. (**B**) Partial likelihood deviations were plotted by validating the optimal parameters in the LASSO model, and dashed vertical lines were plotted based on the 1 standard error criterion.

The outcomes of the subgroup analysis by gender and age are detailed in Supplementary Tables 2 and 3. The results of the subgroup analyses by gender were consistent with our main analysis, showing no significant gender differences. In contrast, subgroup analysis by age demonstrated that only the results for participants over 60 were consistent with the main analysis. The effect of HbA1c on DR was more pronounced in individuals with high ABP aged 60 years or older.

Discussion

This study demonstrated that raised HbA1c levels were strongly correlated with the prevalence of DR. This relationship was further influenced by ABP, with a significantly stronger association observed in individuals with elevated ABP compared to those with normal ABP, particularly during the daytime period. Specifically, suboptimal glycemic control was more detrimental to DR in patients with elevated ABP. Therefore, it is crucial for diabetic patients to prioritize both BP regulation and glycemic control in their comprehensive disease management strategy.

Table 2 HbA1c (%) * Associated with DR Prevalence, According to the ABP Stratification

Variables	Unadjusted Mode	*P*	Adjusted Mode	*P*
	OR (95% CI)		OR (95% CI)	
All Patients	1.223(1.102,1.357)	<0.001	1.228(1.010,1.368)	<0.001
Awake ambulatory BP (mmHg)				
Awake SBP				
<135	1.181(1.032, 1.350)	0.015	1.217(1.057, 1.402)	0.006
≥135	1.342(1.128, 1.596)	<0.001	1.366(1.122, 1.662)	0.002
Asleep ambulatory BP (mmHg)				
Asleep SBP				
<120	1.200(1.037, 1.390)	0.015	1.230(1.052, 1.437)	0.009
≥120	1.244(1.073, 1.441)	0.004	1.234(1.056, 1.442)	0.008
Asleep DBP				
<70	1.131(0.952, 1.345)	0.162	1.150(0.956, 1.383)	0.139
≥70	1.277(1.121, 1.456)	<0.001	1.285(1.118, 1.477)	<0.001

Notes: Adjusted age, BMI, gender, history of hypertension, smoking, drinking.*HbA1c (%) as a continuous variable.

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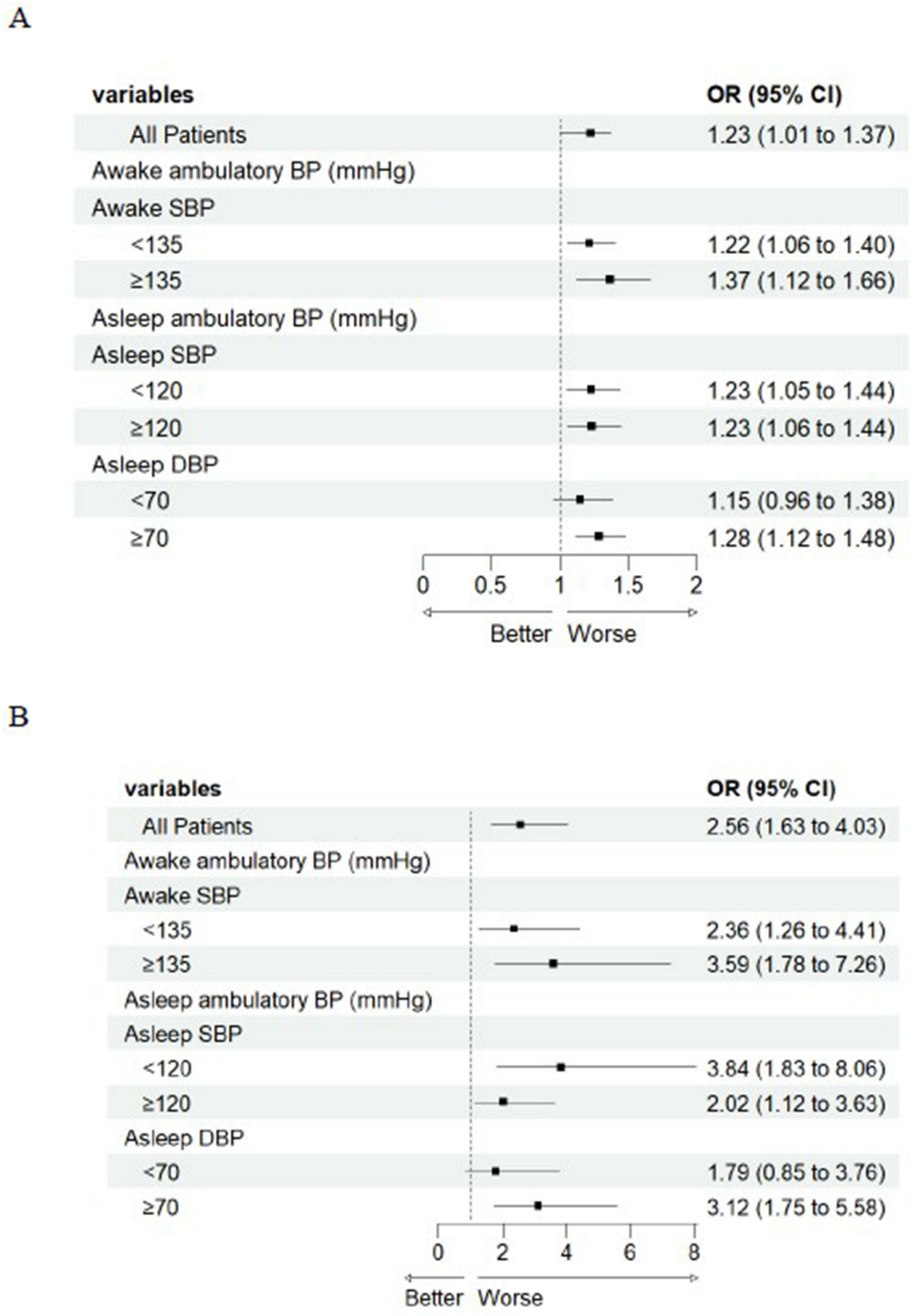

Figure 2 HbA1c associated with DR prevalence, according to the ABP stratification. (**A**) HbA1c as a continuous variable in association with DR prevalence, stratified according to ABP. (**B**) HbA1c as a dichotomous variable(HbA1c <7% or HbA1c ≥7%) in association with DR prevalence, stratified according to ABP, with the category of low HbA1c levels as a reference. Adjusted age, BMI, gender, history of hypertension, smoking, drinking.

Several previous studies have published on the relationship from HbA1c to DR, and our findings generally align with these studies, albeit with some differences. A meta-analysis of 59 studies demonstrated that higher HbA1c levels, renal impairment, and younger age at diabetes diagnosis were significant risk factors for PDR in diabetic persons.[29] Another study conducted in the United States examined factors associated with the prevalence and severity of DR in patients with T2DM and found that poor glycemic control, hypertension, and male gender were significantly associated with the presence of retinopathy.[30] In contrast, no gender differences were observed in our study, which may be attributable to population and geographic differences. These findings, however, require further verification through additional studies.

Table 3 Association of HbA1c (%) * as a Dichotomous Variable with DR According to ABP Stratification, with the Category of Low HbA1c Levels as a Reference

Variables	Unadjusted Mode	*P*	Adjusted Mode	*P*
	OR (95% CI)		OR (95% CI)	
All Patients	2.421(1.565, 3.745)	<0.001	2.562(1.630, 4.027)	<0.001
Awake ambulatory BP (mmHg)				
Awake SBP				
<135	2.303(1.245, 4.259)	0.008	2.358(1.260, 4.413)	0.007
>135	2.778(1.482, 5.208)	0.001	3.594(1.780, 7.256)	<0.001
Asleep ambulatory BP (mmHg)				
Asleep SBP				
<120	3.511(1.748, 7.053)	<0.001	3.841(1.830, 8.062)	<0.001
≥120	1.839(1.748, 7.053)	<0.034	2.020(1.123, 3.634)	0.019
Asleep DBP				
<70	1.803(0.888, 3.657)	0.103	1.786(0.849, 3.759)	0.126
≥70	2.892(1.653, 5.058)	<0.001	3.124(1.748, 5.585)	<0.001

Notes: Adjusted age, BMI, gender, history of hypertension, smoking, drinking. * HbA1c (%) was treated as a dichotomous variable (HbA1c <7% or HbA1c ≥7%), with HbA1c <7% used as the reference category.

Furthermore, age is a well-established, immutable risk factor for hypertension, diabetes, and DR, with prevalence increasing with age. The results of our study align with this trend. Overall, despite some heterogeneity in the subgroup analyses, our findings were consistent with those of the referenced study.

The mechanism by which BP affects DR is currently unknown; however, several studies have demonstrated that elevated BP, particularly SBP and SBP variability, increases the risk of developing DR.[20,22] A meta-analysis that pooled 29 randomized controlled trials conducted in North America, Europe, Australia, Asia, Africa, and the Middle East showed that interventions to lower BP had a modest beneficial effect in protecting against DR for up to five years, yet did not significantly influence its progression.[31] Our study was similar in that the risk of DR was greater in individuals with higher BP, with the key distinction being the use of ABP monitoring in our study. Asians may have greater salt sensitivity and absorption than Westerners, and high salt intake increases sodium concentration in the body, causing water retention and subsequently increasing blood volume and BP.[32,33] It has been shown that sodium chloride (NaCl) loading affects circadian BP variability by attenuating nocturnal BP decline.[34] ABP data may thus provide greater insight into the association between BP glycation, and DR. In addition, the effects of lifestyle factors such as physical activity and stress on BP, blood glucose, and DR should not be overlooked.[35] Several studies have demonstrated that physical activity and stress significantly impact BP, blood glucose, and DR. These findings suggest that physical activity and stress not only directly influence DR but also indirectly affect DR through their impact on BP and blood glucose. However, these relationships require further verification in subsequent studies.

Our research indicated that the association between HbA1c and DR was more significant with increasing BP. We propose the following possible mechanisms. First, in hemodynamics, hyperperfusion takes a center role in the pathogenesis of DR. In the retinal vasculature, hypertension and hyperglycemia cause hyperperfusion, and the resulting rise in shear stress results in elevated blood flow, viscosity, and capillary damage, ultimately leads to retinal ischemia and induction of DR.[36,37] Second, elevated BP may impair microvascular endothelial function, leading to microcirculation disorders.[38] Microcirculation dysfunction affects the utilization and transport of glucose in tissues, resulting in metabolic disorders, which raise HbA1c levels and exacerbate the onset and progression of DR.[21,39] Further, BP variability has been shown to increase oxidative stress, which is critical in the development and growth of diabetic complications, causing insulin resistance and inflammatory responses.[40,41] These processes elevate HbA1c levels, further contributing to DR. In addition, the effect of SBP versus DBP on DR has been controversial, with some longitudinal studies demonstrating the superiority of SBP,[42] as supported by our results. SBP primarily reflects central large artery hemodynamics,[21] and we

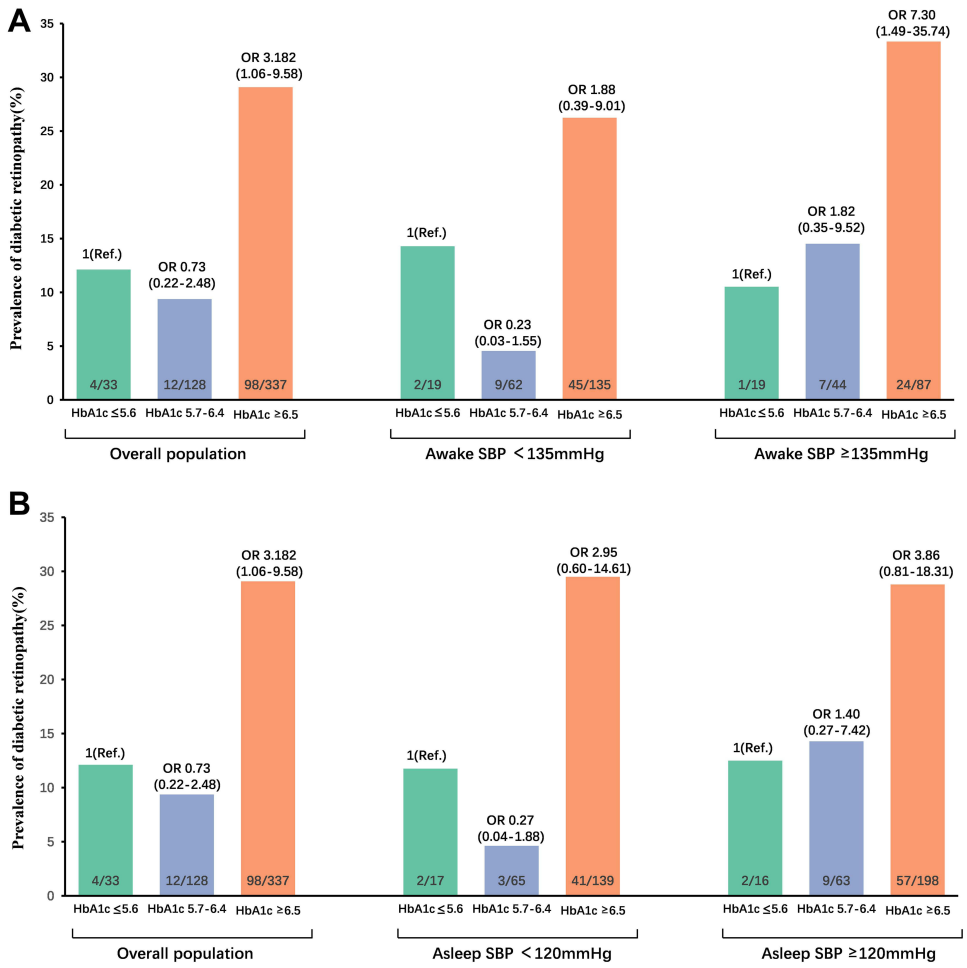

Figure 3 Relationship between HbA1c levels and DR according to type of ambulatory blood pressure. (**A**) Relationship between HbA1c triple classification((HbA1c ≤5.6%, HbA1c: 5.7%-6.4%, or HbA1c ≥6.5%)) and DR, according to the Awake SBP stratification. (**B**) Relationship between HbA1c triple classification((HbA1c ≤5.6%, HbA1c: 5.7%-6.4%, or HbA1c ≥6.5%)) and DR, according to the Asleep SBP stratification. Adjusted age, BMI, gender, history of hypertension, smoking, drinking.

speculate that abnormal central large artery hemodynamics, often leading to arterial stiffening and elevated central BP, disrupts endothelial function in retinal microvessels or causes retinal microvascular dysfunction, thus contributing to DR.

Our results suggest that ABP during wakefulness and sleep are associated with outcomes differently, consistent with other studies. Higher awake BP levels are linked to increased risk of cardiovascular events,[25] while higher 24h and asleep BP levels are associated with greater risk of all-cause mortality and composite cardiovascular outcomes.[24] Since BP is dynamic and influenced by circadian rhythms and fluctuations, a single office measurement may not reflect true BP. Thus, 24h ABPM is advantageous for ruling out white coat hypertension and identifying occult hypertension, improving diagnostic accuracy. However, there are several restrictions to our research. Although 24h ABPM is the gold standard for assessing diurnal BP fluctuations, it has limitations, including the influence of factors such as season, mood, disease state, and lifestyle. Therefore, multiple ABPM measurements or long-term home monitoring are recommended in future studies to minimize variability. As the study design was cross-sectional, causality cannot be established, and continued follow-up is needed for more robust results. Additionally, some outcomes, such as hypertension history, were based on patient self-report. Due to data limitations, we did not differentiate between DR subtypes and classified DR dichotomously. Finally, although we adjusted for some covariates, we were unable to fully account for potential confounding variables.

Conclusion

In summary, our findings demonstrates that high HbA1c levels are connected with the development of DR, and this association is significantly stronger in individuals with elevated ABP, particularly in awake SBP. These discoveries emphasize the

importance of simultaneous management of BP and blood glucose in diabetic individuals for preventing complications. However, further investigations are needed to confirm these causal relationships and underlying mechanisms.

Institutional Review Board Statement

The study was approved by the Medical Ethics Committee of Health Community Group of Yuhuan Second People's Hospital (Project No.1708).

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare no potential conflicts of interest concerning the research, authorship, and publication of this article.

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