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Discordance between Body Mass Index (BMI) and a Novel Body Composition Change Index (BCCI) As Outcome Measures in Weight Change Interventions

Stephen D Nugent[1], Gilbert R Kaats[2*], Harry G Preuss[3]

[1]Mannatech, Inc., Coppell Texas, USA

[2]Integrative Health Technologies, Inc., San Antonio, Texas, USA

[3]Georgetown University, Washington DC., USA

[*]**Corresponding author:** Gilbert R Kaats, Integrative Health Technologies, Inc., San Antonio, Texas, USA. Fax: +12103906142; Tel: +12108244200, +12108612400; E-mail: grk@ihtresearch.com

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Abstract

Objective: There is a general assumption that changes in the BMI are due to changes in Fat Mass (FM). However, the BMI fails to distinguish the type of weight lost or gained-(FM) or Fat-Free Mass (FFM). In contrast, a proposed Body Composition Change Index (BCCI) is a single statistic reflecting composite positive or negative changes in FM and FFM. This study examined the discordance between using the BMI versus the BCCI as outcome measures.

Methods: Data were obtained from 3,870 subjects who had completed DEXA Total Body scans when participating in weight loss interventions. Since height remained constant in this adult cohort, BMI changes were identical to scale weight changes($r=0.994$) and were reported as lbs. to match the statistic used for calculation of the BCCI. Weight losses were scored as positive outcomes, gains as negative. To calculate a BCCI, increases in FFM (lbs.) and decreases in FM (lbs.) were scored as positive outcomes, decreases in FFM and increases in FM as negative. The BCCI is the sum of these positive and negative outcomes. Differences between scale weight changes and BCCI values were subsequently calculated to obtain a “Discordance Score.”

Results: Discordance scores ranged from 0.0 lbs. to >30.0 lbs. with a mean absolute value of between the two measures of 7.79 lbs., (99% confidence interval: 7.49-8.10, $p<0.00001$), SD=7.4 lbs. Similar discordance scores were also found in sub-groups of self-reported gender, ethnicity and age.

Conclusions: A statistically significant difference of 7.79 lbs. was found between assessing the success or failure of weight loss interventions using the BCCI versus using the BMI. Use of the BCCI reflecting the kind, not just the amount, of weight change could contribute to improved diagnostic and treatment precision.

Keywords: Body Composition; Body Fat; Bone Mineral Density; Body Composition Change Index; Fat-Free-Mass

Introduction

The BMI calculated from body weight in kilogram divided by square of height in meters, is a widely used statistic to assess overweight and obesity. In fact, it has become the most widely used assessment of weight status and change in epidemiology, clinical nutrition, and research since it was first suggested in 1835. Its popularity was further enhanced after it was reported to correlate with body fat estimates derived from skin fold measurements. More recently, use of the BMI has become the basis of weight-loss guidelines set forth by the World Health Organization, Institute of Medicine and the US Department of Health and Human Services [1]. The BMI has important limitations despite its general popularity and widespread use as an estimate of changes in FM. As the

U.S. Centers for Disease Control concludes, the BMI can be used as a screening tool but is not diagnostic of the body fatness or health of an individual. It is unreliable for athletes or individuals with high muscularity [2].

However, in spite of its endorsement of using the BMI, the National Heart and Lung Institute cautions that the BMI may overestimate FM in athletes and underestimate FM in older people, particularly those who have sarcopenia or age-related depletion of FFM [3]. However, for people of all ages, the BMI is only a surrogate estimate of FM, not a measurement of FM and generally accounts for only about 33% of the variance associated with actual measurements of FM.

When used as a measure of change in studies involving adult subjects, the BMI provides essentially the same information as changes in scale weight since height remains constant in most adult studies. The BMI also fails to distinguish changes in FFM from changes in FM. The increasing use of imagining techniques such as DEXA have highlighted the importance of FFM as independent predictors of morbidity and mortality and health [4] underscoring the need to assess an intervention's effect on FFM.

A measurement assessing changes in both FM and FFM could offer a more comprehensive view of the effects of interventions and treatment plans where changes in body weight are important considerations. We propose the use of a Body Composition Change Index (BCCI)--a single statistic reflecting net or combined positive or negative changes in both FM and FFM. The BCCI is obtained by scoring gains of FFM and losses of FM as positive, losses of FFM and gains of FM as negative. The BCCI is the sum of these positive and negative outcomes. The goal of this study was to determine if there were significant differences between uses of the BMI versus the BCCI as outcome measures.

Method

Over the past 40 years, one of the authors (GRK) has compiled a 40-year Longitudinal Database of Medical Biomarkers that includes over 25,000 total body scans using GE Lunar's dual-energy DEXA, DPX-IQ and DPX-NT bone densitometers (Madison, WI). All DEXA scans in the database were completed by one of three trained and certified DEXA technologists with repeated interrater reliability in excess of 96%. GE Lunar certified that the reliability of DEXA scans were typically ±98%-- a figure consistent with our own calculations. Height was obtained from stadiometer measurements and body weight using Be Four Strain Gauge Scales, Model FS0900 (Saukville, WI) that was certified by the manufacturer as reliable within ±1/10th of a pound with a reliability coefficient of 0.99 for participants weighing up to 400-pounds. Scale accuracy was periodically cross-checked with known reference weights and independent certifications and was found to support the manufacturer's specifications.

The data used in this study were obtained by selecting from the database all subjects 18 to 85 years of age who had completed baseline and ending DEXA scans of Fat Mass (FM) and (FFM) while participating in a variety of studies longer than 30 days. All subjects in this cohort had previously participated in studies approved by Institutional Review Boards certified by the Health and Human Services Office of Human Protection Services. In conjunction with their participation, all subjects gave written consent to use their redacted data for future research.

The initial selection yielded 4,113 subjects. Although not statistically representative of a U.S. national population sample, the dataset contained measurements from residents of all 50 states and the major ethnic groups. The dataset was subsequently audited to eliminate duplicates, test periods less than 30 days, and inconsistencies between baseline and ending demographic data. Scale weights, measurements of FFM and FM were also examined to ascertain whether distributions was normal using a test for normality. If the assumption of normality was not met, the appropriate logarithmic transformations were used. Outliers were defined as values below -3.29 or above 3.29 standard deviations and were removed from the study cohort along with study periods of less than 30 days. Using these criteria, 131 subjects (3%) were deleted from the original dataset. Additionally, using a definition of outliers as univariate values ±3.29 standard deviations from the mean of their baseline or ending body mass measurements (scale weight, FM and FFM), 112 additional subjects were deleted from the dataset. A total 243 subjects, (6%) were deleted from the original dataset of 3,987 in accordance with the above criteria leaving 3,870 subjects in the final cohort.

Two change scores were calculated for each subject: baseline and ending changes in scale weight and a Body Composition Change Index (BCCI). A correlation between scale weight changes and the BMI suggested that they were virtually identical (r=0.994). Therefore, since height remained constant, to provide comparable statistics in pounds for comparisons between the BMI and BCCI, scale weight changes were used in place of the BMI statistic.

The BCCI was calculated using each subject's DEXA baseline and ending measurements of FM and FFM scoring losses of fat and gains of FFM as positive outcomes and gains of FM and losses of FFM as negative outcomes. The BCCI is the net result of summing these calculations. For example, a subject losing 4.0 lbs. of FM and gaining 2.0 lbs. of FFM would receive a BCCI of +6.0. A subject gaining 4.0 lbs. of FM and losing 2.0 lbs. of FFM would receive a BCCI of -6.0 lbs. A comparison of baseline and ending heights revealed virtually no change in height during the study period.

Losses in scale weight were scored as positive outcomes, while gains in scale weight were negative outcomes. To compare differences between the BCCI and scale weight changes, a Discordance Score (DS) between the BCCI and scale weight changes was also calculated for each subject. The DS represented the net difference (in lbs.) between scale weight changes and the BCCI. For example, a -4.0lb. weight loss was scored as a +4.0-positive outcome, a gain of +4.0 lbs. as a negative outcome. However, if the -4.0lb. loss was the result of a loss of 4.0 lbs. of FFM, the BCCI was scored as a -4.0lb. negative outcome. Thus, there was 8.0 lb. discordance between the two outcome measures. But, if the 4.0 lb. weight loss was the result of a 4.0 lbs. depletion of FM, the discordance between the two measures was ±0. Figure 1 provides examples of how a 10.0 lb. weight loss can result in different BCCIs and discordance scores.

Subject	Baseline			Ending			Change			Outcome		Differ-ence Score	Discord-ance Score*
	WGT	FM	FFM	WGT	FM	FFM	WGT	FM	FFM	WGT (BMI)	BCCI		
1	160	42	118	150	32	118	-10	-10	0	+10	+10	0	0
2	160	42	118	150	30	120	-10	-12	+2	+10	+14	+4	4
3	160	42	118	150	36	114	-10	-6	-4	+10	+2	-8	8
4	160	42	118	150	27	123	-10	-15	+5	+10	+20	+10	10
*All discordance scores are based on absolute values.													

Figure 1: Examples of consistent 10.0 lb. weight losses can be a function of different body composition chang-es and discordance scores.

With regard to using absolute values for the discordance scores, there is general agreement that increases in FM and decreases in FFM are negative treatment outcomes, decreases in FM and increases in FFM are positive treatment outcomes. Therefore, if one assumes the BCCI is a more valid outcome measure than scale weight or BMI, discordance scores could also be viewed as “Error” scores of weight losses and BMI changes. Additional analyses were also conducted to examine DS as a function of baseline self-reported age, gender and ethnicity.

Results

Shapiro-Wilks test of normality revealed that the data were not normally distributed (p<0.001). However, as Howell [5] has suggested, the t-test is robust, despite violations of normality for large sample sizes. Additionally, for the independent sample t-test, the Welch t-statistic was used, which does not assume equal variance or normality. With regard to ANOVA and MANCOVA, a Levene’s test revealed that the assumption of homogeneity of variance was violated. However, as Stevens [6] points out, these analyses are also robust despite violations of equality of variance. The distribution of the discordance scores is shown in Table 1 below.

Discordance Range	Number in Each Range	% of Data Set in each range
30+	57	1.5%
25–30	53	1.4%
20–25	95	2.5%
15–20	270	7.0%
10–15	578	14.9%
5–10	1167	30.2%
4–5	294	7.6%
3–4	329	8.5%
2–3	342	8.8%
1–2	322	8.3%
0.1–1	326	8.4%
0–0.1	37	1.0%

Table 1: Discordance Scores Between Scale Weight Changes vs. the BCCI (N=3,870).

The mean discordance score between using scale weight versus the proposed BCCI was 7.79 lbs., SD=7.4, p = <.00001. To examine the extent to which the conclusions drawn from this study were affected by baseline self-reported gender, ethnicity, and age, the same analyses were also calculated for these sub-groups shown in Table 2 below.

Variables	n	%	Mean	SD
Gender				
Male	890	23%	9.7	9.2
Female	2,980	77%	7.2	6.6
Ethnicity				
Asian & Other	110	3%	7.5	7.7
Black	114	3%	7.9	5.8
Hispanic	318	8%	6.9	5.6
White	3,328	86%	7.9	7.5
Age				
18-24	207	5%	7.0	5.4
25-44	1,523	39%	7.6	7.1
45-64	1,866	48%	8.1	7.8
65-85	274	7%	7.1	6.5

Note. Percentages may not add up to 100 due to rounding.

Table 2: Frequencies & Percentages of Self-Reported Ethnicity, Gender & Age (N=3,870).

With regard to gender, a between-groups t-test showed that females had a significantly lower mean discordance score than males, p< .001. Results of an analysis of variance (ANOVA) of discordance scores by age are shown in Table 3.

Source of Variation	SS	df	MS	F	P-value	F crit
Between Groups	512.5	3	170.8	3.2	0.02	2.6
Within Groups	208,609.1	3,866	54.0			

Table 3: ANOVA of Discordance Scores by Age.

T-tests were conducted between each of the four age categories and found significant differences between the 18-24 age group and the 45-64 age group (p=0.046), the 25-44 age group and the 45-64 age group (p=0.048), and the 45-64 age group and the 65-85 age group (p=0.04), but found no significant differences between the 18-24 age group and the 25-44 age group (p=0.24), the 18-24 age group and the 65-85 age group (p=0.87), and the 25-44 age group and the 65-85 age group (p=0.27).

An ANOVA of discordance scores by ethnicity is shown in Table 4 reveals that there were no significant differences in discordance scores as a function of ethnicity. However, a student t-test between Hispanics and Whites revealed that Hispanics had significantly lower discordance scores than white subjects (p=0.02). None of the other inter-group comparisons reached statistical significance.

Source of Variation	SS	df	MS	F	P-value	F crit
Between Groups	282.5	3	94.2	1.7	0.16	2.6
Within Groups	208,839	3,866	54.0			

Table 4: Results of ANOVA for Discordance by Ethnicity.

Discussion

As shown in Table 2, although not precisely representative of the public at large, this large cohort contains a diverse population of subjects to whom these findings may apply. The 7.8lb. difference and 7.4 lb. SD shown in Table 1 provides compelling evidence that the use of the BMI versus the BCCI can lead to very different conclusions regarding the success or failure of interventions or treatments seeking to alter body weight. While there are some significant differences between the discordance scores of the 10 sub-groups shown in Table 2, the 6.9 to 9.7 range of discordance scores suggest considerable consistency with none approaching "0" where the BMI changes does, in fact, reflect FM loss. While there were significant differences in discordance scores between some of the sub-groups of gender, age, etc., scores for these sub-groups ranged from 6.9 to 9.7 with SDs ranging from 5.4 to 9.7 suggesting that the discordance between the BMI and the BCCI was generally consistent across these sub-groups.

Use of the BCCI and its emphasis on body composition could have immediate application to at least three are-as of bio-medical research: (1) the need for greater diagnostic precision, (2) the unrelenting challenge of obesity, and (3) the increased emphasis on translational research.

With respect to precision, the enactment of HR2: Medicare Access and Chip Reauthorization Act of 2015[7] addressed a major truism in the measurement of the effectiveness of healthcare: if an outcome measurement lacks precision, it lacks the potential to be improved. To address the need for greater precision, the US Depart-ment of Health and Human Services established goals to improve the quality of the healthcare system by im-plementation of strategies to develop meaningful, valid and precise quality measures that are better, smarter and healthier biomarkers [8]. In response, The Institute of Medicine (IOM) published its Vital Signs: Core Met-rics for Health and Health Care Progress defining core metrics as a parsimonious set that provides "…accurate tools for informing, comparing, focusing, monitoring, and reporting change" [1]. Although the IOM selected the BMI as the core metric for measuring overweight and obesity, it fails to meet IOM's precision standards of measurements that distinguish "…a given patient from other patients with similar clinical presentations". Spe-cifically, distinguishing patients of similar body weight, but who have different body compositions. This lack of precision is particularly troublesome when it is used as a measure of change to evaluate the safety and efficacy of interventions or medical treatment plans designed to facilitate safe weight loss. A number of studies have suggested that it is changes in FM and FFM, not body weight, that are more likely to reduce the risk of life-threatening conditions such as cardiovascular disease, cancer, stroke, and diabetes [1]. Other studies have also concluded that actual measures of FM, not estimates from anthropometric and BMI estimates, are better pre-dictors of cardiovascular risk factors. Data from the Dallas Heart Study [9] suggests measures of body compo-sition, rather than BMI, may be more effective predictors of cardio metabolic risk in clinical practice. The BMI has also been shown to lack the precision needed to distinguish disparities in the amounts and dispositions of body fat by age, gender, race and ethnicity [10]. In addition to its imprecision in assessing FM, the BMI is equally as imprecise in assessing FFM and an increasing number of studies have shown the importance of as-sessing changes in FFM in weight loss and medical treatment plans [2]. In additional to its effects on strength and balance, losses of FFM are also is likely to have deleterious effects on metabolism which is strongly influenced by the amount of FFM, thus making weight maintenance more difficult after achieving goal weight, par-ticularly after following low calorie diets which often deplete significant amounts of FFM. Although both FM and FFM have been used to assess the effects of interventions and treatment plan, the BCCI could serve as a simpler statistic when summarizing the net effects on of the intervention on body composition.

With regard to the unrelenting challenge of obesity, being overweight or obese describes 65% of Americans re-sulting in medical costs excess of $200 billion per year on obesity-associated conditions and diseases. For the first time in human history, there are more overweight people (2.1 billion) in the world than those who are un-derweight [11]. Forecasts suggest that the prevalence of obesity will double worldwide in the next 30 years, with the epicenter of the epidemic in China and India as persons in these countries assume Western eating habits. The latest NHANES surveys suggest that the prevalence of obesity in 2013-2014 was 35% among men and 40.4% among women. These investigators found that while there was no significant increasing linear for trend for men, the obesity rate for women showed a significant increasing linear trend between 2005 and 2014and obesity rates among adolescents have steadily increased since 1988.These researchers also point out that this discouraging lack of progress has occurred in spite of the fact that numerous foundations, industries, profes-sional societies, and governmental agencies have provided hundreds of millions of dollars in funding to support basic science research in obesity, clinical trials and observational studies, development of new drugs and devic-es, and hospital and community programs to help stem the tide of the obesity epidemic, In addition, communities, schools, places of worship, and professional societies have become active in attempting to counteract obe-sity, emphasizing exercise, better dietary choices, and nutritional content labeling of foods. Although it is impos-sible to know what the extent of the obesity epidemic would have been without these efforts, these data certain-ly do not suggest much success [11].

Also, a recent finding [12] found obesity was one of the factors most strongly associated with life expectancy and finding that death rates increased for the first 9 months of 2015, compared with the same period in 2014, and were most notably involving causes of death related to obesity. Thus, obesity may be one of the major contributors to the reversal of "…decades of progress in mortality and was unique to the United States; no other rich country saw a similar turnaround" [13].

The 7.8 lb. discordance between the BMI (or scale weight) and the BCCI suggests the failure to assess body composition changes as an outcome measure may have led to the inappropriate rejection or acceptance of weight loss and medical interventions that may have otherwise provided value in meeting the unrelenting chal-lenge of obesity. With regard to translational research, as defined by the National Institutes of Health's Center for Advancing Translations Sciences (NCATS) translation research "…develops novel approaches to improve the process of joining basic science discoveries with initial testing of therapies in humans…with a focus on terms related to study endpoints and biomarkers." [14,15] Working closely with the FDA, NCATS developed the BEST resource (Biomarkers, EndpointS, and other Tools) that aims to capture distinctions between biomarkers and clinical assessments and to describe their distinct roles in biomedical research, clinical practice, and medical product development [16]. Thus, this study's finding of significant differences between using the BMI versus the BCCI appears to contribute to NCATS' biomarker and endpoint goals for translational research. Use of the BCCI could be translated into an immediate application for evaluating the safety and efficacy of interventions or medical treatments where changes in FM and FFM are desired. For example, people often have mistaken perceptions about how overweight or underweight they or their children are. The distinction between over-weight and over-fat is an important distinction and one that needs to be considered when setting realistic goal weights. Misperceptions about what is health your unhealthy about a person's body weight body weight can adversely affect an individual's eating, dieting, and exercise behaviors. For example, a recent meta-analysis, [17] reported that many adolescents of normal weight incorrectly perceived themselves as overweight. Such misperceptions can lead to body dissatisfaction, psychological distress, and eating disorders [18-19] found that adolescents who misperceived themselves as overweight were more likely to report extreme weight-loss behaviors, including the use of diet pills or laxatives, vomiting, or going without food for at least 24 hours. These authors concluded that among normal weight adolescents, those who perceived themselves as overweight had significantly greater chances of becoming obese by early adulthood, compared to those who had accurate self-perceptions. It is important to note that the studies cited above used BMI to assess normal weight whereas body composition measurements could provide patients with more realistic assessments of their current body weights. Helping patients understand the difference between FM and FFM could be useful in countering weight biases and stigmas associated with overweight. In their commentary on Weight bias: a call to action, [18] the authors suggest that there is growing evidence that weight biases and stigmas can lead to the development of eating disorders of anorexia, bulimia nervosa and obesity and have been associated with adverse health outcomes including anxiety, stress, depression, low self-esteem and body image issues. These authors suggest that the social stigma associated with excess weight may actually be causing some of the negative health outcomes associated with excess weight rather than the excess weight itself. People with eating disorders typically report high levels of internalized weight bias wherein they have an intense fear of being fat and a fear that being fat would negatively affect their life. In reality, internalization of weight stigma is actually a fat stigma, not a weight stigma. There are people, particularly adolescents, who, while overweight are actually "over-lean" due to above levels of FFM. When treating a patient suffering from weight stigmas, it is important to include an assessment or estimate of the BCCI as part of the treatment program, particularly when weight gain due to increased FFM is likely to incorrectly perceived as a failure of the intervention. This distinction is particularly important for adolescent's girls who are over-lean, but not over-fat. For the over-lean adolescent girl, well-meaning, parents, friends, coaches and therapists providing encouragement for the adolescent's diet attempts may be making matters worse. Instead of pursuing an unachievable goal weight due to above average levels of FFM, the over-lean adolescent girl would be better served by learning to adjust to a culture that places undue value on thinness in women instead of spending years in search of an unrealistic, and often unachievable, goal weight.

The need to distinguish between changes in FM and FFM is also particularly important in Geriatric and Sports medicine treatments and interventions where the BMI has been found to be the most inaccurate and mislead-ing. In Geriatric medicine, distinctions between and measurements of changes in FM and FFM are critical [19-20] results from the progressive loss of FFM mass with age and is heavily dependent upon measurements of changes in FFM as well as FM to define sarcopenia and sarcopenic obesity.

Use of the BCCI as opposed to the BMI as an outcome measure could directly simplify evaluations of the effects of training and rehabilitation of athletes where use of the BMI has little to no value [21] in view of ath-letes' higher levels of FFM. These researchers also tested non-athletes and found BMI to be significantly inac-curate for both sexes. For college and professional athletes, a variance of even 2% in body fat can also have significant effects on their performance. These implications are not only significant for the athletes who com-pete in popular sports, such as football or baseball, but also for cheerleaders, gymnasts, and cyclists, who tend to be exceptionally lean due to their physical activities.

One of the most important areas for future research would be to investigate the health consequences of using BMI and BCCI to assess weight loss treatments and interventions. A starting point for these analyses would be to search the scientific literature for studies in which body composition measurements were taken along with BMI calculations to examine the extent to which the two measures made practical differences in conclusions drawn from the interventions or treatments. In view of the recent emphasis on the need for replicable studies, replication of this study, using additional data from IHTI, would increase the confidence in the validity of these findings. Future research is also needed on the BCCI statistic itself, which is limited to changes in FFM and FM, without isolating the effects of the intervention on Bone Density (BMD). Such effects could be as important when considering changes to FM and FFM. Reducing the risks associated with obesity while increasing the risks associated with osteoporosis cannot be considered a positive intervention outcome. Of course, this would require decisions as to how to weigh each of the measures or give equal status to changes in FM, FFM, and BMD. The problem with creating a single statistic to reflect these changes is that BMD is a measurement of density, not a measurement of mass, as is used in the current calculation of BCCI. However, this problem could be resolved by calculating the percentage of change from baseline for FM, FFM, and BMD. Since discordant scores are absolutes, a -2% change in FM, a +2% change in FFM, and a +2% change in BMD would equal a score of +6, if each measurement was accorded equal weight. This would further distinguish body composition improvement measures from the BMI, since the BMI does not isolate changes in these three dimensions. At best, the BMI is only suggestive of body fat percentage.

A potential limitation of this is that the data were obtained from archiving a database that contained a disproportional number of Caucasians and may not be representative of the Hispanics Americans, African Americans, and Asian Americans of the U.S. population. Therefore, the data may not be representative of a U.S. population or of a global population. The age range of the study population was also a limitation. The absence of any existing scientific studies or opinions on the differences between using scale weight or BMI versus BCCI to assess the safety and efficacy of weight loss interventions or treatment programs presented a final limitation.

Conclusions

The results of this study of a diverse 3,870 subject cohort, suggest that there was a 7.8 lb. statistically significant discordance between the use of the BMI versus a BCCI as an outcome measure for evaluating changes in body composition. If deletion of FM is the desired outcome, use of the BMI could result in erroneous acceptance or rejection of treatment plans or weight change interventions.

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