PREDICTION OF BODY FAT AMONG ETHNIC GROUPS

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A. Study Purpose and Rationale:

Over the years there have been a multitude of methods and equations designed to predict body fat percentage (BF%) for the purpose of estimating the cardiovascular (CV) risk of being overweight or obese. Many of these methods, however, are quite cumbersome and cannot be performed directly by primary care physicians (PCPs). For example, skin fold thickness requires precise measurements using calipers applied at a specific pressure. Hydrostatic weighing and bioelectrical impedance require facilities and equipment not readily available in most PCP offices. Waist circumference measurements, while not cumbersome, are controversial predictors of CV risk as it has only been validated as a risk factor independent of body mass index (BMI) in women(1,2)and underestimates total visceral adiposity in both Chinese and South Asian men and women.(3)

Given the rudimentary measurements BMI requires, it has become the most widely accepted measure of obesity by the primary care community. The original definition of obesity as a BMI of 30kg/m^2 came from data in Caucasian men and women and correlated with a BF% of 25% and 35% respectively(4). The use of BMI as a marker for obesity stems not from its accuracy in estimating BF%, but from morbidity and mortality associated with a BMI>/=30kg/m^2 in this population(5,6). More recent data that is inclusive of African-Americans (AA) shows that a reduction in longevity does not occur in AA women until a BMI of >/=37mg/m^2 and >/=33kg/m^2 in AA men(7). This would suggest that BMI does not accurately predict BF% in AA men and women. The TIGER study(8) used DEXA imaging as the referent standard and also found that BMI overestimated overweight/obesity prevalence in AA men and women and underestimated prevalence in Asian-Indian men and women, Asian women and Hispanic women.

Dual-energy X-ray absorptiometry (DEXA) is a highly reproducible and valid method of measuring fat mass *(Figueroa-Colon et al, 1998; Wang et al, 1998; Wells et al, 1999)*, however its utility and the cost-effectiveness on a population level has yet to be elucidated. Larsson et al(9) used DEXA to optimize prediction equations for BF% and yielded equations using few anthropometric measures in men and women that were validated in subsequent groups. While the data is convincing, it was conducted in a homogeneous population of Swedish citizens and, therefore, may not be applicable to a more diverse population.

Since simple anthropometric measures alone do not accurately predict BF% across all ethnicities, universal predictions of CV risk are flawed. We hypothesize that direct measurement of BF% by DEXA can be used to extrapolate more accurate equations for predicted BF% based on few anthropometric measures and ethnicity. It is our hope that these equations can be applied on population level by PCPs.

B. Study Design and Statistical Procedures:

We will perform a cross-sectional study of patients and employees at Columbia University Medical Center (CUMC). Study participation will be completely voluntary and subjects will sign informed consent during the first encounter after the goals and objectives of the study have been thoroughly explained. We will recruit subjects during a one year period in order to develop a primary study group and a validation group. The primary study group will be recruited during the first six months of the study and will be used to develop anthropometric-based equations to predict BF%. The validation group will be recruited during the last six months of the study period to test the equations developed in the primary study group.

Participants will be asked to fast overnight prior to their examination day. They will report to the study site at an assigned date and time to record age, sex, self-described ethnicity and anthropometric measures of height, weight, waist and hip circumference. They will then proceed to DEXA scanning for absolute measurement of BF%. Once the DEXA scan is complete, participation in the study will be complete.

Since there is no predefined outcome measure we can only hypothesize a sample size of approximately ten patients per variable in the proposed analysis of each ethnic group. A total of six variables (age, weight, height, BMI, waist circumference and hip circumference) will be analyzed; therefore, we propose a sample of size of 60 subjects per ethnic group (Caucasian, African-American, Hispanic, South Asian and East Asian). This amounts to a total of 300 subjects needed for the primary study group. If all stated variables are found to be significant in the subsequent regression equations, an additional 300 subjects will be needed for the validation group.

Multiple regression analyses will be performed to develop anthropometric-based multivariate equations predicting BF% in both the primary study group and the validation group - significance will be determined by regression coefficients closest to 1.0 (+/- SD). Backward elimination of the variables will be completed to eliminate variables that are not significant.

C. Study Procedures:

Study subjects will report their birth date, sex and ethnicity using a coded demographic form. They will have anthropometric measurements taken while dressed in underwear. Height will be measured while standing barefoot with their backs to a wall-mounted stadiometer to the nearest 0.01m. Weight will be measured to the nearest 0.1kg with the same calibrated scale. Waist circumference will be measured in cm at the end of normal expiration at the level of the navel. Hip circumference will be measured in cm at the level of the trochanter femoris. DEXA scanning will be completed with subjects dressed in hospital gowns.

D. Study Devices:

There are currently 4 DEXA scanners available at CUMC (3 *Hologic* and 1 *Lunar*) capable of computing total body composition. The weight limits for the machines are 300lbs and 350lbs, respectively. A total body scan can be completed in ~10-20mins. Body composition can be computed in a three compartment model – body fat, lean tissue mass and bone mineral content.

E. Study Questionnaires: N/A

F. Study Subjects:

Inclusion criteria include men and women 18-65yo. Exclusion criteria include pregnant women, subjects unable to stand erect unassisted for height and weight measurements, subjects unable to lie flat for DEXA scanning, subjects who have had contrast imaging within 7 days of their scheduled DEXA and subjects >300-350lbs.

G. Recruitment:

Subjects will be recruited from CUMC clinics with permission of their PCP. CUMC employees will be recruited through recruitment posters placed throughout hospital locations.

H. Confidentiality of Study Data:

All study data will be coded to ensure confidentiality of study participants.

I. Potential Risks:

The average radiation dose received from a single DEXA scan is 1-3mrad *(Lang et al. 1991)*. For comparison, a standard chest x-ray has exposures of 8-10mrad *(Kellie 1992)*. Therefore, DEXA can be considered relatively safe in non-pregnant patients.

J. Potential Benefits:

This study hopes to develop a more accurate prediction equation for BF% across ethnic groups, which can subsequently be used to predict CV risk.

K. Alternatives:

It may be possible to use pre-existing equations to estimate BF%. For example, Hodgdon and Beckett of the Naval Health Research Center have developed equations for predicted BF% in men and women based on waist, height, neck and hip measurements. However, the referent standard of BF% for these equations and validation among varied ethnic groups in unknown. An alternative approach for this project would be to simply test Hodgdon and Beckett or other established equations for BF% to see if they can be validated across different ethnicities.

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