Journal of Diabetes and Its Complications 31 (2017) 328–333

Contents lists available at ScienceDirect

Journal of Diabetes and Its Complications

journal homepage: WWW.JDCJOURNAL.COM

# Body mass index and mortality in patients with type 2 diabetes mellitus: A prospective cohort study of 11,449 participants

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ARTICLE INFO

*Article history:*
Received 4 May 2016
Received in revised form 29 September 2016
Accepted 10 October 2016
Available online 17 October 2016

*Keywords:*
Body mass index
Obesity
Type 2 diabetes mellitus
All-cause mortality
Chinese population

ABSTRACT

*Aims:* To investigate the association between body-mass index and mortality in Chinese adults T2DM.
*Methods:* 11,449 participants of Kailuan Study with T2DM were included in this prospective cohort study. All-cause mortality was calculated using Kaplan–Meier analysis. Cox proportional hazards analysis was used to estimate the association between BMI and mortality.
*Results:* During a mean follow-up period of 7.25 ± 1.42 years, 1254 deaths occurred. The number of deaths of the underweight, normal weight, overweight, and obese group was 23, 389, 557, and 285; the corresponding mortality was 25.0%, 13.4%, 10.3%, and 9.4%, respectively. The obese group had the lowest all-cause mortality rate (log-rank chi-square = 48.430, $P < 0.001$). After adjusting for age, sex, fasting blood glucose, smoking status, systolic blood pressure, history of hypertension, stroke, cancer and myocardial infarction, compared with the normal weight group, Multivariate Cox proportional hazard regression analysis showed that HR (95% CI) of all-cause mortality in the underweight, overweight, and obese group was 1.497 (0.962, 2.330), 0.833 (0.728, 0.952), and 0.809 (0.690, 0.949). After stratifying for age tertiles, this trend remained.
*Conclusions:* In T2DM patients in north China, the risk for all-cause mortality was lower in the overweight and the obese groups than those in the normal weight and the underweight groups.
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## 1. Introduction

In 2011, there were 366 million people with diabetes worldwide; by 2030, the number is estimated to be 552 million. In China, among adults aged 20–79 years, the prevalence of diabetes was 9.3%, which is expected to rise to 12.1% in 2030 (Whiting, Guariguata, Weil, & Shaw, 2011). Compared with people without diabetes, the risk for all-cause mortality and cardiovascular mortality had a twofold and a threefold increase among those with type 2 diabetes mellitus (T2DM) (Taylor et al., 2013). Prevention of diabetes is a major measure for reducing the burden of cardiovascular disease.

Obesity is a risk factor for diabetes, weight gain increases the risk for new-onset diabetes, and weight loss reduces the risk for diabetes (Wilding, 2014). However, an "obesity paradox" has been observed in patients with end-stage renal disease, hypertension, and heart failure, as in these patient populations, the risk for mortality decreased for those who were overweight or obese (Lavie, Milani, Ventura, & Romero-Corral, 2010; Schmidt & Salahudeen, 2007; Uretsky et al., 2007). More recently, the "obesity paradox" has been reported in patients with T2DM (Costanzo et al., 2015). It is not clear whether the "obesity paradox" exists in the Chinese T2DM population. In the current study, we analyzed data collected from the Kailuan Study to investigate the impact of body mass index (BMI) on all-cause mortality in a Chinese T2DM population.

## 2. Methods

### 2.1. Study population

In 2006–2007, the Kailuan Group (Hebei, China) organized a general medical examination for its serving and retired employees in 11 hospitals including Kailuan Hopsital, Zhaogezhuang Hospital, Tangjiazhuang Hospital, Fangezhuang Hospital, Jinggezhuang Hospital, Lvjiatuo Hospital, Linnancang Hospital, Qianjiaying Hospital, Majiagou Hospital, and the Branch of Kailuan Hospital. Besides the

Competing interests: The authors have nothing to disclose.

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http://dx.doi.org/10.1016/j.jdiacomp.2016.10.015
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medical examination, relevant health information was also collected (The Kailuan Study, Trial identification: ChiCTR-TNC-11001489; Trial registration site: http://www.chictr.org.cn/index.aspx; Registration number: 11001489). In 2008–2009 (the 2nd), 2010–2011 (the 3rd), and 2012–2013 (the 4th), 3 more medical examinations were carried out. The same groups of medical professionals who performed the first examination were requested to perform the subsequent examinations for the same groups of Kailuan Group employees. The same medical facilities were used in the medical examinations, and the anthropometric and laboratory measurements were repeated. The examination dates were arranged in an order to keep the time intervals between examinations similar for all participants.

The 2006–2007 medical examination included 101,510 people. Among the 101,133 people examined in the 2nd medical examination, 25,337 did not participate the 1st examination. In the current analysis, only those who took part in the medical examination for the first time in either the 1st or the 2nd examination were eligible. The inclusion criteria of the current study were: (1) ≥18 years of age, (2) it was the first time, either in 2006–2007 or 2008–2009, to participate the examination, (3) agreed to participate in this study and signed informed consent; and (4) fasting blood glucose (FBG) ≥7.0 mmol/L or FBG <7.0 mmol/L but had been diagnosed with diabetes previously and had been taking glycemic control medications. The exclusion criteria were: (1) incomplete information of weight, height, age, and sex, (2) became pregnant during the examination period; and (3) refused to sign the informed consent. The current study was approved by the Ethics Committee of the Kailuan General Hospital, and the study protocol was in accordance with the Declaration of Helsinki.

### 2.2. Data collection

The content of epidemiological survey, the anthropometric indicators, and the biochemical parameters were published previously (Wang et al., 2011; Wu et al., 2012). Smoking status was defined as: not smoking, already quit smoking, smoking occasionally, and smoking every day. History of hypertension, myocardial infarction (MI), stroke, and cancer was defined as having a formal diagnosis made by qualified doctors from a hospital classified Grade Two Class A and above.

Physical examination included height, weight, and other parameters. All measurements were taken by trained medical professionals strictly following the appropriate standards. Calibrated RGZ-120 scales were used to measure height and weight. The measurements were taken between 7:30 and 9:00 am, the participants were asked to wear light clothes (i.e., single layer clothes) with hat/cap and shoes removed before stepping onto the scale. They were asked to stand as straight as possible in a military "Attention" posture for the measurement of height. The accuracy of readings was 0.1 cm for height and 0.1 kg for weight. BMI was calculated as weight/height$^2$ with the unit of kg/m$^2$.

Study participants were asked to fast for more than 8 h and blood samples (5 mL) were taken at 7:00–9:00 am the following morning. EDTA (ethylenediamine tetraacetic acid) coated vacuum tubes were used. Blood samples were centrifuged at room temperature for 10 min at 3000 $\times g$ and the serum was used within 4 h for the measurements of FBG. Hexokinase method was used to measure glucose in the plasma using reagents from BioSino Bio-Technology & Science Inc., China and Hitachi 7600 Automatic Biochemical Analyzer. At 5.55 mmol/L, the coefficient of variation was <2% and the linear upper limit was 33.3 mmol/L. The experiments were carried out by trained technicians strictly following the protocol and the operation manual and instructions. Quality control was performed within each sample batch.

Follow-up started from the completion of the medical examination in either 2006–2007 or 2008–2009, and the end of follow-up period was 31 December 2014. The endpoint event was all-cause mortality, which was defined as death due to any cause (except accident) during follow-up. Information of mortality was obtained annually from the Social Security Information System of Kailuan.

### 2.3. Statistical methods

Medical data were entered at each participating hospital and were stored in the study database (Oracle 10.2g) hosted in the server at Kailuan Hospital. The exported PDF files were used for statistical analysis using SPSS 13.0. Continuous variables were presented by mean ± standard deviation (SD) and compared using one-way ANOVA. Categorical variables are presented as n (%) and compared using chi-square test. Kaplan–Meier method was used to calculate all-cause mortality for different BMI groups, and the log-rank test was used to check whether there were differences in all-cause mortality between different BMI groups. Multivariate Cox proportional hazards regression model was used to analyze the factors affecting all-cause mortality. $P < 0.05$ (two-tailed) was considered statistically significant.

In addition, the natural spline function was used to test whether BMI and the risk for all-cause mortality are linearly related. When a non-linear relationship was not statistically significant, the linear model was applied to analyze the relationship between BMI and the risk for mortality. When a non-linear relationship was statistically significant, the natural cubic function was used to analyze the relationship between BMI and the risk for all-cause mortality. The degree of freedom of the natural spline function was selected based on the Akaike information criterion. A hazard ratio curve of BMI and the risk for all-cause mortality was generated.

## 3. Results

### 3.1. Baseline characteristics of the study population

101,510 serving and retired employees of the Kailuan Group took the 1st medical examination in 2006–2007. In the 2nd examination, 25,337 participants did not take the 1st examination. Among these 126,847 people, 11,668 met the diagnosis criteria for diabetes, but data of height, weight, sex, or age were not available for 219 participants. Therefore, a total of 11,449 people were included in the current study cohort, among whom, 9512 (83.1%) were male and 1937 (16.9%) were female. Age ranged between 21 and 91 years and the mean (SD) was 56.50 ± 10.65 years.

### 3.2. BMI groups

The participants were divided into 4 groups based on their BMI using the cut-off points recommended in the 2003 Chinese Guideline for the Prevention and Control of Overweight and Obesity in Adults (The Pilot Edition). The underweight group had BMI <18.5 kg/m$^2$; the BMI of the normal weight group was 18.5–24 kg/m$^2$; for the overweight group, the BMI was 24–28 kg/m$^2$; and for the obese group, the BMI was ≥28 kg/m$^2$. Age, percentage of male participants, FBG, follow-up time, and prevalence of hypertension were significantly different among the BMI groups. With increasing BMI, the level of systolic blood pressure increased (Table 1).

### 3.3. BMI group and all-cause mortality

The average follow-up time (mean ± SD) was 7.25 ± 1.42 years. During this period, a total of 1254 deaths occurred. The number of deaths of the underweight, normal weight, overweight, and obese group was 23, 389, 557, and 285, respectively; the corresponding cumulative all-cause mortality rate was 26.4%, 15.3%, 11.6%, and 10.8%, respectively. For the study population, the lowest cumulative all-cause mortality rate was found in the obese (BMI ≥28 kg/m$^2$)

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