Absence of Obesity Paradox in All-Cause Mortality Among Chinese Patients With an Implantable Cardioverter Defibrillator: A Multicenter Cohort Study

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Background: The results of studies on the obesity paradox in all-cause mortality are inconsistent in patients equipped with an implantable cardioverter-defibrillator (ICD). There is a lack of relevant studies on Chinese populations with large sample size. This study aimed to investigate whether the obesity paradox in all-cause mortality is present among the Chinese population with an ICD.

Methods: We conducted a retrospective analysis of multicenter data from the Study of Home Monitoring System Safety and Efficacy in Cardiac Implantable Electronic Device–Implanted Patients (SUMMIT) registry in China. The outcome was all-cause mortality. The Kaplan–Meier curves, Cox proportional hazards models, and smooth curve fitting were used to investigate the association between body mass index (BMI) and all-cause mortality.

Results: After inclusion and exclusion criteria, 970 patients with an ICD were enrolled. After a median follow-up of 5 years (interquartile, 4.1–6.0 years), in 213 (22.0%) patients occurred all-cause mortality. According to the Kaplan–Meier curves and multivariate Cox proportional hazards models, BMI had no significant impact on all-cause mortality, whether as a continuous variable or a categorical variable classified by various BMI categorization criteria. The fully adjusted smoothed curve fit showed a linear relationship between BMI and all-cause mortality (p-value of 0.14 for the non-linearity test), with the curve showing no statistically significant association between BMI and all-cause mortality [per 1 kg/m^2 increase in BMI, hazard ratio (HR) 0.97, 95% CI 0.93–1.02, p = 0.2644].
INTRODUCTION

Being overweight or obese is a global health problem, with almost two-thirds of American adults experiencing overweight or obesity (1) and the latest epidemiological survey data from China show that the proportion of adults in China who are overweight and obese is 28.1 and 5.2%, respectively (2). Being overweight or obese can promote inflammatory responses, cardiac hypertrophy, and fibrosis, which can lead to an increased incidence of cardiovascular disease (CVD) and is associated with numerous adverse CVD prognostic events (3–5). Although obesity is a risk factor for CVD, a phenomenon known as the “obesity paradox” has been identified. “Obesity paradox” means that patients who have already suffered from many types of CVD may have a better prognosis if they are classified as overweight or obese (6). The obesity paradox in all-cause mortality has been identified when better survival is seen in people with higher body mass index (BMI) among the patients with hypertension, coronary heart disease, atrial fibrillation, and heart failure (3–5, 7–13).

For patients equipped with an implantable cardioverter defibrillator (ICD), the results of studies on the obesity paradox in all-cause mortality are inconsistent (14–17). Moreover, the previous studies have focused on European and American populations, and there is a lack of studies on the Chinese population with large sample size. This study retrospectively analyzed multicenter data from China to investigate whether the obesity paradox all-cause mortality is present in the Chinese population with an ICD.

METHODS

Study Population

Based on data from the Study of Home Monitoring System Safety and Efficacy in Cardiac Implantable Electronic Device–implanted Patients (SUMMIT) registry, we conducted a retrospective cohort analysis enrolling the patients between May 2010 and May 2015 in China. Inclusion criteria were as follows: (i) patients aged more than 18 years; (ii) patients met indications of primary or secondary prevention of sudden cardiac death (SCD) according to clinical practice standards (18–20); and (iii) patients were implanted with an ICD or cardiac resynchronization therapy defibrillator (CRT-D) (collectively referred to as ICD) (Biotronik, Germany) device with home monitoring (HM). Exclusion criteria were as follows: (i) patients under the age of 18 years and (ii) patients with missing clinical data. Figure 1 depicts the flowchart of the research population. The study protocols were approved by the Ethics Committee of Fuwai Hospital, the Chinese Academy of Medical Sciences (the lead institute), and all other collaborating organizations (Zhongshan Hospital, Fudan University, and so on). The protocols followed the Declaration of Helsinki.

Conclusions: The obesity paradox in all-cause mortality was absent in the Chinese patients with an ICD. Prospective studies are needed to further explore this phenomenon.

Keywords: obesity paradox, body mass index, all-cause mortality, implantable cardioverter-defibrillator, Chinese
RESULTS

Baseline Characteristics of the Study Population

A total of 1,015 patients from the SUMMIT dataset between May 2010 and May 2015 were initially included. After inclusion and exclusion criteria, 970 patients were enrolled. Table 1 shows the overall baseline characteristics of the study population. The average age of the study population was 60.3 years, with 72.9% male. The percentage of New York Heart Association (NYHA) class III/IV was 49.9 and 27.4% of patients were implanted with CRT-D. In total, 394 patients met the secondary
prevention of SCD criteria. Among these patients, 236 (60%) had documented sustained ventricular tachycardia (VT), 98 (25%) had documented ventricular fibrillation (VF) and resuscitated SCD, and 60 (15%) experienced unexplained syncope and may be induced to VT or VF during the electrophysiological study. We performed a comparison of baseline characteristics based on the Chinese grouping criteria for BMI. Most of the variables were not significantly different, except that the obese population had a higher proportion of men, higher systolic and diastolic blood pressure, a greater proportion of ischemic cardiomyopathy, a higher proportion of hypertension, and a greater history of stroke (all $P < 0.05$).

**Influence of BMI on All-Cause Mortality**

The median follow-up was 5.0 years (interquartile, 4.1–6.0 years). During follow-up, 213 (22.0%) patients experienced all-cause
TABLE 2 | Association of BMI with all-cause mortality in different Cox proportional hazards models.

| BMI (kg/m²) | Model 1 | Model 2 | Model 3 | Model 4 |
|------------|---------|---------|---------|---------|
| Continuous | No. of death | HR (95% CI) | P-value | HR (95% CI) | P-value | HR (95% CI) | P-value | HR (95% CI) | P-value |
| Tertiles   |         |         |         |         |         |         |         |         |         |
| <22.1      | 213     | 0.98 (0.94, 1.03) | 0.4405 | 0.98 (0.93, 1.02) | 0.3507 | 0.97 (0.92, 1.02) | 0.1937 | 0.97 (0.93, 1.02) | 0.2644 |
| 22.1–24.4  | 126     | 0.87 (0.63, 1.20) | 0.4002 | 0.86 (0.62, 1.19) | 0.3560 | 0.80 (0.64, 1.25) | 0.5163 | 0.80 (0.63, 1.25) | 0.4991 |
| > 24.4     | 130     | 0.79 (0.57, 1.10) | 0.4405 | 0.77 (0.55, 1.07) | 0.1175 | 0.72 (0.51, 1.01) | 0.0571 | 0.72 (0.52, 1.04) | 0.0793 |
| P-trend value | 0.1645 |         |         | 0.1178 |         | 0.0560 |         | 0.0791 |
| WHO criterion |       |         |         |         |         |         |         |         |
| <25        | 245     | Reference |         | Reference |         | Reference |         | Reference |         |
| 25–30      | 100     | 0.82 (0.59, 1.13) | 0.2313 | 0.80 (0.57, 1.10) | 0.1692 | 0.72 (0.52, 1.01) | 0.0570 | 0.76 (0.54, 1.06) | 0.1048 |
| ≥30        | 7       | 0.99 (0.40, 2.40) | 0.9757 | 1.02 (0.42, 2.49) | 0.9685 | 0.89 (0.36, 2.20) | 0.8004 | 0.99 (0.40, 2.40) | 0.9757 |
| P-trend value | 0.3221 |         |         | 0.2701 |         | 0.0941 |         | 0.1296 |
| Asian criterion |       |         |         |         |         |         |         |         |
| <23        | 138     | Reference |         | Reference |         | Reference |         | Reference |         |
| 23–27.5    | 183     | 0.84 (0.64, 1.11) | 0.2186 | 0.82 (0.62, 1.08) | 0.1583 | 0.79 (0.59, 1.06) | 0.1129 | 0.84 (0.64, 1.11) | 0.2186 |
| ≥27.5      | 31      | 0.81 (0.46, 1.42) | 0.4679 | 0.77 (0.44, 1.34) | 0.3910 | 0.71 (0.40, 1.26) | 0.2433 | 0.72 (0.40, 1.29) | 0.2726 |
| P-trend value | 0.2181 |         |         | 0.1420 |         | 0.0870 |         | 0.0968 |
| Chinese criterion |       |         |         |         |         |         |         |         |
| <24        | 197     | Reference |         | Reference |         | Reference |         | Reference |         |
| 24–28      | 131     | 0.87 (0.65, 1.16) | 0.3286 | 0.84 (0.63, 1.12) | 0.2364 | 0.79 (0.59, 1.06) | 0.1105 | 0.80 (0.60, 1.08) | 0.1520 |
| ≥28        | 24      | 0.80 (0.42, 1.52) | 0.4888 | 0.79 (0.42, 1.50) | 0.4739 | 0.72 (0.38, 1.39) | 0.3335 | 0.73 (0.38, 1.42) | 0.3574 |
| P-trend value | 0.2694 |         |         | 0.2074 |         | 0.0901 |         | 0.1219 |

Model 1: adjusted for none. Model 2: adjusted for age, gender. Model 3: adjusted for variables in Model 2 plus NYHA, Class III/IV, primary prevention, ischemic cardiomyopathy, hypertension, diabetes mellitus, atrial fibrillation, LVEF, LVEDD, β-blocker, ACEI or ARB, a loop diuretic, aldosterone antagonists, dilated cardiomyopathy. Model 4 adjusted for all covariates presented in Table 1. HR, hazard ratio; other abbreviations are shown in Table 1.

Using different clinical classification criteria for BMI and the results remained consistent. Additionally, we analyzed different subgroups and the results were still robust (Figure 3).

A cubic spline function model and smoothed curve fitting (penalized spline approach) were performed to assess the dose-response association between BMI and all-cause mortality. The fully adjusted smoothed curve fit showed a linear relationship between BMI and mortality (p-value of 0.14 for the non-linearity test) (Figure 4), with the curve showing no statistically significant association between BMI and all-cause mortality (per 1 kg/m² increase in BMI, hazard ratio (HR) 0.97, 95% CI 0.93–1.02, p = 0.2644).

Univariate and Multivariate Risk Factors of All-Cause Mortality

Table 3 shows the univariate Cox proportional hazards models of all-cause mortality. Older age, NYHA class III/IV, primary prevention, ischemic cardiomyopathy, hypertension, diabetes, atrial fibrillation, lower LVEF, wider LVEDD, β-blocker, ACEI/ARB, a loop diuretic, aldosterone antagonist, and dilated cardiomyopathy were the univariate predictors of all-cause mortality in the overall group. Older age (HR 1.02; 95% CI 1.01–1.04; P < 0.001), NYHA Class III/IV (HR 1.55; 95% CI 1.1–2.19; P < 0.012), ischemic cardiomyopathy (HR 1.54; 95% CI 1.14–2.07; P < 0.005), wider LVEDD (HR 1.02; 95% CI 1.01–1.03).
FIGURE 3 | The association between BMI and all-cause mortality in subgroups. Abbreviations are shown in Table 1.

1.01–1.04; p = 0.01) were independent predictors of increased all-cause mortality.

DISCUSSION

Major Findings

The following are the main findings of study: (1) according to Kaplan–Meier curves and Cox proportional hazards models, BMI had no significant impact on all-cause mortality in the patients with ICD, whether as a continuous variable or a categorical variable classified by various BMI categorization criteria. (2) A linear relationship between BMI and all-cause mortality was identified with the curve showing no statistically significant association between BMI and all-cause mortality.

Compared With Previous Studies

This study applied various statistical methods for data analysis, all of which indicated that there was no obesity paradox in the Chinese ICD population. This is consistent with the results of a Spanish study (14). However, another research from the United States reported that low BMI was independently associated with death at 1 year (15). In the Multicenter Automatic Defibrillator Implantation Trial-II (MADIT II) study, a study of a retrospective analysis of patients with left ventricular dysfunction after myocardial infarction, obese patients (BMI ≥ 30 kg/m²) had a higher survival rate than non-obese patients (16). Another study in the United States found a greater benefit of higher BMI on survival in patients with ICDs, particularly in the older patients (17). The inconsistent results may be due mainly to differences in demographic characteristics, ethnic groups, sample size, or adjusted covariates. In addition, from the MADIT era (26), the pharmacological treatment and prevention strategies for heart failure optimize over the years (27), which may contribute to a lower rate of all-cause mortality. This may make it harder to observe associations of BMI and all-cause mortality. However, the obesity paradox does not appear to be present in
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Risk Factors Related to All-Cause Mortality Among Patients With an ICD

Our study found that older age, NYHA Class III/V, ischemic cardiomyopathy, and wider LVEDD were independent predictors of increased all-cause mortality. Compared with the patient in NYHA Class I/II, patients with NYHA Class III/V had a 55% increased risk of all-cause mortality. Higher NYHA Class was reported to be associated with a higher rate of 1-year all-cause mortality (15). Thus, our study extended the above findings to a 5-year follow-up, suggesting that the effect of cardiac function class, a very clinically assessable index, on all-cause mortality can last that long. This suggests that we need to pay more attention to the assessment and management of cardiac function class in patients with ICD. Similarly, we should improve the evaluation and management of patients with advanced age, ischemic cardiomyopathy, and left ventricular enlargement.

Clinical Implications

This study had some clinical implications. First, it clarified that the obesity paradox was not found in the Chinese with an ICD for the time being, adding evidence from the Chinese population to this controversial topic. Second, it illustrated that the Chinese ICD population as far as the results of this study are concerned.

### TABLE 3 | The univariate and multivariate risk factors of all-cause mortality.

| Variable                              | Crude model (HR (95% CI)) | P-value | Adjust model* (HR (95% CI)) | P-value |
|---------------------------------------|---------------------------|---------|-----------------------------|---------|
| BMI                                   | 0.98 (0.94–1.03)          | 0.44    | 0.97 (0.93–1.02)            | 0.262   |
| Male                                  | 1.2 (0.86–1.65)           | 0.246   | 1.05 (0.75–1.48)            | 0.778   |
| Age                                   | 1.03 (1.02–1.04)          | <0.001  | 1.02 (1.01–1.04)            | <0.001  |
| NYHA Class III/V                      | 2.49 (1.86–3.32)          | <0.001  | 1.55 (1.1–2.19)             | 0.012   |
| SBP                                   | 0.99 (0.98–1)             | 0.072   | 0.99 (0.98–1)               | 0.054   |
| DBP                                   | 0.99 (0.98–1.01)          | 0.398   | 1.09 (0.99–1.02)            | 0.586   |
| Primary prevention                    | 1.41 (1.06–1.87)          | 0.018   | 0.88 (0.61–1.27)            | 0.492   |
| CRT-D                                 | 1.59 (1.2–2.1)            | 0.001   | 0.9 (0.62–1.31)             | 0.58    |
| Ischemic cardiomyopathy               | 1.91 (1.46–2.5)           | <0.001  | 1.54 (1.14–2.07)            | 0.005   |
| Dilated cardiomyopathy                | 1.47 (1.1–1.96)           | 0.01    | 1.02 (0.73–1.44)            | 0.897   |
| Hypertrophic cardiomyopathy           | 0.46 (0.17–1.23)          | 0.121   | 0.87 (0.31–2.42)            | 0.793   |
| Long QT syndrome                      | 0.33 (0.05–2.36)          | 0.271   | 0.61 (0.08–4.5)             | 0.627   |
| Hypertension                          | 1.7 (1.29–2.23)           | <0.001  | 1.36 (0.99–1.86)            | 0.054   |
| Diabetes mellitus                     | 1.84 (1.28–2.66)          | 0.001   | 1.19 (0.8–1.77)             | 0.379   |
| Stroke                                | 1.58 (0.7–3.56)           | 0.27    | 1.09 (0.46–2.56)            | 0.852   |
| Atrial fibrillation                   | 1.61 (1.11–2.33)          | 0.012   | 1.19 (0.81–1.78)            | 0.382   |
| Pre-implant syncope                   | 0.84 (0.59–1.19)          | 0.326   | 0.95 (0.65–1.39)            | 0.788   |
| LVEF                                  | 0.97 (0.96–0.98)          | <0.001  | 1 (0.98–1.01)               | 0.609   |
| LVEDD                                 | 1.03 (1.02–1.04)          | <0.001  | 1.02 (1.01–1.04)            | 0.001   |
| β-Blocker                             | 1.46 (1.1–1.94)           | 0.009   | 1.28 (0.94–1.73)            | 0.113   |
| Amiodarone                            | 0.84 (0.62–1.13)          | 0.253   | 0.81 (0.58–1.13)            | 0.212   |
| ACE or ARB                            | 1.43 (1.09–1.87)          | 0.009   | 0.92 (0.68–1.25)            | 0.599   |
| Diuretic                              | 2.01 (1.54–2.64)          | <0.001  | 0.78 (0.42–1.44)            | 0.43    |
| Loop diuretic                         | 1.83 (1.39–2.41)          | <0.001  | 1.26 (0.8–1.97)             | 0.324   |
| Aldosterone antagonists               | 1.95 (1.49–2.55)          | <0.001  | 1.33 (0.84–2.1)             | 0.229   |

*Adjusted for all covariates presented in Table 1 except the independent variable itself. Abbreviations are shown in Tables 1, 2.
risk stratification for all-cause mortality based on baseline BMI was not desirable in the Chinese population with an ICD and that there was no need to focus specifically on the value of baseline BMI for the time being. Third, this study suggested that we should pay more attention to the patients with advanced age, ischemic cardiomyopathy, NYHA Class III/IV, and left ventricular enlargement.

**Strengths and Limitations**

The study had the following strengths. First, the study was a multicenter study with a relatively large sample size and good generalizability. Second, the study used multiple statistical methods to maximize the exploration of the relationship between BMI and all-cause mortality. Third, the study used various BMI grouping criteria to enhance the robustness of the results. However, the study had some limitations. First, the study was a retrospective observational study and there was some selection bias. Second, the study did not collect data on the blood tests, ECG, etc. that may have influenced the effect of BMI on mortality. We were unable to adjust for these substantial confounders; therefore, prospective studies that collect more variables are needed for further in-depth study. Third, in our study, we used conventional programming setting otherwise the proposed high-rate therapy and delayed ICD therapy were proposed in the Multicenter Automatic Defibrillator Implantation Trial-Reduce Inappropriate Therapy (MADIT-RIT) study (28). The effect of different programming settings on all-cause mortality should be considered. However, all the patients in our study received the same programming setting. So, the prognostic impact of the programming setting on each individual was close. Fourth, the relatively small number of obese patients in the study limited the generalizability of the findings. Last, in our investigation, we did not gather data on adiposity distribution (waist-to-hip ratio or waist circumference) or body fat percentage which were also indicators for obesity. However, it is undeniable that it is used in a wide range of studies (8, 10, 13–17) as a commonly used and easily accessible indicator. In the future, prospective studies that include larger sample sizes to ensure a balanced sample across groups and collect more indicators that respond to obesity are awaited to better illustrate the obesity paradox of all-cause mortality in the Chinese population with an ICD.

**CONCLUSIONS**

Using various statistical methods of analysis and different BMI grouping criteria, the obesity paradox in all-cause mortality did not emerge in the Chinese population with an ICD. Prospective studies are still needed to further explore this topic.

**DATA AVAILABILITY STATEMENT**

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

**ETHICS STATEMENT**

The studies involving human participants were reviewed and approved by Ethics Committee of Fuwai Hospital, the Chinese Academy of Medical Sciences (the lead institute), and all other collaborating organizations (Zhongshan Hospital, Fudan University, and so on). The patients/participants provided their written informed consent to participate in this study.

**AUTHOR CONTRIBUTIONS**

The study was conceived and designed by SZhang, MT, and BZ. The ICD was implanted by MT, KC, WH, YS, JY, ZL, and WX. The data were collected by SZhao. The data were analyzed and the manuscript was written by BZ, XS, and NY. The manuscript was revised by SZhang and MT. The final manuscript was read and approved by all authors.

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**SUPPLEMENTARY MATERIAL**

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fcvm.2021.730368/full#supplementary-material

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