Published in final edited form as:
Obes Res Clin Pract. 2008 December ; 2(4): 277–281. doi:10.1016/j.orcp.2008.09.002.

Validity of Clinical Body Weight Measures as Substitutes for Missing Data in a Randomized Trial

David Arterburn, MD, MPH[*,†], **Laura Ichikawa, PhD**[*], **Evette J. Ludman, PhD**[*], **Belinda Operskalski, MPH**[*], **Jennifer A. Linde, PhD**[‡], **Emily Anderson, MA**[‡], **Paul Rohde, PhD**[||], **Robert W. Jeffery, PhD**[‡], and **Greg E. Simon, MD, MPH**[*]

[*] Group Health Center for Health Studies, Seattle, WA, USA

[†] University of Washington, Seattle, WA, USA

[‡] University of Minnesota, Minneapolis, MN, USA

[||] Oregon Research Institute, Eugene, OR, USA

Abstract

Background—Long-term follow-up of weight loss interventions is essential, but collecting weights can be difficult, and self-reports inaccurate. We examined the relationship between weight measures obtained in the context of a weight loss trial and in routine clinical care.

Methods—Body weight data from a trial of behavioral obesity treatment among 88 obese women and 203 women age 40 to 65 years with comorbid obesity and depression were compared against weight data entered into an electronic medical record (EMR) during routine clinical care. Study and EMR weights and weight changes were then compared at 6 and 12 months using scatterplots, Pearson's correlations, and t-tests.

Results—The 12-month follow-up rate for this trial was 77%. Among the 224 12-month completers, 142 women (63%) had an EMR weight within 90 days of their 12-month study weight. Study and EMR weights were highly correlated (0.99), with a mean difference of 0.1 kg. The correlation between two measures of 12-month weight change using study and EMR weights was 0.96. These results were robust to sensitivity analyses that explored the impact of different-sized windows for matching clinical weights with study weights. Among the 67 women who were missing study weights at 12 months, 33 (49%) had an EMR weight available within 90 days of their missed follow-up appointment.

Conclusions—Weight measures routinely obtained in clinical care are highly correlated with those obtained by trained research staff and may be used, without statistical correction, to achieve higher rates of long-term follow-up in weight loss studies.

Keywords

Body weight; reliability; research design

Address correspondence to David Arterburn, MD, MPH, Group Health Center for Health Studies, 1730 Minor Ave, Suite 1600, Seattle, WA 98101. [Tel: 206-287-4610; Fax: 206-287-2871] E-mail: arterburn.d@ghc.org.

Introduction

Obesity is now one of the leading health concerns in the United States. There is a strong demand for clinical research studies to meet the needs of an increasingly obese population. However, the area of obesity research has long been troubled by high rates of loss to follow-up, which approach 40% in many long-term clinical trials of obesity interventions. Participant attrition reduces the validity of the study results, because any subsequent analysis of weight data is vulnerable to bias resulting from systematic differences between participants who completed the trial and those who did not.[1,2] Self-reported follow-up weights are poor surrogates for measured weights because of recall bias and embarrassment.[3] As a result, considerable effort has been placed on statistical methods for handling missing weight measures in obesity trials.[4] However, none of the available imputation methods can ensure a valid result when rates of attrition are high.

One potential strategy for reducing missing data in clinical trials of obesity interventions is to use weight measures that are collected during routine clinical care. This option is particularly attractive when participant recruitment occurs in the setting of an integrated health care delivery system with an electronic medical record (EMR). Little is known about the accuracy of weights obtained during routine clinical care. Two previous studies found close agreement between research study weights and routine clinical weights among 85 patients admitted for elective surgery [5] and 64 patients enrolled in a managed care system's behavioral weight loss program,[6] respectively. Here we report on the availability and accuracy of weights collected during routine outpatient care, examining the agreement between research weights and clinical weights for both absolute weight and weight change over 12 months for a total of 291 women.

Research Methods and Procedures

We conducted this study at Group Health, a mixed-model prepaid health plan and delivery system serving approximately 500,000 members in Washington State and northern Idaho. The Group Health institutional review board reviewed and approved all study procedures.

Clinical Trial Data

We analyzed data from a trial of behavioral obesity treatment among 88 obese women and 203 women with both obesity and clinical depression conducted from April 2003 to March 2006. The methods for this trial are described elsewhere.[7] Briefly, this trial recruited two populations of obese women—those with and without comorbid depression—age 40 to 65 years. Subjects were contacted via mail and telephone and invited to participate in a one-year comparison of two structured group-therapy programs: one focused only on weight loss and the other on both depression and weight loss. All subjects provided written informed consent.

Trained research staff obtained standardized weight measurements at baseline, and follow-up weights were assessed at 6 and 12 months (study weights). Weight was measured in light street clothes, without shoes, on a calibrated balance-beam scale.

Medical Record Data

In the Group Health delivery system, nursing staff obtain weight measurements during routine clinical care and enter these into our electronic medical record (EMR weights). Care standards indicate that weights should be obtained at each outpatient visit without extra clothing and shoes (if possible). For this study, we extracted all available weight measurements from the EMR for each of our 291 study participants.

Statistical Analyses

To examine baseline participant characteristics, means and standard deviations were calculated for continuous measures and frequencies and proportions for categorical measures. A baseline study weight was available for all subjects. To examine differences between study and EMR weights at 6 and 12 months, we selected the EMR weights that were nearest in time to the 6- and 12-month study weights. We excluded EMR weights that occurred more than 90 days before or after the 6- or 12-month study weights. When more than one EMR weight was available in the time period surrounding a study weight, we chose the EMR weight with the shortest time interval from the study weight. Mean changes in body weight were calculated for study weights (follow-up study weight minus baseline study weight) and EMR weights (follow-up EMR weight minus baseline study weight). Study and EMR weights and weight changes were then compared at 6 and 12 months using scatterplots, Pearson's correlations, and t-tests. Additional analyses compared study and EMR height measurements. All analyses were conducted using SAS software version 9.1, and statistical tests were based on a $P < 0.05$ significance level.

Results

Table 1 shows the demographic characteristics of the 291 women in our study population. Baseline study weights were available on all participants. Their mean age was 52.2 years, 81% were white, and 54% were married. Their mean body mass index (BMI) was 38.5 kg/m^2, with 32% having a BMI of 40 kg/m^2 or greater.

Follow-up study weights were obtained by research staff on 238 participants at 6 months (82% 6-month completers) and 224 participants at 12 months (77% 12-month completers) (Table 2). Among the 238 6-month completers, 143 women (60%) also had an EMR weight within 90 days of their study weight, and these weights were highly correlated (0.96), with a mean difference of −0.2 kg. Among the 224 12-month completers, 142 women (63%) had an EMR weight within 90 days of their study weight, and these weights were again highly correlated (0.99), with a mean difference of 0.1 kg.

The correlation between the two measures of weight change using 6-month study weights and EMR weights was 0.76 (Figure 1). For 12-month changes, the correlation was 0.96 (Figure 2). Among the 53 women who were missing study weights at 6 months, 32 (60%) had an EMR weight available within 90 days of their missed study follow-up date and 4 (8%) had disenrolled from the health plan. Among the 67 women who were missing study weights at 12 months, 33 (49%) had an EMR weight available and 11 (16%) had disenrolled from the health plan.

Additional analyses among 38 women with a height measurement available in the EMR found that these measures were also highly correlated with study measures. The mean (s.d.) study height was 65.3 (2.3) inches versus 65.3 (2.5) for EMR heights. The mean difference between study and EMR heights was less than 0.1 inches, and the correlation between the two measures was 0.94.

Sensitivity Analyses

To assess the impact of our 90-day window for EMR weights surrounding each study weight, we conducted sensitivity analyses comparing correlations for windows of 30 days or less and more than 30 days; these results were substantively similar at both 6 and 12 months.

The modest correlation we observed between study and EMR weight changes at 6 months (0.76) was heavily influenced by one outlying EMR weight measurement (Figure 1); when this outlier was removed, the correlation for weight change at 6 months improved to 0.89.

Discussion

We found that weight measures obtained by nursing staff during routine clinical care were highly correlated with those obtained by trained research staff in the context of a prospective trial of behavioral treatment for obesity and comorbid depression. Our findings are consistent with the results of two previous studies that found close agreement between weights obtained by research and clinical staff among 85 patients admitted for elective surgery [5] and among 64 patients enrolled in a behavioral weight loss program at a managed care system,[6] respectively. Our study extends the current literature by demonstrating high correlations among research and clinical measures of body weight change at 12 months in a larger group of 291 total patients. These results were robust to sensitivity analyses that explored the impact of different-sized windows for matching clinical weights with study weights. The agreement between clinical weights and study weights is remarkable considering that no effort was made to standardize weighing procedures during routine outpatient clinic visits.

Given the close agreement between clinical and study weights, we conclude that clinical weights can be safely used, without statistical correction, to impute missing study weights when participants are lost to follow-up. In our study, using EMR data to impute missing study weights would increase our 12-month follow-up rate from 77% to 88%, improve our statistical power, and increase our confidence in the results.

Our study's main limitations are its sample size (291)—small, although larger than the two previous studies—and restriction to women age 40 to 65 years in a single delivery system in the Pacific Northwest. In addition, although it is economical to use EMR data, their retrospective nature makes it difficult to detect potential sources of random or systematic error in them. Further research is needed to determine if these findings are generalizable to other populations and settings. We found differential availability of EMR weight measures among the women who were missing study weights at 6 months and 12 months, which was partially explained by disenrollment from the health plan. Unfortunately, our study did not collect data on other reasons for missing EMR weight data at these two time points. Future studies should seek to understand the nature of missing EMR weight data, including factors such as provider/staff bias and patient embarrassment.

In summary, we found that body weight measures obtained during routine clinical care may serve, without statistical correction, as reasonable substitutes for research weights when study subjects have missing data. Our results should also interest practicing clinicians, who routinely use clinical measures of body weight to evaluate patients' response to weight loss interventions.

Acknowledgments

This project was supported by NIH Research Grant #MH68127 funded by the National Institute of Mental Health and the Office of Behavioral Social Sciences Research.

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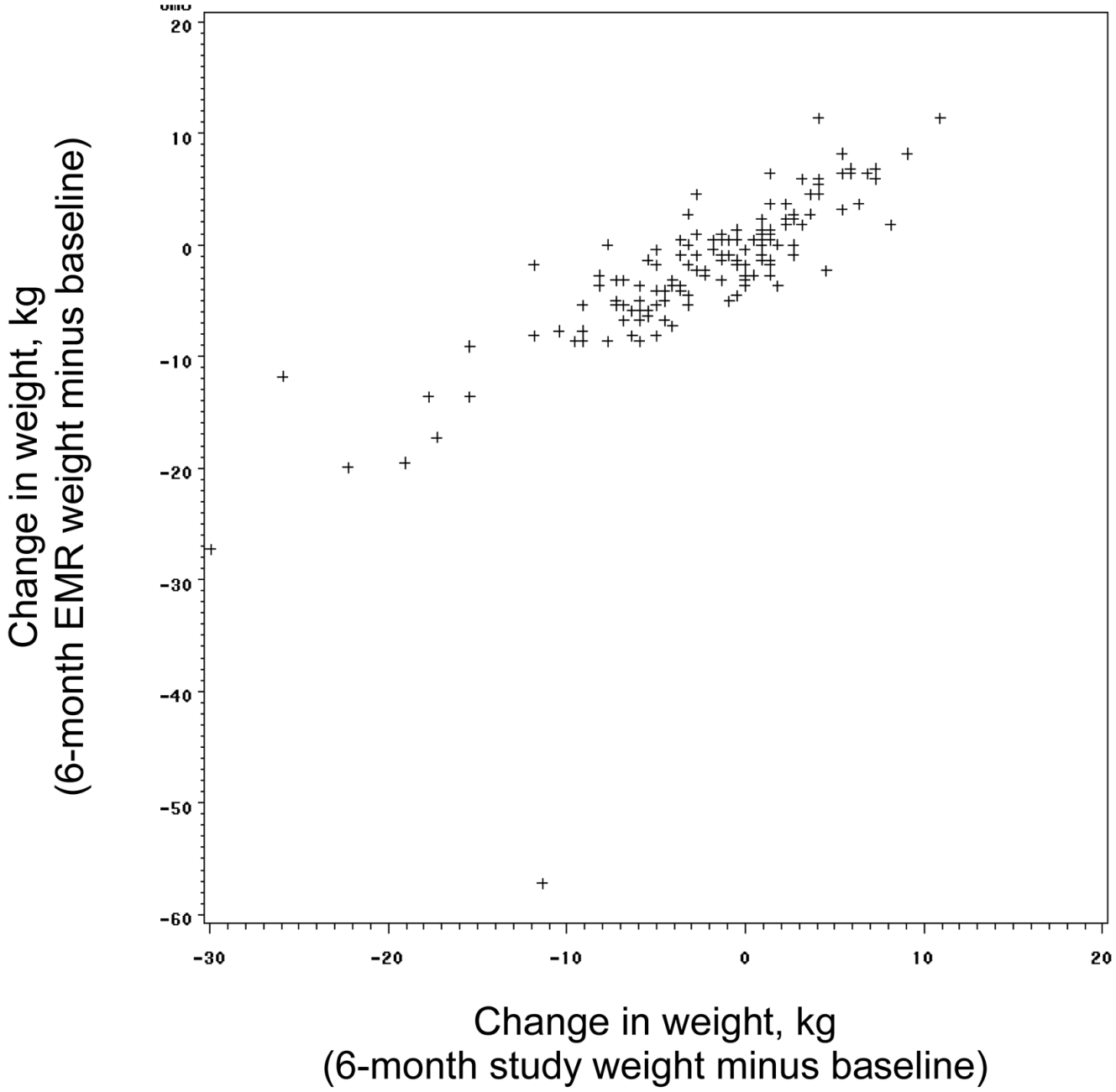

Figure 1.
Scatterplot comparing change in body weight at 6 months.

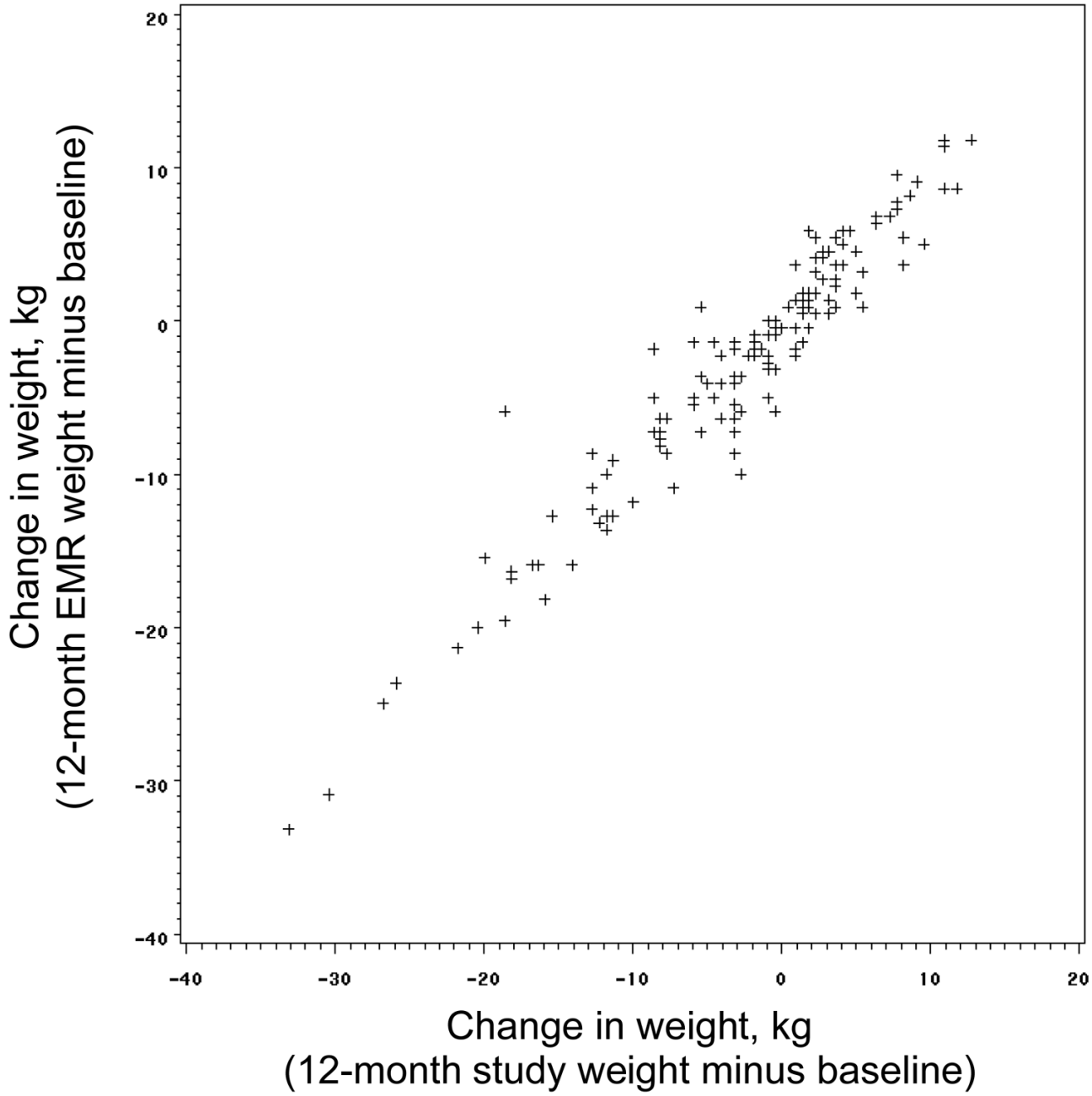

Figure 2.
Scatterplot comparing change in body weight at 12 months.

Table 1

Baseline characteristics of study participants (N = 291)

Number of participants		291
Age, years: mean (s.d.)*		52.2 (6.3)
Race, %		
White		81%
Hispanic origin		3%
Other		16%
Education beyond high school, %		89%
Married, %		54%
Weight, kg:† mean (s.d.)		103.7 (19.3)
BMI,‡ kg/m^2: mean (s.d.)		38.5 (6.9)
BMI category, %		
Overweight (BMI 25.0–29.9)		1%
Obese	Class I (BMI 30.0–34.9)	38%
	Class II (BMI 35.0–39.9)	29%
	Class III (BMI≥40.0)	32%

*s.d.= standard deviation;

†kg = kilograms;

‡BMI = body mass index.

Table 2

Relationship between body weight measurements obtained in weight loss study and routine clinical care at 6 and 12 months.

	Month 6 study completers (*n* = 238)	Month 12 study completers (*n* = 224)
EMR* weight available, *n* (%)	143 (60%)	142 (63%)
Study vs. EMR weight		
Study weight, kg:† mean (s.d.) ‡	100.9 (18.2)	101.3 (19.7)
EMR weight, kg: mean (s.d.)	101.0 (18.3)	101.2 (19.5)
Difference, kg: mean (s.d.)	−0.2 (4.8)	0.1 (2.4)
Correlation	0.96	0.99
Study vs. EMR weight change from baseline study weight		
Study weight, kg: mean (s.d.)	−2.5 (6.4)	−2.7 (8.6)
EMR weight, kg: mean (s.d.)	−2.3 (7.3)	−2.9 (8.2)
Difference, kg: mean (s.d.)	−0.2 (4.8)	0.1 (2.4)
Correlation	0.76	0.96

*EMR = electronic medical record;

†kg = kilograms;

‡s.d.= standard deviation.