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Cardiovascular disease risk by assigned treatment using the 2013 and 1998 guidelines for management of overweight and obesity

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Abstract

Objective—The 1998 and the 2013 guidelines on management of overweight and obesity in adults provided algorithms for identification of patients to be treated with weight loss. To date the cardiovascular disease (CVD) risk in the groups recommended or not recommended for weight loss treatment have not been estimated and compared.

Methods—Baseline data for the Atherosclerosis Risk in Communities study (ARIC) were collected between1987-9 from adults aged 45-64. Black and White men and women free of CVD were followed over 22.8 years (median), and 2,907 incident CVD events were recorded.

Results—The hazard ratios (HRs) adjusted for demographic variables in adults not recommended for treatment vs adults recommended for treatment were 0.54 (95% CI: 0.50, 0.59) for the 1998 algorithm and 0.63 (95% CI: 0.58, 0.69) for the 2013 algorithm, respectively. No gender or ethnic differences were detected when the 2013 algorithm was applied, but using the 1998 algorithm CVD risk between the groups recommended or not recommended for treatment were more pronounced in Black women than in Black men.

Conclusions—The 2013 algorithm performed similarly in Black and White men and women, but did not improve upon the 1998 algorithm in terms of discriminating risk of CVD.

Keywords

overweight and obesity; guideline; weight loss; cardiovascular disease

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Introduction

The 1998 "*Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults*" sponsored by the National Heart, Lung and Blood Institute (NHLBI) had far-reaching impact on the definition and treatment of excess body weight. The report established body mass index (BMI) cutoffs to define underweight (<18.5 kg/m), normal weight (18.5-24.9 kg/m), overweight (25.0-29.9 kg/m) and obesity (≥30kg/m). Waist circumference (WC) cutoffs to indicate increased risk of cardiovascular disease (CVD) were set at >88 cm in women and >102 cm in men. In November 2013, an update based on a systematic evidence review sponsored by NHLBI was released under the auspices of The American Heart Association, The American College of Cardiology and The Obesity Society entitled "Guideline for the Management of Overweight and Obesity in Adults". Both reports presented algorithms to guide health care providers in making weight management recommendations with the ultimate goal of preventing or treating CVD.

The algorithms relied heavily on the opinions of expert panels, and there was no direct connection drawn between each element used to determine patients in need of treatment and supporting evidence. Variables used in both algorithms included BMI, WC and traditional CVD risk factors. Differences between the 1998 and 2013 algorithms related to the choice, definitions and number of risk factors used to determine groups to be recommended for weight loss. Neither report, nor any other publication known to us, has presented CVD risk estimates for each of the categories of patients specified to be treated or untreated according to either algorithm. This information would contribute insight into the potential of the guidelines to impact CVD risk in the American population. The purpose of this study was to estimate the incidence of fatal and nonfatal CVD in Black and White adults by weight loss treatment recommendation according to the two algorithms using data from the Atherosclerosis Risk in Communities (ARIC) Study cohort.

Methods

Data for these analyses are from the ARIC study, a prospective, multi-center investigation of atherosclerosis in 15,792 Black and White men and women aged 45-64 years sampled from four US communities (Forsyth County, NC; Jackson, MS; Forsyth County, NC; Minneapolis, MN; and Washington County, MD) . Approximately 46% of the eligible participants in Jackson and 65% in the other three communities entered the cohort . Baseline data were collected in 1987-1989**.** The study was approved by the Institutional Review Boards (IRB) of the four field centers and the Coordinating Center; this analysis was approved by the IRB of the University of North Carolina at Chapel Hill.

Body weight was measured to the nearest pound using a beam balance scale with participants wearing a scrub suit. Height was measured to the nearest centimeter using a metal ruler attached to a wall and a standard triangular headboard with participants wearing no shoes. WC was measured at the level of the umbilicus with a metal or plastic tape to the nearest centimeter with the participant standing. Cardio-metabolic risk factors were measured using standard techniques .

Population subsets recommended for weight loss treatment

We used algorithms in the 1998 and the 2013 guidelines to categorize participants into those who were recommended for weight loss treatment and those who were not (Table S1). The 1998 guidelines recommended treatment for motivated adults with the following characteristics: (1) with obesity (BMI ≥30 kg/m); (2) overweight (BMI 25.0-29.9 kg/m) plus ≥2 CVD risk factors; or (3) high WC (>102 cm for men and >88 cm for women) plus ≥2 CVD risk factors. Risk factors included age (men: ≥45 years; women: ≥55 years or postmenopausal), smoking, hypertension (≥140/90 mmHg or use of antihypertensive medication), LDL-cholesterol ≥160 mg/dl or use of lipid-lowering medication, HDL-cholesterol <35 mg/dl, fasting glucose ≥110 mg/dl or use of hypoglycemic medication, and family history of premature coronary heart disease (CHD: definite myocardial infarction (MI) or death from heart attack at ≤55 years of age in father or other male first-degree relative, or ≤65 years of age in mother or other female first-degree relative).

The 2013 guidelines recommended weight loss for adults who are: (1) with obesity; or (2) overweight plus ≥1 CVD risk factor(s) or other obesity-related comorbidities. We did not include other obesity-related comorbidities because no clear definition was provided in the 2013 guidelines. CVD risk factors included: type 2 diabetes mellitus (here defined as fasting glucose ≥126 mg/dl or use of hypoglycemic medication), prediabetes (here defined as fasting glucose ≥100 to <126 mg/dl), hypertension (≥140/90 mmHg or use of antihypertensive medication), dyslipidemia (total cholesterol ≥240 mg/dl, LDL-cholesterol ≥160 mg/dl, HDL-cholesterol <40 mg/dl for men and <50 mg/dl for women, triglycerides ≥200 mg/dl or use of lipid-lowering medication), and high WC (>102 cm for men and >88 cm for women). More details on risk factor cutoffs are available elsewhere .

Ascertainment of incident CVD

CVD was defined as first-onset of fatal or non-fatal CHD event or ischemic stroke. CHD included cardiac death and nonfatal MI, silent MI and coronary procedures. We performed separate analyses excluding silent MIs and/or procedures, and similar patterns were observed. To ascertain incident cases, ARIC staff annually contacted partitipants' homes by phone, surveyed discharge lists from local hospitals and local obituaries, and reviewed vital statistics. Hospital charts were reviewed and abtracted, and death certificates were obtained. CHD and ischemic stroke were classified according to International Classification of Disease, Ninth Revision, and final determinations were adjudicated by cardiovascular experts. Participants were followed for events from baseline through December 31, 2011 and median follow-up time was 22.8 years.

Analytic sample

Per ARIC standard protocol, we excluded Blacks from Washington County or Minneapolis (n = 55) and participants who were not White or Black (n = 48) from the 15,792 participants. After excluding participants who were underweight (n=142), missing information on BMI or any CVD risk factors (n=1,008), had prevalent CHD or stroke (n=1,180), 13,359 individuals were included in the analysis.

Statistical analysis

We used age as the time scale and handled left truncation by adjusting the risk set, such that a participant was considered at risk for CVD at age t when he or she had not had a CVD event and was in the study at that age. We compared hazard ratios (HRs) for incident CVD across groups defined in the 1998 and 2013 guidelines using Cox proportional hazards regression models. The proportional hazards assumptions were tested and satisfied by visually examining the Kaplan-Meier Curves and the graphs of the log(-log(survival)) versus log of age at event or censor for each categorical variable. Primary models were adjusted for gender, race and field center. In order to keep the reference category consistent across all our analyses, we used participants with obesity as the reference as they were uniformly designated to be treated by both algorithms. To examine whether the HRs for the hazard in untreated relative to treated differed between the two guidelines, we tested the interaction between indicators identifying the guideline used (1998 or 2013) and the designated treatment group (treated or untreated) in a proportional marginal hazard model for clustered data adjusting for covariates. Each participant contributed two observations to the data set, one for the 1998 and one for the 2013 guideline. The two observations from the same participant were treated as a cluster, and a robust variance was used to take into account the correlation within a cluster. Analyses were performed using SAS, (version 9.4, SAS Institute, Cary, USA).

Results

Participants were on average 54.0 years of age, and the average BMI was within the overweight category (27.7 kg/m) (Table 1). BMI and WC tended to be highest in Black women and lowest in White women. Given that the intended age range in the ARIC cohort at baseline was 45 to 64, and that the age cutpoint named in the 1998 algorithm was >45 for men, essentially all men were in the older category. Blacks tended to have a higher prevalence of hypertension and diabetes and more favorable HDL-C levels compared to White of the same gender. Normal weight and overweight participants with more risk factors categories tended to be older at baseline(Table S2 and Table S3) and more likely to be smokers (Table S2) than those with fewer risk factors. Among those with ≥2 risk factors, normal weight participants had a greater prevalence of smoking compared to overweight participants (Table S2). Normal weight adults were less likely to have one or more cardio-metabolic risk factor(s) than adults with overweight or obesity (defined using the 2013 algorithm 69.9%, 91.2% and 99.5% in the 3 groups respectively). The overall crude incidence rate of CVD was 1,128 per 100,000 person-years. Up to 58.2% of participants were recommended for weight loss treatment by the 1998 guidelines, while this proportion was 63.0% for the 2013 guidelines. Fifty-four percent of participants were recommended for weight loss treatment by both algorithms (data not shown).

Figure 1 shows the HRs for the 9 subgroups defined by the 1998 algorithm adjusted for gender and ethnicity-field center. All 5 untreated groups were at lower risk of CVD compared to participants with obesity; however, normal weight-normal WC adults with ≥2 risk factors were at higher risk (less protected) compared to similar participants with <2 risk factors. Combined, the treated group without obesity had a HR similar to that of the group

with obesity, and the untreated group had a lower HR (0.52, 95% CI: 0.47, 0.57). Less than 2% of participants were normal weight - high WC with less than 2 risk factors, and with only 19 events, results in that group could be unstable.

HRs for CVD in the 5 subgroups defined by the 2013 algorithm are shown in Figure 2. CVD risk was lower in the combined untreated group compared to the group with obesity (HR=0.57, 95% CI: 0.52, 0.63), and also slightly lower in the treated group without obesity (HR=0.84, 95% CI: 0.77, 0.92). Among the three untreated groups shown in Figure 2, the normal weight with ≥1 risk factor(s) had the highest risk. Compared to participants with obesity, those recommended for weight loss by either or neither algorithm were at lower risk of CVD, with those recommended by the 2013 algorithm only having the lowest risk (HR: 0.37, 95% CI: 0.31, 0.46) (Table S4).

The HRs for the combined groups designated to be untreated compared to those treated (reference) are also shown by race-gender groups in Table 2. The interaction analysis adjusted for demographic variables (Model 1) indicated slightly more protective effect for untreated relative to treated using the 1998 compared to the 2013 guidelines in overall participants, Black women, White women and White men ($p < 0.01$ for all interactions). Further adjustment for smoking and family history of premature CHD (Model 2) attenuated the differences between the 1998 and the 2013 guidelines, but significant interactions remained in overall participants and Black women ($p < 0.05$ for both).

Race specific analyses that examined the 1998 guidelines showed effect modification indicating a lower (more protective) HR in Black women compared to Black men. This effect modification was seen in both models shown, but there were no gender interactions in Whites. Using the 2013 guidelines, there was no effect modification of the risk in the untreated compared to the treated by race or gender.

Discussion

In our analysis, both the 1998 and 2013 guidelines identified subgroups of adults for weight loss treatment that were at increased risk of CVD, and the overall HRs for the untreated vs treated indicated that the 1998 algorithm performed slightly better than the 2013 in the models that adjusted for demographic variables (HR: 0.54 (95% CI: 0.50, 0.59) vs 0.63 (95% CI: 0.58, 0.69) respectively). This difference was even smaller when models were additionally adjusted for family history of premature CHD and smoking: exposures known to increase CVD risk, which are not impacted by weight loss. We know of only one study that investigated different groups defined by the 1998 guidelines. Mason et al. examined 18,666 men from the Aerobics Center Longitudinal Study after an average of 10.3 years of follow-up and found that compared to men not recommended for weight loss, those recommended for weight loss were at increased risk of all-cause mortality (HR: 1.46 (95%CI: 1.20,1.78)) and CVD mortality (HR: 2.16 (95% CI: 1.53-3.04)). Although this study evaluated mortality rather than CVD events examined here, their results were consistent with our findings.

In our examinations of the subgroups defined by the 1998 and 2013 algorithms we assigned the group with obesity to be the reference because all members of that group were recommended for treatment by both algorithms, and the common reference group facilitated comparisons. The reference group with obesity included adults with and without cardio-metabolic risk factors, which is important to consider when making comparisons to groups without obesity stratified by risk factor status. If the reference group had been similarly stratified and composed only of participants with risk factors, there would have been greater discrepancies in risk between the reference and the untreated without obesity.

Three differences between the 1998 and 2013 algorithms are the application of WC, criteria for the number of CVD risk factors and the specific risk factors chosen for inclusion. The 1998 algorithm used WC to determine recommendations for weight loss in normal weight individuals with ≥2 risk factors; whereas, in the 2013 algorithm a high WC influenced the assignment only in the overweight with no other risk factors. Our analysis of the 1998 algorithm showed that normal weight individuals with ≥2 risk factors had about the same risk of CVD whether or not their WC was large. Using the 2013 algorithm, 9% of the overweight with ≥1 risk factor(s) had a high WC as their only risk factor. Since the 2013 algorithm required only 1 risk factor in that group, these participants would be recommended for treatment by that algorithm, but might not be by the 1998 algorithm.

The 1998 algorithm listed more and somewhat different risk factors compared to the 2013 version. As mentioned above, the 1998 algorithm included smoking and family history of premature CHD as risk factors, but the 2013 did not. In addition, the 1998 guidelines, but not the 2013 guidelines, included age as a risk factor placing greater emphasis on recommending weight loss in men over 45 years old and women over 55. Nevertheless, it has been shown that obesity in young adulthood is associated with increased risk of CVD, even after adjusting for subsequent weight change . In addition, up to at least the age of 75 , the difference in the absolute number of CVD deaths in the normal weight compared to participants with obesity is larger in older than younger adults, although the relative risk follows the opposite trend. This dichotomy is driven by the much higher rates of mortality in older compared to younger adults at every BMI level (including normal weight), and the impact of the uniformly higher death rates on estimates based on ratios compared to differences . Given all these issues, inclusion of age as a factor to indicate need for weight loss is not well justified. In fact, it may be better justified to alter the algorithm such that adults in old age (>80 years) would be less likely rather than more likely to be recommended for weight loss .

The 1998 algorithm provided clear definitions and cutoffs for cardio-metabolic risk factors including hypertension, impaired glucose tolerance, diabetes and high WC, but cut offs for dyslipidemia were less clear. In contrast, none of the cardio-metabolic risk factors were defined with operational precision in the report of the 2013 guidelines, and therefore our analysis relied on cutoffs cited by other expert groups. More detailed definitions would be helpful to researchers and may also assist health care providers, although it could be argued that the 2013, more general approach allows flexibility as new guidance on risk factors is released. We note that the recent controversy involving age and blood pressure cutpoints

does not impact the analysis here because the debate concerns identification of patients for pharmaceutical treatment of hypertension rather than the definition of hypertension , .

The intent of both obesity guidelines was to give primary care providers guidance on weight management decisions to reduce and prevent increased risk of CVD and obesity-related conditions. Inherent in this goal is not just identification of patients at increased CVD risk, but also identification of patients who will benefit from weight loss. The analyses presented here addressed only the first of these two goals. The recent review of meta-analyses and systematic reviews by members of the 2013 obesity guidelines expert committee supported the usefulness of weight loss in patients with overweight and obesity to reduce risk factors. They concluded that weight reduction of 5-10% with lifestyle treatment lowered risk of developing type 2 diabetes, improved levels of HbA1c, triglycerides, LDL-C and blood pressure and reduced the need for diabetes medication.

Nevertheless, the only large randomized trial to examine the effects of voluntary weight loss on CVD events resulted in null findings. In the Look AHEAD trial, more than 5,000 participants with type 2 diabetes were randomized into an intensive lifestyle intervention to promote weight loss or a diabetes support and education control group. After a median follow-up of 9.6 years, CVD rates were not reduced in the treatment compared to control group although several CVD risk factors were improved.

It is difficult to reconcile the impact of weight loss on CVD risk factor reduction with mixed evidence on CVD events. Evidence from previous studies is strong that elevated BMI is associated with increased risk factors, and that risk factors increase CVD rates . Also, the beneficial effects of weight loss on traditional CVD risk factors is well documented, and there is evidence that weight reduction through bariatric surgery is associated with a decrease in CVD events in subjects with obesity . However, evidence to support an effect of non-surgical intentional weight loss on CVD events is weak. The complex interplay between BMI, risk factors and CVD could involve the duration of elevated BMI and cardiometabolic risk factor exposures. Also, there could be residual deleterious effects of elevated risk factors that are not entirely resolved by their reduction. These possibilities point to the importance of prevention of risk factor development and, thus, suggest a potential value of weight loss in overweight adults with no risk factors; a group not recommended for treatment in either set of guidelines.

The 2013 guidance on management of overweight and obesity was part of a more comprehensive, long-term effort by NHLBI to provide evidence-based guidelines to promote CVD prevention in adults by periodically convening expert panels in critical areas. Review of the evidence to produce the 2013 obesity guidelines was conducted concurrently with reviews targeting blood cholesterol , lifestyle and risk assessment. Additionally, the 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults,was released by members appointed to the Eighth Joint National Committee (JNC8). Since the release of the 5 sets of most recent guidelines, several studies have been published that evaluated potential impact of these guidelines in a Western population, . One of these addressed the obesity guidelines and found that approximately 60%, or 133 million American adults were candidates for weight loss treatment according to the 2013 obesity

guidelines, an increase of 20.9% over the previous guideline. No other study has compared the observed risk of CVD events by weight loss treatment recommendations as stipulated by the new compared to the previ ous obesity guidelines, as we have done here.

Limitations of our study include lack of information on primary health providers' recommendations for weight loss and participant's intentional weight change, and therefore we cannot evaluate the association between a recommendation for weight loss and CVD risk. Further, we excluded patients who had a CVD event before the baseline examination from our analysis, thus our findings are not applicable to those patients. The research base used by the Guidelines Committee examined incidence of first event, and so our approach is consistent with the data reviewed. Our study has several strengths. The ARIC study is a biracial cohort representing diverse communities in the US.Other strengths include laboratory measurements of risk factors, a long period of follow-up (22.8 years) and carefully adjudicated CVD events determined using multiple sources of information including hospital records.

Ideally trial evidence would be generated to estimate the impact of implementation of the entire set of the five 2013 guidelines intended to assist caregivers in the prevention of CVD in their patients. Unfortunately, a definitive randomized trial with that goal is not feasible, and therefore researchers need to continue to generate useful, albeit imperfect, evaluations using observational data. Analyses such as those described here are needed by policy makers who will likely continue to weave together information from multiple types of research and expert opinion to evaluate the success or failure of the 2013 guidelines for the prevention of CVD and the promotion of health.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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What is known

- Guidelines were released in 1998 and updated in 2013 to help primary care providers identify patients in need of weight loss in order to reduce cardiovascular risk.

What this study adds

- Adults not recommended for weight loss were at lower risk of cardiovascular disease than adults recommended for weight loss, regardless of which guideline was used.
- Although risk of cardiovascular disease was similar in Blacks and Whites using the 1998 and the 2013 guidelines, in Blacks the gender difference in risk according to treatment assignment was reduced using the newer guidelines.

BMI category	Waist category	No. of risk factors*	n (%) of participants	No. of events	HR (95% CI)**
Obese (reference)			***3571 (26.7)***	***917***	***1***
Non-obese recommended for treatment			***4205 (31.5)***	***1189***	***0.93 (0.85, 1.02)***
Overweight	High	≥2	1893 (14.2)	485	0.94 (0.84, 1.05)
Overweight	Normal	≥2	1925 (14.4)	630	0.97 (0.88, 1.09)
Normal	High	≥2	387 (2.9)	74	0.76 (0.60, 0.97)
Not recommended for treatment			***5583 (41.8)***	***801***	***0.52 (0.47, 0.57)***
Overweight	High	<2	805 (6.0)	71	0.37 (0.29, 0.47)
Overweight	Normal	<2	687 (5.1)	69	0.32 (0.25, 0.41)
Normal	High	<2	250 (1.9)	19	0.33 (0.21, 0.52)
Normal	Normal	≥2	2239 (16.8)	519	0.79 (0.71, 0.88)
Normal	Normal	<2	1602 (12.0)	123	0.30 (0.24, 0.36)

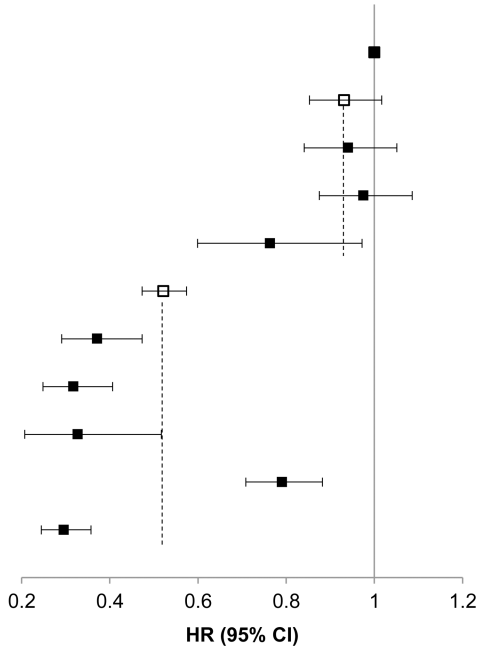

Figure 1.

Hazard ratios for cardiovascular disease by BMI, waist circumference and CVD risk factor categories defined in the 1998 Clinical Guidelines Open squares and closed squares represent 2 separate models using the category with obesity as reference. * Risk factors are age, smoking, family history of premature CHD, hypertension, high LDL-C, low HDL-C and diabetes. ** Adjusted for race-field center and gender.

BMI category	No. of risk factors*	n (%) of participants	No. of events	HR (95% CI)**
Obese (reference)		***3571 (26.7)***	***917***	***1***
Non-obese recommended for treatment		***4841 (36.2)***	***1200***	***0.84 (0.77, 0.92)***
Overweight	≥1	4841 (36.2)	1200	0.84 (0.77, 0.91)
Not recommended for treatment		***4947 (37.0)***	***790***	***0.57 (0.52, 0.63)***
Overweight	0	469 (3.5)	55	0.33 (0.25, 0.43)
Normal	≥1	3131 (23.4)	606	0.70 (0.63, 0.78)
Normal	0	1347 (10.1)	129	0.36 (0.30, 0.43)

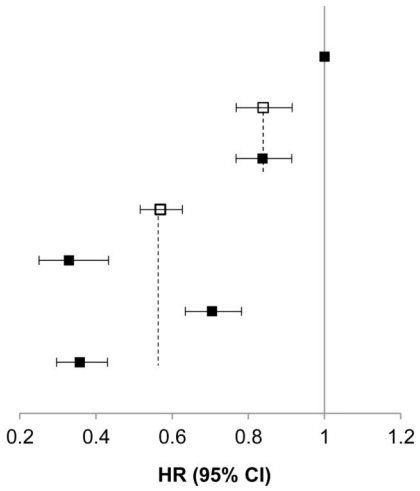

Figure 2.

Hazard ratios for cardiovascular disease by risk factor categories defined in the 2013 Clinical Guidelines Open squares and closed squares represent 2 separate models using the category with obesity as reference. * Risk factors are hypertension, dyslipidaemia, pre-diabetes, diabetes, and high waist circumference. ** Adjusted for race-field center and gender.

Table 1

Baseline characteristics of the Atherosclerosis Risk in Communities Study, 1987-2009

Characteristics	All	Black		White	
		Women	Men	Women	Men
		n (%)			
Analysis sample size	13 359	2 118 (63.0)	1 243 (37.0)	5 477 (54.8)	4 521 (45.2)
Incident CVD cases	2 907	400 (54.2)	338 (45.8)	815 (37.6)	1 354 (62.4)
		Prevalence (%)			
High age *	73.8	48.6	99.4	56.2	99.8
Current smokers	27.5	23.8	41.0	24.2	29.4
Family history of premature CHD *	21.0	18.0	11.8	24.7	20.4
Hypertension	36.2	57.7	52.3	31.3	27.6
Diabetes or glucose ≥110 mg/dl	20.7	28.2	27.6	14.6	22.8
Pre-diabetes (100≤FBG<126 mg/dl)	37.0	35.1	39.7	29.8	45.9
Diabetes (FBG ≥126 mg/dl or medication)	9.5	16.6	13.3	7.0	8.1
LDL-C ≥160 mg/dl or medication	27.1	28.5	27.8	25.3	28.5
HDL-C <35 mg/dl	12.7	4.0	13.2	5.5	25.4
Dyslipidemia	56.4	54.8	51.6	53.0	62.7
Waist (>102 cm for men; >88 cm for women)	50.7	76.9	28.2	57.9	35.8
		Median (IQR) / Mean (SD)			
Follow-up time (years)	22.8 (8.6)	22.8 (7.5)	21.0 (12.0)	23.1 (4.9)	22.2 (11.2)
Age at baseline survey (years)	54.0 (5.7)	53.2 (5.7)	53.6 (5.9)	53.9 (5.7)	54.6 (5.7)
BMI (kg/m^2)	27.7 (5.2)	30.8 (6.4)	27.6 (4.7)	26.7 (5.4)	27.4 (3.9)
Waist (cm)	97.0 (13.7)	100.6 (15.9)	97.0 (12.5)	93.3 (14.6)	99.8 (10.4)

* high age was defined as >45 y for men; >55 y or menopause for women.

Table 2

Hazard Ratios and Hazard rates (and 95% CI) for cardiovascular disease in adults not recommended versus recommended for weight loss treatment by the 1998 and the 2013 guidelines

	All (n= 13 359)	Black		White	
		Women (n=2 118)	Men (n=1 243)	Women (n= 5 477)	Men (n=4 521)
1998 Guidelines					
Hazard rate per 100,000 person years					
Not recommended for treatment	705	418	1146	471	1170
Recommended for treatment	1461	1183	1784	1034	1964
Hazard ratios					
Model 1 *	0.54 (0.50, 0.59) ‡	0.40 (0.30, 0.54) ‡ §	0.64 (0.50, 0.81)	0.53 (0.46, 0.62) ‡	0.59 (0.52, 0.66) ‡
Model 2 **	0.57 (0.53, 0.62) †	0.42 (0.31, 0.56) †§	0.64 (0.50, 0.82)	0.59 (0.51, 0.68)	0.61 (0.54, 0.69)
2013 Guidelines					
Hazard rate per 100,000 person years					
Not recommended for treatment	798	618	1163	557	1230
Recommended for treatment	1333	1044	1770	883	1880
Hazard ratios					
Model 1 *	0.63 (0.58, 0.69)	0.61 (0.45, 0.82)	0.65 (0.51, 0.83)	0.66 (0.57, 0.76)	0.64 (0.56, 0.72)
Model 2 **	0.61 (0.56, 0.66)	0.56 (0.41, 0.75)	0.61 (0.48, 0.78)	0.63 (0.55, 0.73)	0.62 (0.55, 0.70)

* Model 1: for all participants covariates included gender and ethnicity-field center; for ethnic-gender groups covariates included field center.

** Model 2: Model 1 plus smoking status and family history of premature CHD.

† P < 0.05 for difference in HR between 1998 and 2013 guidelines.

‡ P < 0.01 for difference in HR between 1998 and 2013 guidelines.

§ P < 0.05 for difference in HR between women and men within ethnicity. The difference was tested in race-specific datasets using models that included the covariates from model 1/model 2 plus the interaction of gender with treatment groups.