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Reporting weight change: Standardized reporting accounting for baseline weight

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Abstract

Background—Although it is recognized that a standardized approach to reporting weight change is essential to permit meaningful comparisons among cohorts and across studies, consensus is lacking.

Objective—Propose a method of reporting weight change allowing meaningful comparisons among studies of patients who underwent bariatric surgery and to demonstrate its utility using an example from the Longitudinal Assessment of Bariatric Surgery (LABS).

Methods—Relationships among several measures of weight change are described. Results from an observational, longitudinal cohort study of adults undergoing bariatric surgery and from simulation studies are used to illustrate the proposed method.

Setting—University Hospitals

Results—Baseline weight is a critical parameter when assessing weight change. Men undergoing a bariatric procedure other than gastric bypass or adjustable band tended to have greater weight loss twelve months after surgery than men undergoing gastric bypass when not accounting for baseline weight, but the opposite was found when results were adjusted for baseline weight.

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Simulation results show that with relatively modest sample sizes, the adjusted weight loss was significantly different between the two groups of men.

Conclusion—A consistent metric for reporting weight loss following bariatric surgery is essential to interpret outcomes across studies and among subgroups. The baseline weight adjusted % weight loss (A%WL) uses a standard population, e.g., the LABS cohort, to account for differences between cohorts with respect to baseline weight and its use can change the interpretation of results compared to an unadjusted measure.

Keywords

obesity; bariatric surgery; weight change

Introduction

Despite several attempts at standardizing reports of weight change in general, and weight loss in particular, consensus is lacking. However, the importance of weight change as an outcome measure for surgical and non-surgical clinical trials and for informing patients endeavoring to manage their weight requires standard, meaningful reporting methods.

Numerous measures of weight change have been proposed, including the performance index ^[1], the percentage of people losing fixed amounts of weight or body mass index (BMI) ^[2], the reduction index ^[3], absolute and percentage weight loss (e.g. ^[4]) and absolute and percentage excess weight (or BMI) loss (e.g., ^[5–7]).

Selecting a particular measure of weight change requires consideration of why such a measure is used. The best measure to use depends in part upon whether it is to: (1) inform patients, families or study participants in a clinical trial, (2) encourage patients or study participants regarding their weight loss to enhance compliance or retention through positive feedback (3) assess clinical significance, or (4) compare outcomes of various treatments or of cohorts.

Weight loss is probably the most useful measure for informing, since it is easy to understand, commonly used, and in the lexicon of most people. Slightly more complex but generally understood is percentage of weight lost (%WL) ^[8]. To provide encouragement, the percentage of excess weight lost (%EWL) is a larger number than %WL which may translate to perception of greater success. However, it is a more complex concept than weight loss. It requires defining a base (“ideal”) weight from which excess can be defined, but ideal weight is itself a difficult and controversial subject. Suggestions for ideal weight include those in the 1983 Metropolitan Life Insurance Company tables ^[9], a formula to approximate those values ^[7], a constant value for BMI ^[7,10] and variable values of BMI that depend on initial BMI ^[5].

As an example of several of these metrics, a 55 woman weighing 280 pounds has a BMI of 46.7 kg/m². Weight loss (WL) of 85 pounds translates to %WL of 30%. Her “ideal” body weight is 134 pounds using the formula of Deitel (^[7], Table 1) and 150 pounds using a BMI of 25 kg/m². Thus, depending on which “ideal” weight is used, her %EWL is 58% or 65%, respectively. Note that while the value of %EWL depends on ideal weight, both values of %EWL are larger than %WL, being approximately double.

With respect to clinical significance, and a simple way to inform people of their progress, a useful measure is whether or not weight loss meets a particular goal associated with health benefits. Though loss of a certain percentage of body weight, or meeting a BMI goal, are simple concepts, thresholds of clinically significant weight loss depend upon the outcome of

interest, e.g., reduction in mortality risk, reduction in co-morbidities, reduction in, and distribution of, body fat. In the case of weight loss interventions, a meaningful goal also depends on the nature of the intervention since satisfactory weight loss for a medical treatment with minimal side effects may not be adequate for surgery, considering its potential risks.

Finally, and the focus of this manuscript, is a measure which can be used to compare treatments, or different cohorts undergoing the same treatment. Although standards have been called for [4,8,11], they have not yet been agreed upon. Issues described above have been used as arguments against proposed standards, and they are legitimate. The goal here is to suggest a standard for comparing obesity treatments that overcomes a common argument regarding %WL and %EWL, i.e., initial weight is important and the meaning of various statistics differs depending on initial weight or, equivalently in adults, BMI. We illustrate our proposal using one year weight change data from the Longitudinal Assessment of Bariatric Surgery (LABS) cohort [12].

Materials and Methods

Relationship between %WL and %EWL

%WL and %EWL are functions of each other, i.e., one can be derived from the other with the relationship determined in part by the ideal weight from which excess weight is determined. Using $BMI=25 \text{ kg/m}^2$ to calculate ideal weight, %EWL is a function of %WL, baseline weight and height. Using the formula approximating the midpoint of the Metropolitan Life Insurance Company tables [7] for ideal weight, %EWL is a function of the above plus sex since, in those tables, the relationship of ideal body weight to height depends on sex. Thus, the relationship between %WL and %EWL can be determined for any cohort, but it differs depending on the cohort distributions of baseline weight and height in the first case and also sex in the second case. Because the relationship between %WL and %EWL depends on other parameters, the relationships are not particularly simple, but can be shown graphically (Figure 1). Using ideal body weight from Deitel, 2007, for a given BMI (40 kg/m^2 in the top graphs and 65 kg/m^2 in the bottom graphs) and height (z-axis), the relationship between %WL (x-axis) and %EWL (y-axis) approximates a straight line, although there is a slight curvature in the plane, being more obvious at 40 kg/m^2 than at 65 kg/m^2 . Examining the left and right (long) edges of the planes shows that the “slope” of the relationship between %WL and %EWL decreases with increasing height. Comparing the top pair of graphs to the bottom pair shows that, for a given height regardless of sex, %EWL is a greater multiple of %WL for lower BMI than for higher BMI, i.e., the “slope” is greater when BMI is lower. This graphically demonstrates that the actual relationship between %WL and %EWL depends on baseline BMI and height, and by sex if ideal weight differs by sex for a given height. Importantly, it also shows that the relationship differs in cohorts that differ with respect to BMI and height (or sex). Thus, two cohorts with the same distribution of %WL would have different distributions of %EWL due to differences in cohort member characteristics.

The Longitudinal Assessment of Bariatric Surgery Consortium (LABS)

LABS is a multi-center consortium of 6 clinical centers including 11 hospitals in the United States. Beginning in 2005, LABS recruited 5076 consecutive consenting adults (LABS-1) who underwent bariatric surgery and collected information to address short term (30 day) safety [7,12–14]. A subset of LABS-1 participants plus additional participants were recruited into a cohort of 2458 participants with more extensive data collection than LABS-1 to examine longer term safety and efficacy (LABS-2). There were 6382 participants in LABS-1, LABS-2, or both. For both LABS-1 and LABS-2, pre-surgical weight was

measured within 30 days of surgery using a LABS-purchased Tanita™ scale when possible and according to a LABS-derived protocol to standardize weight measurement across centers. LABS-2 participants were weighed post-surgery using the same scale when possible. Height was measured according to a common protocol using a wall mounted stadiometer.

LABS protocols and consent forms were approved by the Institutional Review Board at each institution.

Adjustment

Adjustment, also referred to as standardization, is a technique used to compare statistics in groups that differ with respect to characteristics that may influence those statistics, but are not the focus of study [15]. For example, age-adjustment is commonly used when reporting mortality rates or incidence rates of diseases known to increase with age. Since mortality increases with age, the relationship of age with mortality is not usually the focus of an investigation comparing mortality among groups. One needs to account for differing age distributions in the groups to see if any mortality difference is accounted for by one group tending to be older than another. Without age adjustment, older cohorts, whose members are more likely to die than are younger people, would have higher (crude) mortality rates, even if everything else other than age was the same. Similarly, even if weight loss is the same in two cohorts, the %WL will be higher in cohorts with lower compared to higher baseline weights because the denominator for %WL is smaller when baseline weight is lower. The basic idea behind adjustment is to put the cohorts on an equal footing with respect to baseline weight, i.e., adjusted %WL (A%WL) is better than crude (unadjusted) %WL because it takes into account differences in baseline weights between groups which lead to differences in %WL for people who lose the same amount of weight. Equality of A%WL between subgroups was tested by the independent two-sample t test with unequal variance using A%WL and its standard error.

Simulation Study

Utilizing the weight change data and the total cohort baseline weight distribution from LABS-2, we simulated two samples of various sizes ($n = 50, 100, 250, 500$) from two populations with the same distributions of baseline weight, and the same averages and standard deviations of %WL in baseline weight categories as the samples of men undergoing gastric bypass surgery and men undergoing an “other” procedure in the LABS-2 cohort, respectively. Crude and A%WL were calculated for the simulated data.

Results

LABS-2 Participants

As one would expect, the 1931 women in LABS-2 weighed less before surgery than did the 527 men. The median (25th percentile, 75th percentile) weight in women was 125 (112, 139) kg compared to 151 (135, 172) kg among men (Table 1). Corresponding values for BMI were 45.7 (41.6, 51.0) kg/m² for women and 46.9 (42.5, 52.8) kg/m² for men. Those having an adjustable band tended to weigh less prior to surgery (median=123 kg.) than those who underwent a gastric bypass (median=130 kg.). Those who underwent an “other” surgical procedures (sleeve gastrectomy, banded gastric bypass, or biliopancreatic diversion with switch) tended to weigh the most (median=148 kg.).

Weight Change

Weight change at 12 months was available for 1808 women and 501 men whose weights were measured at both baseline and 1 year. Mean (standard error) weight loss among

females for gastric bypass was 44.3 (0.3) kg, for adjustable band was 18.4 (0.5) kg and for “other” surgeries was 45.2 (1.5) kg. Men tended to lose slightly more weight than women, with mean (standard error) of 50.5 (0.9), 20.0 (1.1), and 58.7 (4.1) kg for gastric bypass, adjustable band, and “other” procedures, respectively

For both sexes, those having an adjustable band lost less weight at 1 year than those having the other operations, whether as an absolute value or as %WL.

Relationship between %WL and %EWL

Differences in baseline weight and height distributions between men and women cause the relationship between %WL and %EWL to differ by sex. Though the relationship between these two measures is not linear, it is well approximated by a line with slope of about 2, i.e., %EWL is approximately double %WL. This approximation holds for many cohorts of people undergoing bariatric surgery because the underlying distributions of baseline weight and height of adults undergoing bariatric surgery do not differ sufficiently to have a major impact on the slopes. There is some impact, though such that the multiplier of %WL to obtain %EWL is less in cohorts with higher BMI than in cohorts with lower BMI, and in cohorts whose members tend to be taller than others (Figure 1).

To avoid complications induced by using %EWL (depends on choice of ideal body weight, relationship with actual weight loss depends on height and baseline BMI), we propose using an A%WL as the metric for reporting weight change.

To take into account baseline weight using the direct method for adjustment^[15], one takes the %WL in baseline weight categories for each group and applies those values to the baseline weight distribution of a standard population. Doing so yields the %WL in the standard population that would be expected if the weight-specific %WL distribution of the groups held in the standard population. (See Table 3 for details of how to calculate the baseline weight A%WL).

To illustrate, suppose we want to compare the 1-year %WL in men undergoing gastric bypass surgery with men who underwent surgery other than gastric bypass or adjustable band. As shown in table 1, men who underwent an “other” procedure tended to have higher baseline weights (median 172 kg) than those who underwent gastric bypass (median 154 kg). The crude average 1 year %WL among those who underwent gastric bypass was 31.7% (95% Confidence Interval (CI), 30.8%–32.6%) and in the “other” group was 32.1% (95% CI, 28.9%–35.3%). Hence, on average, the point estimate for weight loss was slightly higher for men undergoing an “other” bariatric surgical procedure than for men undergoing gastric bypass. This may be because the additional weight lost by those undergoing the “other” bariatric surgical procedures (average 58.7 kg) compared to gastric bypass (average 50.5 kg) overcame the “advantage” of a smaller denominator for %WL that the gastric bypass cohort has. However, taking the difference in baseline weight into account and utilizing the entire LABS cohort, i.e., LABS-1 or LABS-2 (n=6382, see Table 2), weight distribution as the standard population, the relationship reverses, the baseline weight-adjusted average %WL among men undergoing an “other” bariatric surgical procedure was less (27.1% and 95% CI, 24.1%–30.2%) than among those men who underwent gastric bypass (29.8% and 95% CI, 28.4%–31.1%). Note that in our example, the test for the equality of the estimates in the two surgery groups was not statistically significant for either the crude (p=0.84) or adjusted (p=0.13) means. However, the point being made is that the relationship could change and the A%WL provides a measure which accounts for the “nuisance” of a different baseline weight distribution between groups.

The adjusted rates can be interpreted as the average %WL that would have been observed in the LABS cohort (the standard population) if all participants had undergone gastric bypass (29.8%) or if all participants had undergone an “other” bariatric surgical procedure (27.1%).

Simulation Results

The sample of men who underwent an “other” surgical procedure was relatively small (n=33) in LABS-2. When simulating data from distributions of baseline weight and weight loss that were the same as LABS-2, the point estimates of the crude %WL for men undergoing gastric bypass were contained in the 95% CI for the crude %WL for men undergoing an “other” procedure, and vice versa (Table 4). Hence, the differences in crude %WL are likely to not differ significantly. However, when adjusting for the tendency for men undergoing an “other” procedure to have higher baseline weight than those undergoing bypass surgery, for sample sizes of at least 250, the respective point estimates for the A %WL were outside the 95% CI of the A %WL for the other group, indicating the differences are significantly different.

Discussion

The goal of bariatric surgery and other interventions is to induce weight loss and improve weight-related conditions. However, despite efforts at standardization, the measure of weight loss remains variable in the literature. Recognizing that utilizing different methods will complicate interpretation, the journals *Surgery for Obesity and Related Diseases* and *Obesity Surgery* require that weight loss be expressed several ways; %EWL using the Metropolitan Life insurance tables, % WL, and % Excess BMI lost (%EBMIL) with excess greater than 25 kg/m². The journal *Obesity Surgery* in 2007 “strongly encouraged” the use of %EWL based on the “old Metropolitan Tables” [7] or %EBMIL. This recommendation is curious since the interpretation of %EWL is affected by the choice of the “ideal” body weight [11,16] and the concept of an ideal body weight, whether it be from the Metropolitan Life Tables or particular value(s) of BMI is inherently flawed [8].

Recognizing that an appropriate measure of weight loss is, in part, influenced by the target audience of the statistic, we recommend that %WL be the basic measure for comparisons of weight loss. Due to differences in height among comparison groups, the BMI might be preferable to weight loss but since height is essentially constant for adults, %WL and %BMI loss are the same. However, comparison groups often differ with respect to baseline weight. For example, both men and women in LABS-2 who underwent a bariatric surgery procedure other than gastric bypass or adjustable band tended to weigh more at baseline than did the entire LABS-2 cohort. Furthermore, as shown in Table 3, there tended to be increased %WL among men as baseline weight increased. The method of adjustment proposed here eliminates the baseline weight differential when comparing men undergoing the various bariatric surgery procedures. The simulation results (Table 4) demonstrate that, regardless of sample size, the A %WL is lower than the observed %WL among men undergoing an “Other” procedure, indicating that had they weighed less at baseline, then they would have been observed to have lower percentage weight loss.

Hence, we propose that direct standardization be utilized by which baseline weight group-specific average %WL is applied to a standard population. The directly standardized A %WL is interpreted as the %WL that would be seen in the standard population if the %WL in the comparison groups held. When appropriate, other statistics should be reported as well.

The utility of this approach is seen when comparing %WL in men undergoing gastric bypass surgery and men undergoing weight loss surgery other than bypass or adjustable band In LABS. The average unadjusted %WL in the former group is numerically, though not

statistically significantly, less than the latter group but when adjusted to a standard population the relationship flips. The simulation studies shows that even with sample sizes as small as 250 per group, the differences in A%WL are statistically significant, whereas those of the crude %WL are not.

The choice of a standard population is somewhat arbitrary, though it should be representative of the cohorts being compared. Thus, for example, a standard population of people with BMI below 30 kg/m² would not be appropriate for standardizing cohorts of people undergoing bariatric surgery. For reporting weight loss in cohorts of people who underwent bariatric surgery, we propose using as the standard population the baseline weight distribution of the LABS cohort of over 6000 people undergoing bariatric surgery at 11 hospitals in the United States whose weights were carefully measured using a common scale and standard protocol.

Other methods of adjustment are possible, e.g., indirect adjustment [15]. An advantage of direct, over indirect, adjustment is that the former allows comparisons, and therefore rankings, of adjusted rates in different subgroups or over time since they use the same standard population. Indirect adjusted rates of groups are not comparable when the baseline weight structures differ; they can only be compared with the standard. An alternative to either of the aforementioned adjustment methods is via regression or analysis of covariance to calculate baseline weight adjusted (least squares) means. This has the advantage over direct adjustment that it does not require grouping baseline weights into categories. Grouping baseline weights “assigns” the same weight loss to all members of the category which could be problematic if the categories are too large. In the case of our proposed standard population (the LABS cohort), we selected weight categories of 10–20 kg so that every group had at least 100 observations. It is possible to have more categories each with a smaller range of weight, reducing the size of the standard population in each. It is also possible to search for other, larger standard populations that would allow narrower weight groups as well, and this would have the benefit of “assigning” weight loss to those whose baseline weights are more similar to each other. An “artificially” constructed standard could also be used, but using an existing population allows a meaningful statement such as the A %WL is the weight loss that would have been seen in an existing population. Despite the advantage of not requiring weights to be grouped, the least squares mean is only an internally consistent adjustment; different populations will have different adjustments, and they are not to an external standard. Also, if the baseline weight distribution is shown, as it often is in descriptions of cohorts, then direct adjustment can be performed whereas least squares means require the data for each individual observation be available to perform the adjustment. Whereas those with the individual level data can perform the adjustment, the data are not readily available to others.

Finally, while in our example, the adjustment did not result in identifying statistically significant differences in weight change between men who underwent gastric bypass and men having an “other” bariatric surgery, this could be a function of the sample size in these groups. The LABS-2 cohort of 2458 is relatively large compared to single center studies, but only 33 men underwent an “other” bariatric surgery. The results of the simulation study demonstrated that with larger subgroups, and not particularly large, and more precise estimates, the differences in A%WL values for various subgroups differed significantly, whereas the crude %WL did not.

Conclusion

We suggest that %WL should be the consistent measure of weight loss for comparing weight loss between or among cohorts. This is consistent with the United States Food and

Drug Administration draft of Guidance for Industry Developing Products for Weight Management. We also propose direct standardization for baseline weight, with the LABS cohort as a common baseline weight distribution, to allow appropriate comparisons of cohorts of people undergoing bariatric surgery with respect to %WL. To allow for meaningful comparisons of interventions and centers, we urge investigators to begin reporting directly standardized A%WL utilizing the LABS cohort as the standard population because of its size, multi-center nature, and uniform way that weight was measured.

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Figure 1.
Relationship among percent weight loss, percent excess weight loss by height, sex and baseline body mass index (BMI). Ideal body weight from formula of Deitel (2007)

Table 1

Baseline weight and body mass index (BMI) LABS-2 cohort (n=2458)

n Weight (kg): Median (Q1, Q3) * BMI (kg/m²): Median (Q1, Q3) *	Gastric bypass	Adjustable band	Other[#]	Total
Female	1389 126 (114, 140) 46.3 (42.2, 51.5)	465 119 (108, 131) 43.8 (40.4, 47.9)	77 136 (114, 155) 50.6 (43.6, 57.3)	1931 125 (112, 139) 45.7 (41.6, 51.0)
Male	349 154 (137, 175) 47.7 (43.2, 53.1)	145 140 (127, 160) 44.0 (40.3, 48.8)	33 172 (160, 207) 57.4 (49.2, 63.6)	527 151 (135, 172) 46.9 (42.5, 52.8)
Total	1738 130 (116, 150) 46.5 (42.4, 51.9)	610 123 (111, 139) 43.9 (40.4, 48.1)	110 148 (123, 168) 51.8 (44.3, 59.7)	2458 129 (115, 147) 45.9 (41.8, 51.4)

* Q1 and Q3 are 25th and 75th percentiles

[#] Other procedures include sleeve gastrectomy, banded gastric bypass, and biliopancreatic diversion with duodenal switch

The Longitudinal Assessment of Bariatric Surgery (LABS)-2 cohort includes 2458 participants recruited to assess safety and efficacy of bariatric surgery.

Table 2

Distribution of baseline weight in the standard population (n=6382)

Baseline weight (kg)	Frequency	Percentage
< 90	119	1.9%
90 ~ <100	314	4.9%
100 ~ <115	1255	19.7%
115 ~ <125	1073	16.8%
125 ~ <135	981	15.4%
135 ~ <150	1106	17.3%
150 ~ <165	682	10.7%
165 ~ <180	423	6.6%
180 ~ 200	260	4.1%
200	169	2.7%

Table 3

Calculation of Direct Baseline Weight Adjusted % Weight Loss (A%WL)

Baseline weight (kg)	Standard Population (N=6382)	Men in LABS-2 undergoing gastric bypass surgery (n=330)		
	Frequency (A)	Mean of % weight loss (B)	Variance of % weight loss (C)	Frequency (D)
< 90	119	- *	- *	- *
90 ~ <100	314	- *	- *	- *
100 ~ <115	1255	27.9	28.7	8
115 ~ <125	1073	27.0	104.9	23
125 ~ <135	981	29.2	53.4	39
135 ~ <150	1106	31.0	54.8	70
150 ~ <165	682	32.7	66.8	66
165 ~ <180	423	32.7	68.4	64
180 ~ 200	260	34.7	57.2	33
200	169	34.1	51.4	27

Baseline weight (kg)	Expected % weight loss in Standard Population-Sum total across all people in the Standard Population in each weight stratum $E=(A \times B)^*$	Expected variance of % weight loss in Standard Population $(A^2 \times C/D)$
<115 [#]	47095.2	10222022
115 ~ <125	28971.0	5251061
125 ~ <135	28645.2	1317694
135 ~ <150	34286.0	957619
150 ~ <165	22301.4	470762
165 ~ <180	13832.1	191230
180 ~ 200	9022.0	117173
200	5762.9	54372
Total	189915.8	18581934

Baseline weight A%WL= $180015.8/6382 = 29.8$	Standard error for baseline weight A%WL = $(18581934)^{0.5}/6382 = 0.68^{\dagger}$
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* No observations in this weight group. Therefore, the first three weight groups were collapsed.

* To calculate A%WL (the methods are identical for men undergoing an “other” procedure; the same weight groups were used):

1. In each baseline weight group, multiply the mean % weight loss in that group (column B) by the number of observations in the standard population in that baseline weight group (column A). Put the result in column E.
2. Add those values across the baseline weight groups (Total=189915.8)
3. Divide the total (189915.8) by the number of observations in the standard population (6382). The result is the A%WL.

[#] Weight groups were collapsed because there were no observations among men undergoing gastric bypass surgery

[†] Approximate 95% confidence interval (CI) for baseline weight adjusted %WL is $29.8 \pm 1.96 \times 0.68 = 28.47-31.13$.

The Longitudinal Assessment of Bariatric Surgery (LABS)-2 cohort includes 2458 participants recruited to assess safety and efficacy of bariatric surgery.

Table 4

A Hypothetical Example of Crude %WL vs. A%WL

Size (n)	Sample 1 (Men Undergoing Gastric Bypass Surgery)				Sample 2 (Men Undergoing an "Other" Procedure)			
	%WL	95% CI for %WL	A%WL	95% CI for A%WL	%WL	95% CI for %WL	A%WL	95% CI for A%WL
50	30.9	(28.7, 33.1)	29.3	(27.4, 31.2)	31.4	(29.0, 33.9)	29.2	(26.2, 32.2)
100	32.9	(31.4, 34.4)	31.6	(28.0, 35.2)	33.4	(31.5, 35.3)	29.2	(25.4, 33.0)
250	31.7	(30.7, 32.7)	30.8	(29.5, 32.1)	31.5	(30.2, 32.8)	26.1	(23.3, 28.8)
500	31.5	(30.8, 32.3)	29.1	(28.2, 30.0)	32.2	(31.4, 33.1)	26.5	(25.1, 27.9)

%WL: Percent Weight Loss

A%WL: Adjusted Weight Loss

CI: Confidence Interval