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Are the Current Diagnostic Criteria for Osteoporosis Appropriate for African- American Women Aged 50 Years and Older?

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Abbreviations: DEXA: Dual-Energy X-Ray Absorptiometry; BMD: Bone Mineral Density; WHO: World Health Organization; FRAX: Fracture Risk Assessment Tool; ISCD: International Society for Clinical Densitometry; NHANES: National Health and Nutrition Examination Survey; US: United States; SCORE: Simple Calculated Risk Estimation; NCHS: National Center for Health Statistics; NOF: National Osteoporosis Foundation; MEC: Mobile Examination Centers; BMI: Body Mass Index

ABSTRACT

Purpose: The purpose of this research study was to explore the feasibility of using ethnic specific normative values when calculating T-scores for African American women aged 50 years and older, to increase the diagnostic accuracy of osteoporosis in postmenopausal African- American women.

Methods: This was a retrospective descriptive study using secondary data. The sample derived from NHANES 2013-2014 and included 1,304 cases of Black and White women between the ages of 40 and 80 years old.

Statistical Analysis: SPSS 25 was used for statistical analyses. Survey-specific design and weights were used. Differences between means were calculated using t- tests.

Results: There was a statistically significant difference between T scores of Black and White women based on White women's norms ($p<0.05$). Effect size = 0.59. They also showed that there was a statistically significant difference between T scores of Black and White women when ethnicity- specific norms were used ($p<0.05$). Effect size was 0.41.

Conclusion: While this study highlights several potential shortcomings of the current standard of diagnosing osteoporosis using T scores, it does not prove that ethnic specific norms would necessarily rectify the inconsistences and gaps in the continuum of care for osteoporosis. Indeed, all women aged 50 years and older, regardless of race, should be considered at risk for osteoporosis.

Keywords: NHANES; Osteoporosis; Black or African American; T- Scores; Diagnosis

Introduction

Osteoporosis is a chronic disease marked by progressive deterioration of bone tissue, causing low bone mass, quality, and strength, which subsequently increases the risk of fracture. The skeletal system, being metabolically active, is naturally subject to a continuous process of cortical and trabeculae bone cell turnover and remodeling [1]. Disproportional activity between osteoblasts and osteoclasts, lack of mechanical loading, declining hormone levels, and poor diet can all lead to osteopenia and osteoporosis [1]. Osteoporosis increases in prevalence with advancing age and in women [1]. Peak bone mass is the amount of bony tissue present at the end of the skeletal maturation [2,3]. Skeletal maturation is typically completed in the third decade of life, while age related loss in bone mass begins in the fourth decade. This gradual process of bone loss is accelerated in women post-menopause, due to estrogen deficiency [2,3]. Additionally, prevalence is higher in Caucasian women is due to lower peak bone mass, especially when compared to African American women, thus making Caucasian a widely accepted non-modifiable risk factor for osteoporosis [1]. Despite the abundance of research reporting higher bone mass in African American women, clinical experts in the management of

bone health in postmenopausal African - American women remain ambivalent regarding the interpretation of T-scores produced by Dual-Energy X-Ray Absorptiometry (DEXA) for the diagnosis of osteoporosis.

While research concerning African American women and bone health offers some insight into the nuance of how determinants of bone health may present in various populations, the literature also leaves much to be explored. Furthermore, subjects of early research that helped establish current clinical practice regarding Bone Mineral Density (BMD), osteoporosis, and the predicative values of DEXA machines included very few, if any, African - American women [4]. The fact that this research largely excluded African American women suggests that, "these values [predicative values produced by densitometry machines] may not give providers the most accurate assessment of the risk of future osteoporotic fractures for their African-American patients" [5,6]. BMD, is used to calculate T scores, which the World Health Organization (WHO) uses to define, and diagnose, osteoporosis and osteopenia, as well as estimate fracture risk in postmenopausal women over 50 years of age. T scores are calculated by taking the difference between one's measured BMD and the mean BMD value of young healthy adults (reference population) and dividing it by the standard deviations of the gender- matched reference population. Under current guidelines by the International Society for Clinical Densitometry (ISCD), Caucasian women aged 20-29 years comprise the reference population of young healthy adults used to calculate T scores for all populations.

Current clinical practice guidance outlined by WHO defines osteoporosis as having a T-score of -2.5 and below, osteopenia if the value falls between -2.5 and -1, and normal/healthy if scores fall between -1 and +1 [7,8]. While BMD gives insight into factors contributing to bone structure and strength, the use of T-scores to diagnose osteoporosis in African American women presents some limitations. It is widely accepted that T scores depend on peak bone mass scores of healthy young adults in the reference population, yet research has shown that peak bone mass varies in different ethnic populations. Despite this variance, ISCD recommends that in North America, the BMD norms or young normal Caucasians be used to calculate T scores, regardless the subject's race [5]. Indeed, with research reporting greater mean peak BMD among young healthy African Americans (as much as 10-15% greater) in comparison to young healthy Caucasians, [9] the use of healthy Caucasian normative values in the calculation of T scores may call the diagnosis of osteoporosis in African - American women into question. Data from National Health and Nutrition Examination Survey (NHANES) III have already shown the importance of gender based normative values when calculating T scores from DEXA scans [6].

Researchers speculate that using ethnicity - specific T scores can result in more persons being diagnosed with low bone mass and osteoporosis despite a corresponding lower fracture risk at the same BMD as a White subject.6 Yet, this theory remains to be in African-American women. A study comparing the use of ethnic specific normative values on osteoporosis diagnosis in postmenopausal Chinese American women has posed similar issues. A study published by the International Osteoporosis Foundation reports that "a large portion of Chinese women [were] reclassified from osteoporosis to osteopenia [with the use of Chinese American BMD reference data]." This was reportedly because Asians tend to have lower BMD that Caucasian women, which further highlights the concept that using Caucasian normative values when calculating T score may lead to misdiagnosis of other ethnic groups [10]. Even though BMD is perhaps the most significant parameter used in measuring bone health, it has led to other measures of bone health such as Fracture Risk Assessment Tool (FRAX) and Osteoporosis Risk Simple Calculated Risk Estimation (SCORE). Perhaps is due to ambivalence surrounding T scores, that FRAX and SCORE were developed to increase the accuracy of predicting low impact fractures. The United States (US) version of the FRAX estimates 10-year fracture prediction using separate algorithms for Caucasian, Black, Hispanic, and Asian persons.

These scores are then, per National Osteoporosis Foundation (NOF) guidelines, used to define treatment eligibility through both elevated FRAX and low BMD [11]. The National Health Statistics Report states that clinical risk factors for fracture include previous fracture, parental history of fracture, cigarette smoking, high alcohol intake, glucocorticoid use, and rheumatoid arthritis [12]. Yet, FRAX algorithm reports show a 10-year risk of major osteoporotic fracture for White women two times higher than of White women with identical risk factors [11]. Indeed, by systematically lowering the risk of osteoporosis and fracture in Black patients, may in turn delay further evaluation and intervention with osteoporosis therapy in African American women, who are more likely to die after hip fracture, have longer hospital stays, and are less likely to be ambulatory at discharge [13]. Despite treatment guidelines deeming a FRAX score of 3% or greater eligible for osteoporosis treatment, 20% of White women and 12% of African American women who meet guidelines receive treatment [13]. The premise of this study was that the current standards of diagnosing osteoporosis, based on norms from Caucasian women, place African- American women at risk of being misdiagnosed and left out of the continuum of care for osteoporosis management.

Therefore, the purpose of this research study was to assess whether using ethnic specific normative values when calculating T-scores for African American women aged 40 to 80 years, is effective in diagnosing osteoporosis in postmenopausal African

American women. Specifically, this research attempted to answer the following questions:

a. In women 40-80 years old, would T-scores based on White women's norms be any different between Black and White Women?

b. In women 40-80 years old, would the T-scores of Black women using Black norms be any different than T-scores of White women using White norms?

c. In Black women 40-80 years old, would T-scores based on White women's norms be any different than T-scores based on Black Women's norms?

Methodology

Research Design

This study utilized data extracted from the 2013-2014 NHANES [14]. The National Center for Health Statistics (NCHS) has been responsible of conducting NHANES on periodic basis since 1971 [15]. Every year, approximately 7,000 people representing all age groups participate in an interview in their homes [15]. Approximately 5,000 of these people also participate in the health examination component of NHANES, which are typically conducted in mobile examination centers (MEC) [15]. The NHANES survey design employs a multistage probability sample, and its target population is the civilian, non-institutionalized United States (US) population [15]. It typically over-samples certain at-risk segments of the population (low-income persons, adolescents 12-19 years, persons 60 years of age and older, African Americans and Mexican Americans) [15]. The specific design, procedure and content of each survey are available on the internet: ttps://www.cdc.gov/nchs/nhanes/index.htm [15]. NHANES documents race/ ethnicity by self- report and uses the terms Black or African American interchangeably. Therefore, the authors of this study will also use these terms interchangeably.

Procedure

From the data collected in NHANES, the following parameters were utilized:

Demographics: Age, gender, race/ ethnicity.

Dietary Interview:

a. Total daily intake of vitamin D (D2+ D3) and Calcium.

b. Dietary supplements of total vit D and Calcium.

Examination:

a. Body measures: Height, weight, body mass index (BMI).

b. Dual-Energy X-ray Absorptiometry (DEXA) Scan: Total femur bone mineral density (BMD), FRAX score for femur fracture

c. Osteoporosis: Diagnosis, fractures, medicines

d. Physical activity questionnaire: Instances of moderate and vigorous activity

Statistical Analysis

SPSS 25 (IBM Corporation, Armonk, NY, US) was used for statistical analyses. Survey-specific design and sample weights were used in the statistical analysis. Differences between means were calculated using a two- tail t- test for independent groups or related groups as needed ($p<0.05$). Prevalence of osteoporosis was calculated using descriptive statistics.

Results

Description of the Sample

The sample derived from NHANES 2013-2014 includes 1,304 cases of Black and White women between the ages of 40 and 80 years old. (Table 1) summarizes the descriptive statistics of the sample.

Table 1: Descriptive statistics of the sample.

	Frequencies	Sample Percent
Gender		
Male	0	0.0%
Female	1304	100.0%
Total	1304	100.0%
Age (years)		
40-49	315	24.2%
50-59	313	24.0%
60-69	300	23.0%
70-80	376	28.8%
Total	1304	100.0%
Race/Ethnicity		
African American	392	30.1%
Caucasian	912	69.9%

Total	1304	100.0%
Weight Status (BMI)		
Underweight	21	1.7%
Normal	296	23.8%
Overweight	341	27.4%
Obese	588	47.2%
Total	1246	100.0%
Total Femur BMD		
Normal	41	4.1%
Osteopenia	289	28.6%
Osteoporosis	681	67.4%
Total	1011	100.0%
Hip FRAX, no previous fracture		
Low risk	1208	92.6%
High Risk	96	7.4%
Total	1304	100.0%
Osteoporosis*		
No	750	57.5%
Yes	554	42.5%
Total	1304	100.0%

Note: *Based on answer to the question have "you ever been told you have osteoporosis/fragile bones?"

Question One

Question one examined whether T-scores based on White norms statistically significantly differed between Black and White women, using a two- tail, independent T- test. The results showed that there is a statistically significant difference between the T scores of Black and White women based on White norms ($p<0.05$). The effect size is 0.59. Refer to (Table 2).

Table 2: Comparison of mean t-scores; Black & White Women using White norms.

Group Statistics	**Total Femur T-scores**				
Race	**Mean**	**Std. Deviation**	**Std. Error Mean**	**Percent**	
African American	-1.9622	1.54064	0.0006	12.9%	
Caucasian	-2.7823	1.40083	0.00021	87.1%	
				100.0%	
	Independent T-test for Difference of Means				**Effect Size: 0.59**
	t	**p-value**	**Mean Difference**		
Equal variances assumed	-1395.359	0.000	-0.82012		
Equal variances not assumed	-1300.277	0.000	-0.82012		

Question Two

Question two assessed the effect of using race specific normative values when calculating T-scores by examining whether there was a statistically significant difference between the T score of Black women based on Black norms and the T-scores of White women based on White norms, using a two- tail, independent T- test. The results showed that there is a statistically significant difference between the T scores of Black women based on Black norms and T scored of White women based on White norms ($p<0.05$). The effect size is 0.41. Refer to (Table 3).

Table 3: Comparison of mean t-scores; Black & White women using race- specific norms.

Group Statistics	Total Femur T-scores				
Race	**Mean**	**Std. Deviation**	**Std. Error Mean**	**Percent**	
African American	-2.2193	1.33969	0.00052	12.9%	
Caucasian	-2.7823	1.40083	0.00021	87.1%	
				100.0%	
	Independent T-test for Differences of Means				**Effect Size 0.41**
	t	**p-value**	**Mean Difference**		
Equal variances assumed	-976.113	0.000	-0.56301		
Equal variances not assumed	-1009.002	0.000	-0.56411		

Question Three

Question three assessed the effect of using race specific normative values when calculating T-scores in Black women by examining whether there was a statistically significant difference between the T score of Black Women based on Black norms and the T-scores of Black women based on White norms, using a two-tail, paired samples T- test. The results showed that there is a statistically significant difference between the T scores of Black women based on Black norms and T scored of White women based on White norms ($p<0.05$). The effect size is 0.34. Refer to (Table 4).

Table 4: Comparison of mean t-scores; Black women using White norms & Black women using Black norms.

Group Statistics	Total Femur T-scores				
Race	**Mean**	**Std. Deviation**	**Std. Error Mean**		
AA based on AA norms	-2.2193	1.33969	0.00052		
AA based on White norms	-1.9622	1.54064	0.0006		
				Effect Size 0.34	
	Paired Samples t-Test				
	t	**p-value**	**Mean**	**Std Deviation**	**Correlation**
	3310.334	0.000	0.2571	0.20095	1.00

Discussion

The purpose of this research study was to explore the feasibility of using ethnic specific normative values when calculating T-scores for African American women aged 50 years and above, to increase the diagnostic accuracy of osteoporosis in postmenopausal African-American women. The first question one examined whether T-scores based on White norms were statistically significantly different between Black and White women. The results indicate that, based on the current standards of using White women's norms to calculate T scores, Black and White women's T scores were statistically significant at $p<0.05$. Although this result did not support the notion that there would be no difference between the T scores of the two populations, it supported claims from some previous studies that Black women have higher BMD than White women [3,1]. The moderate effect size (0.59) of these results suggests that this difference is strong enough to make an impact clinically. For example, T scores derived from a reference population that most closely fits the subjects in which T score are being calculates for, leads to more accurate values [16,17]. In saying this, it can be postulated that since postmenopausal White women fit the description of the reference population more closely than postmenopausal women of other ethnicities, they therefore may have more accurate T scores. Indeed, perhaps T scored derived using WHO's current standards are inherently more accurate for White women, as evidenced by less variability of T scores among White women in the sample even though in the sample White women outnumbered Black women approximately seven to one.

Furthermore, with higher mortality rates following hip fractures(a sequelae of osteoporosis), [13] and some studies reporting that Black women over the age of 75 years lose bone mass at a higher rate than their White counterparts, [13] it is critical to ensure that that these differences are interpreted from a public heath perspective considering that Black women have higher morbidity and mortality rates following hip fracture 12 and are underrepresented in studies investigating osteoporosis. The second question two assessed whether using race specific normative T-scores yielded a statistically significant difference between the T score of Black women based on Black norms and the T-scores of White women based on White norms. The results indicate that when ethnic specific norms are used to calculate the T scores, Black and White women still have significantly different T scores. It is also worth noting that using specific norms decreased Black women's average T score from -1.9622 to -2.2193, thus placing them closer to both the T scores of White women and receiving a diagnosis of

osteoporosis. Like question one, this result supports the literature in that Black women have higher BMD, and therefore T scores than White women. 9,15,16 However, it is important to note that these results are contrary to ISCD's premise for recommending that in North America, the White normal be used to calculate T scores for every ethnic group "because race-adjusted T scores results in similar prevalence of osteoporosis in every racial group" [7].

This suggest that the WHO's current standards of diagnosing osteoporosis, in accordance with ISCD recommendations, may be based on a theory that as of NHANES 2013-2014 data, is not evident— the theory that using White norms for T scores result in similar osteoporosis prevalence in all ethnicities. The fact that Black women's T scores decreased by 0.2571 after ethnic specific norms were used, suggests that Black women who may be at risk for osteoporosis due to low T scores, may be misdiagnosed as having osteopenia (T scores between -2.5 and -1) instead osteoporosis (T scores below -2.5), and therefore left out of the continuum of care for osteoporosis. The fact that using ethnic specific norms bring the average T scores of both groups closer together and reduces the effect size (0.41), suggests that ethnic specific norms may be a method of better standardizing T scores across various ethnicities. Question three assessed whether T scores in Black women based on Black norms were statistically significantly different than the T-scores of Black women based on White norms. The results indicate that there is a statistically significant difference between the T score of Black Women based on Black norms and the T-scores of Black women based on White norms. These results further counter the premise behind WHO's current position that using ethnic specific norms produces similar results as using White norms for all ethnicities. It is interesting to note that the effect size was reduced even more (0.34.).

This may not only support the idea that T scores are more accurate when calculated using reference populations that is not significantly different from the population for whom T scores are being calculated, 7,17 and that T score values are more consistent when ethnic norms are used. By showing a statistically significant difference between T score of Black women based on Black norms and Black women based on White norms, the results of this study contradict the supposition behind current standards of diagnosing osteoporosis. Indeed, using White norms to calculate T score of all ethnic groups systemically increases the odds of postmenopausal Caucasian women being diagnosed with osteoporosis, while simultaneous lowering the odds of postmenopausal African American women being diagnosed with osteoporosis. By placing Black women further away from the continuum of care for osteoporosis, these current standards set by the ISCD and WHO16 have the potential of further perpetuation Black women's already existing higher morbidity and mortality rates following hip fracture. Furthermore, the precedence set by the NIH listing Caucasian as a non-modifiable risk factor for osteoporosis, creates a consensus in healthcare that osteoporosis does not affect Black women. This consensus has the potential of making healthcare professionals less inclined to pursue further evaluation into BMD for Black women, thus potentially thwarting prevention efforts for Black women who may be at risk for osteoporosis.

The issue with this consensus is two-fold: it uses race as a proxy for genetics despite the controversy surrounding the use of race in medicine and secondly, its intensities structural socioeconomic conditions in which medical attention is directed to White patients rather than ethnic minorities thus perpetuating existing health disparities. Despite the obvious interpretation of the results of this study, the safety and effectiveness of using race- specific standards for the diagnosis of osteoporosis in African- American women have not been established. It is possible that by increasing the number of African- American women being diagnosed with osteoporosis it could also unnecessarily expose them to the potentially dangerous adverse effects of the drugs that treat osteoporosis. The authors recommend that all postmenopausal women, regardless of race, be treated as they are at risk for osteoporosis, to counter already existing healthcare disparities by ensuring that Black women at risk of osteoporosis enter the continuum of care for osteoporosis. The following limitations were identified in this study: Based on the type of data required, only one cycle of NHANES was available for this study. NCHS recommends at least two NHANEs cycles. Therefore, due to the use of only one cycle of NHANES, the accuracy and of the population estimates poses a limitation to the study. Since this study was secondary data research, the authors lacked control over, assessed variables and data collection, which limited the research questions that the authors could generate.

Finally, due to the observational nature of this study the results show association between variables and not cause and effect. This study should be replicated with at least two more recent cycles of NHANES cycles of NHANES the accuracy of population estimates. Additionally, randomized clinical trials are necessary to establish cause and effect relationships. Lastly, further research is warranted to assess the safety and effectiveness of using race- specific diagnostic criteria for osteoporosis in African- American women. Without well-rounded data that is both specific and reliable to include marginalized communities, we are likely to overmedicate women of color or underestimate fall risk in the same population. It is imperative that healthcare providers continue to draw attention to these research disparities in interdisciplinary conversations, and that every plan of care is inclusive of the multiple factors contributing to a woman's bone health over the age of 50. The research is promising, but we cannot allow what we know today to stop us from learning and doing more.

Declarations of Interest

None.

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