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The impact of plantar callosities, arm posture, and use of electrolyte wipes on the reliability of body composition measurements by BIA in morbidly obese adults

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Masters Thesis in Clinical Health Science – Applied Clinical Research

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Abstract

Objective: The purpose of this study was to evaluate the reliability and validity of body composition measurements in morbidly obese adults. These measurements were obtained using multiple-frequency bioelectrical impedance analysis (BIA) under different conditions: pre and post pedicure for removal of callosities, with and without InBody electrolyte wipes and custom-built axillary pads. For validity purposes, body composition measurements from BIA were compared with measurements from air displacement plethysmography (ADP).

Design: Repeated measures, clinical intervention study testing the reliability and validity of BIA in the morbidly obese.

Subjects: 36 morbidly obese patients from St. Olav University Hospital **(**13 males, 23 females, aged 28-70, BMI 41.6 ± SD 4.3) with moderate to severe callosities.

Measurements: Body composition was assessed as percentage of body fat (%BF) using ADP and multiple-frequency BIA. Body weight and height measurements were also taken; plantar callosities were photographed and scored for severity using a 5-point scale by an authorized podiatrist. BIA measurements were taken before and after removal of plantar callosities (pedicure), and with or without InBody electrolyte wipes and custom-built axillary pads.

Results: The study participants' %BF measurements were found to be significantly higher with axillary pads than without ($p < .001$). No statistically significant differences were found in %BF measurements pre to post pedicure, and with vs. without usage of electrolyte wipes. There were also no statistically significant differences in %BF between BIA and ADP.

Conclusion: Multiple-frequency BIA is a valid method for estimating %BF in morbidly obese adults. Arm posture appears to have a significant impact on %BF assessed by BIA, as opposed to the presence of plantar callosities and usage of InBody electrolyte wipes, which showed no significant effect. Further examination of the effect of skin contact between the arm and trunk on the accuracy of BIA measurements is warranted. For clinical and scientific purposes, standardization of BIA measurement procedures is recommended.

Keywords: bioelectrical impedance analysis; air displacement plethysmography; body composition; morbid obesity; callosities

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With much love and gratitude,

Jess

Introduction

More and more people are becoming overweight and obese due to an overconsumption of energy dense, nutrient poor, highly caloric foods rich in sugars, oils, and animal fats (1). This, combined with a dramatic reduction in physical activity due to the popularity of sedentary activities, the presence of various modes of transportation, and increasing urbanization has made the obesity epidemic one of the greatest public health challenges of the 21st century (2). The World Health Organization (WHO) defines obesity as an abnormal or excessive fat accumulation that presents a risk to health and is most commonly measured by body mass index (BMI), an index of weight-for-height calculated from a person's weight in kilograms divided by the square of his height in meters (kg/m^2) (3). The prevalence of obesity is staggering, as the WHO estimates that more than 1.4 billion adults are currently overweight (BMI 25-29.9 kg/m^2) and more than half a billion are obese (BMI $\geq$ 30.0 kg/m^2) (4). The WHO further reports that 65% of the world's population lives in countries where overweight and obesity are linked to more deaths than underweight (3). It is considered the fifth leading risk for global preventable deaths (3). Obesity is known to cause physical disabilities as well as psychological problems; the presence of excess weight on the human body increases a person's risk for developing adverse health effects from non-communicable diseases such as diabetes, cancer, and cardiovascular diseases (2). In turn, the presence of one or more of these non-communicable diseases increases the risk of premature death and reduces life expectancy (5, 6).

The WHO has further subdivided obesity into three classes, where BMI 30 – 34.9 kg/m^2 corresponds to class 1 or moderate obesity, BMI 35-39.9 kg/m^2 is indicative of class 2 or severe obesity, and $\geq$ 40 kg/m^2 is considered class 3 or very severe obesity (7). As the prevalence of obesity continues to increase, many parts of the world are progressively facing a rise in the number of people who fall under obesity class 2 and 3 (8). This is of great concern, especially because severe (morbid) obesity is associated with a significant reduction in life expectancy (6). The National Health and Nutrition Examination Surveys (NHANES Mortality Studies) conducted a study that looked at the life expectancy of Caucasians and found that the average years of life lost (YLL) for men

and women with BMI ≥ 35 kg/m^2 were around 9 to 13, respectively, whereas those who were in the lower range of BMI (<17 to 19 kg/m^2) had YLL values that ranged from 1 to 9 (9). Since morbid obesity is characterized by large alterations in body compartments when compared to overweight or non-obese individuals, there is a need for the evaluation of the body composition of severely obese persons (8). There is little published research available on what methods of body composition measurement can be used on this population (10-13).

Body composition

BMI is often used as a surrogate measurement of body composition in epidemiological studies and recommended as a screening tool for the initial clinical assessment of obesity due to its simplicity, inexpensiveness, and relatively good correlation with body fat (14-16). It has been invaluable for the current obesity classification system and its advantages have been utilized across various disciplines (17, 18). Although BMI has served as a great tool for studying nutritional status, it is not a good indicator of body composition because it does not distinguish muscle from fat mass (19). The assessment of fat mass and its distribution in the body is critical when examining the relationship between adiposity and the risks associated with metabolic diseases (diabetes, hypertension, hyperlipidemia) (20). Worryingly, studies have revealed that BMI tends to underestimate fatness calculated as body fat percentage (%BF) and therefore, in order to correctly identify obese individuals, %BF and waist circumference should also be measured (21, 22).

Anthropometric measures are estimated from the densities of fat mass (FM) and fat-free mass (FFM) compartments of the body (23). Many studies have reflected upon the challenges in making anthropometric assessments on the severely obese (8). Traditional assessment methods that have often been used to measure body composition in non-obese, overweight, and obesity class 1 individuals, have appeared to be either inaccurate or inappropriate for practical reasons when measuring individuals in obesity class 2 or higher (13). Though measuring height can easily be done using a stadiometer, weighing morbidly obese persons can be difficult because scales need to provide valid

and reliable measurements while having platforms that are wide enough for them to comfortably stand (8). Densitometry and Dual-energy X-ray absorptiometry (DEXA) have been used as reference techniques for body composition assessment in overweight and obesity class 1 individuals, but those with class 2 obesity or higher frequently exceed the weight limits of these instruments and in certain situations have not been able to physically fit into the measurement compartment (24, 25). Air displacement plethysmography (ADP), using the commercial system BodPod (COSMED, Italy), is another method commonly utilized to measure body composition in pregnant women, children, and the severely obese (25). This method is often employed because it is user-friendly and has demonstrated to have good agreement with body composition measurements derived from hydrostatic weighing (HW), a method seen as the "gold standard" for measuring body composition (26, 27). Body volume is measured using Boyle's law, where body volume is equal to the reduction of volume in the chamber (28). During measurement, air is displaced when an individual is sitting in the sealed chamber. Body volume, combined with body weight (mass), is used to determine body density so that %BF and lean body mass (LBM) can be calculated using either the Siri or Brozek formula (29). Another technique that has been used to measure body composition in severely obese individuals is bioelectric impedance (BIA) (8, 12, 30).

Bioelectrical impedance

Since BIA was introduced in the 1980s, it has become an increasingly popular tool for estimating body composition because it is user-friendly, noninvasive, relatively inexpensive, portable, and can be performed across a wide range of subjects (30-32). It has been often used to predict body composition components such as fat free mass (FFM), total body water (TBW) and body fat. In BIA, a small alternating electrical current is applied to the body so that the resistance or impedance of the body to the current can be measured as it passes across body tissues (33). Single frequency BIA technology at 50 kHz can determine the impedance of body tissues. Impedance provides a valid estimate of TBW that can be used to estimate FFM and adiposity (31, 32). According to Hu, the method is based on the principle that the resistance applied to an alternating electrical current is a function of tissue composition (24). The greater the FFM

of an individual, the faster the current will pass through; thus, the greater the fatty tissue, the greater the resistance is to the current (24). Under most conditions, single frequency BIA can provide reliable estimates of TBW as it can serve as a practical technique for the analysis of body composition in healthy individuals and in those with conditions where major water disturbances are not eminent (27). However, it is important to note that BIA values can be affected by a several factors, including: body position, hydration status, consumption of food and beverages, ambient air and skin temperature, recent physical activity, and conductance of the examining table (31, 34). Therefore, the standardization of measurement conditions is required in order to obtain accurate, valid, and reliable data (31, 34).

The quality of BIA has improved greatly over the last years with the introduction of a multiple frequency BIA (24). An example of a multi-frequency impedance body composition analyzer is InBody 720 (Biospace, Korea), an instrument that estimates body composition by using a segmental, eight-point tactile electrode method and is able to measure resistance and reactance at multiple frequencies (30). The InBody 720 consists of a platform with an integrated scale, hand and feet electrodes, and a display operation unit. InBody 720 is currently being used in clinical practice among obese individuals in many parts of the world, including Norway (35). More studies are warranted on the reliability and validity of BIA in the severely obese demographic, as the available literature has shown multiple shortcomings. The percentage of FM (BF % > 30%) is often underestimated and FFM overestimated when compared to DEXA (36-38).

The underestimation of the percentage of FM using BIA may be caused by the lack of standardization during BIA measurements. For instance, the InBody 720's manual instructs the individual being measured (the examinee) to form an angle of 15° between the arms and sides while holding on to the hand electrode (39). The manual, however, does not provide specific instructions on how this is to be done, nor does it explain the significance of holding such an angle. The InBody 720 manual also recommends the use of InBody electrolyte wipes when an error message appears and the analyzer stops the test due to an incorrect standing posture or due to the examinee's dry palms and soles.

The manual simply instructs the user to wet the palms and soles of the feet prior to re-initiating the test. The lack of information provided and the instructions given for this procedure are unclear and difficult to standardize. Standardization of BIA procedures is of high clinical importance and needs to be explored further.

Callosity

As mentioned earlier, some of the factors that may affect BIA measurement values include hydration status and skin temperature. While measurements are taken using BIA instruments such as InBody 720, the skin becomes occluded from coming into contact with the instrument's metal electrodes (40) Thus, the rate of water accumulation at the contact sites may be affected during the BIA procedure, as skin contact with the BIA instrument introduces systematic error by disrupting natural transpiration (40, 41). The rate of water accumulation in the stratum corneum is further exacerbated by the presence of callosities, as new stratum corneum that is formed underneath calluses have been found to be less hydrated than normal (41). 'Callosity', or hyperkeratotic lesions, is an umbrella term for corns and calluses (42). Callosities are formed when the skin becomes irritated by either internal or external pressure and results in the development of a corny layer of epithelium (40).

Plantar callosity (hyperkeratosis) is considered one of the most common skin disorders that affects obese persons (43). Callosities in the foot are often painful and have been associated with reduced walking speed, impaired balance, and difficulty in ascending and descending stairs (44). Garcia-Hidalgo and colleagues (1999) conducted a cross-sectional study on 156 obese patients belonging to classes 1-3 and concluded that plantar hyperkeratosis should be considered as a cutaneous stigma of severe obesity (45). Obese individuals are known to have difficulty in doing daily activities such as bathing, dressing, and giving themselves pedicures because their excess weight lowers their mobility, flexibility, and dexterity (46). The reduction in mobility and flexibility poses challenges for obese persons in maintaining hygiene. As pedicures can be troublesome for those who have poor dexterity, it may be helpful for them to obtain professional assistance in managing corns and calluses (47). Garcia-Hidalgo and colleagues (1999)

have also claimed that the formations of plantar callosities are likely to have resulted from pressure due to excess weight (45). The challenges of maintaining proper foot hygiene may be worsened due to the social stigmatization of the obese population. The act of being socially marginalized may contribute to the shift in hygienic standards by lowering obese individuals' motivation for maintaining body hygiene. This reduction in the upkeep of body hygiene may intensify callosity-related problems in this population (45). To our knowledge, no study has looked at the potential impact of plantar callosities on the reliability of BIA measurements. Due to the lack of knowledge on this topic, further research is warranted.

This study's aims and hypotheses will be discussed on the next page.

Aims and hypotheses

Purpose of study

The purpose of this study was to evaluate the reliability and validity of body composition measurements in morbidly obese adults obtained using BIA.

Primary aims:

- To evaluate whether plantar callosities have an impact on the reliability of body composition measurements in morbidly obese adults obtained by BIA using the InBody720 (Biospace, Korea).
- To evaluate whether arm posture has an impact on the reliability of body composition measurements in morbidly obese adults obtained by BIA using custom-made axillary pads made of Plastazote®, angled at 15° (15° arm posture is recommended by the InBody 720 manual).
- To evaluate whether the use of InBody electrolyte wipes (recommended for use by InBody) has an impact on the body composition measurements in morbidly obese adults obtained by BIA.

Secondary aim:

- To evaluate the validity of body composition measurements obtained through BIA in morbidly obese adults by comparing BIA results with those acquired by air displacement plethysmography (ADP), using BodPod (COSMED, Italy), as the gold standard.

Hypotheses

Primary hypotheses:

- Plantar callosities have an impact on the reliability of body composition measurements obtained using BIA in morbidly obese adults.
- Arm posture has an impact on the reliability of body composition measurements obtained using BIA in morbidly obese adults.

- InBody electrolyte wipes have an impact on the reliability of body composition measurements obtained using BIA in morbidly obese adults.

Secondary hypothesis:

- BIA underestimates the percent body fat of morbidly obese adults when compared with ADP.

Methods

Study design

This study used a repeated measures design, where body composition was assessed using BIA before and after interventions under various circumstances. Pre and post intervention BIA results were compared to one another and to results obtained by ADP. All of the participants were treated as one group, tested under all conditions, and served as their own controls.

Participants

Inclusion criteria: Adults with class 2 and 3 obesity (BMI $\geq$ 35.00 kg/m^2) and with moderate to severe callosities (as assessed by podiatrist affiliated with the study on a scale out of 5, participants with callosities ranging from 3-5 were included).

Exclusion criteria: Intractable plantar keratosis (IPK) – painful plantar calluses located under the metatarsal heads (40). Individuals who were pregnant or were suffering from diseases that cause water retention (edema, renal insufficiency, hypertension, etc.) were also excluded from this study.

Main outcome variables

Data collected: Body weight and height, body composition using BIA and ADP, sole and heel of foot (through photograph).

Detailed description of the study

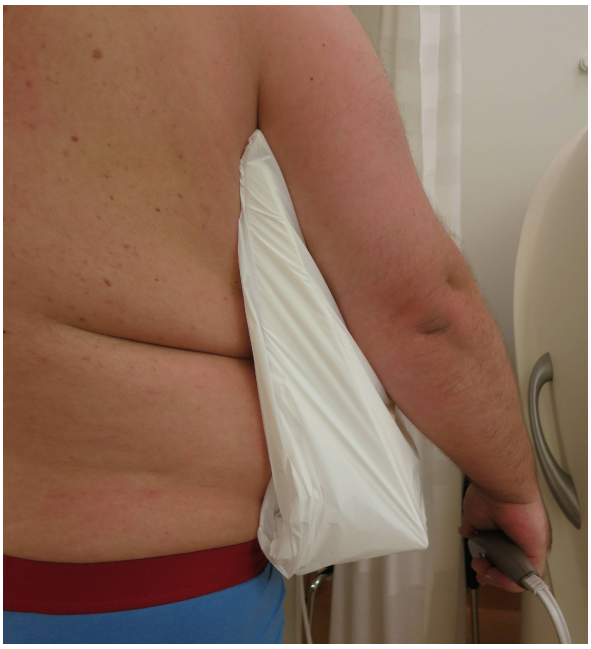
36 study participants (13 males, 23 females, aged 28 - 70) were recruited from the Obesity Outpatient Clinic of St. Olavs University Hospital in Trondheim, Norway from September 2012 until March 2013. All participants were patients of the Outpatient Clinic and were recruited either during scheduled checkups or through courses offered by the Outpatient Clinic on obesity care for patients undergoing bariatric surgery. Initial data was collected at the Outpatient Clinic from severely obese patients who were interested in this study, by nurses working at the Outpatient Clinic. The nurses took photographs of the soles of the feet of these individuals; these photographs were then given to an authorized podiatrist affiliated with the study for an eligibility assessment. Study participants whose feet were given a severity score of 3 or higher were included in the study. Information regarding the study was given to the participants who had fulfilled the eligibility criteria at the start of the study. Individuals who sought to participate in this study were given written information about the study and a consent form. This study was approved by REK, the Norwegian Regional Medical Ethics Committee (REK Midt Ref no. 2012/1018). Participation in the study was voluntary and involved no known risks as these tests have been proven to be non-invasive to the target population. Study participants were able to withdraw their consent to participate at any time without stating any particular reason.

Procedure

The intervention took place over a span of two consecutive days. During both days, participants were given an appointment to meet at the Obesity Outpatient Clinic of St. Olavs University Hospital, having fasted and emptied bladder before testing to achieve optimal test accuracy and for standardization purposes. On Day 1, study participants first had their feet photographed by the researcher, had their height measured using a stadiometer, and then were measured by BIA (InBody 720) using form-fitted clothing (undergarments). Four sets of body composition measurements were taken using the InBody 720 on Day 1.

During the first measurement, the participant was asked to step onto the InBody 720 and have their arms extended out at approximately 15° arm posture (InBody recommended arm posture). For the second measurement, the participant was given axillary pads made out of Plastazote®, a non-conductive, water resistant material, that were custom built for the study to help participants hold their arms out at an exact 15° angle (see **Figure 1**). This test was performed in order to determine if the recommended 15° posture is crucial for obtaining precise measurements. The InBody 720 was weight-adjusted to compensate for the weight of the axillary pads. The third and fourth measurements were very similar to the first and second. However, in addition, participants were also asked to moisten the palms of their hands and soles of their feet with an InBody electrolyte tissue that was recommended for usage when taking measurements using InBody720. These wipes were designed by Biospace to help moisten the hands and feet of those whose palms and soles are too dry or have too much hard skin. However, for the purposes of this study, we have assumed that all participants had dry skin and required their palms and soles to be wiped with electrolyte wipes, regardless of the presence of error messages.

Figure 1. Study participant being measured on InBody 720 using custom-made axillary pads



Following the completion of InBody 720 measurements, each participant underwent one final measurement using air displacement plethysmography (ADP) performed by the BodPod. Once the researcher had computed patient information and completed volume calibration, the study participant was asked to take a body weight measurement by stepping on a scale connected to the BodPod and then sit inside the BodPod chamber using form-fitted clothing (undergarments) and a swim cap for two 50-second body volume measurement periods. Once the participants had been measured, they were allowed to break their fast and eat breakfast provided by the study. Following breakfast, the study participants were sent over to the podiatrist (fotterapeut) located at the St. Olavs University Hospital campus where calluses and corns were removed (pedicure). This procedure lasted for approximately one hour.

During Day 2, the study participants had their feet photographed again by the researcher prior to the measurements on the InBody 720 that were taken again in a fasted state (for comparison pre – post pedicure). Body composition measurements taken using form-fitted clothing on Day 2 were similar to the third and fourth measurements performed on Day 1: two sets of measurements were taken at an arm posture of 15° and InBody electrolyte wipes (once with axillary pads and once without). Study participants were also served breakfast upon completion of all body composition measurements.

Flow chart of study participants undergoing the study

- Upon approval from REK, Patients of the Obesity Outpatient Clinic at St. Olavs University Hospital were informed about the study during checkups or courses offered by the Outpatient Clinic.
- Interested patients were given written information study.

↓

- Patients who signed consent forms had their feet photographed for eligibility assessment.
- The photographs were evaluated by an authorized podiatrist affiliated with the study.

↓

- Patients who fulfilled the eligibility criteria received appointments to meet with the researcher during two consecutive days (October 2012 – March 2013).

↓

Day 1: Participants met the researcher at a fasted state for measurements and callosity removal (pedicure).

- Photograph of sole and heel of feet were taken, height measured using a stadiometer,
- 4 sets of measurements were taken using the InBody720 under different circumstances (with and without axillar pads, with and without InBody electrolyte wipes).
- BodPod measurements also taken.
- Participants broke their fast and ate breakfast provided by study, and received a pedicure from the podiatrist.

↓

Day 2: Participants met having fasted for measurements.

- Photographs of sole and heel of feet were taken for pre and post pedicure comparisons, 2 sets of measurements (with and without axillar pads, with InBody electrolyte wipes).
- Breakfast was also provided following Day 2 measurements.

Statistical Analysis

The SPSS statistical package 20.0 (SPSS Inc., IBM Company, Chicago, IL, USA) for Macintosh was used for statistical analysis. Data was assessed for normality using normal probability plots and the Anderson–Darling test for normality. These assessments showed that the data was not normally distributed. Various common transformations for data were applied to see if the data could be transformed to have a normal distribution, but the transformed data also did not appear normal. Statistical significance was set at ($p < .05$). The following analyses were performed:

Limits of Agreement using Bland Altman plots

Limits of agreement for body fat percentage (%BF) measured were visualized using Bland-Altman difference plots for all four interventions (pre and post pedicure, with and without axillary pads, with and without InBody electrolyte wipes, and BIA and ADP). Limits of agreement analyzed using Bland Altman plots are designed primarily to look at how two methods of clinical measurements agree with one another statistically (48). It is expected that if two methods are designed to measure the same parameter, they should produce good correlation. Therefore, even though the plots can provide insight into the impact of interventions performed on BIA, it is more beneficial when observing how %BF values obtained by BIA agree with the values given by ADP. Bland-Altman plots are constructed when the differences between the two methods (y-axis) are compared with the averages of the two methods (x-axis). These plots are designed to investigate the presence of any systematic differences and to identify potential outliers. The mean difference serves as the estimated bias, while the standard deviation of the differences is plotted to measure the random fluctuation around the mean.

Wilcoxon signed-rank test with continuity correction

Testing for the effect of interventions was done in order to determine whether the difference in %BF was statistically significant for each intervention we performed. Paired t-tests were initially conducted due to the nature of the comparisons, however, not all of the values were normally distributed. As a result, all differences were treated the same

and non-parametric tests were used. Thus, non-parametric Wilcoxon signed rank tests with continuity correction were performed. Had paired t-tests been performed, the conclusions reached using the Wilcoxon signed-rank test would have been similar at a 5% significance level.

Linear regression analysis

Linear regression analysis was performed for the %BF measurements obtained when the participants were measured using BIA with InBody electrolyte wipes and no axillary pads during Day 1 (shown on Table 3 in results section). These measurements were used for regression analysis because they were conducted using the recommendations given by the InBody720 manual. Linear regression was used to look for tendencies with variables (age, gender, BMI, severity of callosities) that could explain the differences in %BF. Additional linear regression analyses were also performed using the differences in %BF for each intervention to see if the potential predictors could explain the variability.

Results

Overall characteristics of the participants included in the study can be seen in **Table 1** below. For measurements obtained with and without axillary pads, the results of 4 study participants were excluded due to technical difficulties associated with the InBody 720 machine (BIA). There was also one participant who was physically unable to fit inside the BodPod chamber (ADP) due to his size and thus, measurements were unable to be taken for comparative purposes.

Table 1. General characteristics of study participants*

	Male	Female	Total
Number of participants	13	23	36
Age (years)	44.8 ± 11.3	46.8 ± 10.6	46.1 ± 10.6
Height (cm)	181.2 ± 7.1	168.0± 5.7	172.7 ± 8.9
Weight (kg) [a]	142.4 ± 19.8	114.6± 12.3	124.6 ± 20.4
BMI (kg/m^2)[a]	42.5 ± 5.2	40.6 ± 4.0	41.6 ± 4.3

** Data presented as ± standard deviation*

[a] Weight and BMI reported were measured using BIA following the equipment guidelines (with electrolyte wipes, no pads)

The mean percent body fat before and after each BIA intervention can be seen in **Table 2**.

Table 2. Percent body fat (%BF) assessed under different interventions

Intervention	N	Mean %BF	Standard Deviation	z-score[a]	p	r[b]
Pedicure				-1.71	.09	.29
Pre	36	46.63	6.26			
Post		47.01	5.96			
Difference		0.38	1.06			
Electrolyte wipes				-0.99	.32	.17
No wipes	36	46.87	5.85			
With wipes		46.63	6.26			
Difference		0.24	1.05			
Axillary pads				-4.66	< .001	.82
No pads	32*	46.63	6.26			
With pads		47.67	6.01			
Difference		1.04	0.87			
Instruments				-0.71	.48	.12
ADP	35*	47.22	5.42			
BIA		46.63	6.26			
Difference		0.33	3.31			

** Missing values were unobtainable because of technical difficulties and inability for a study participant to be measured due to size.*

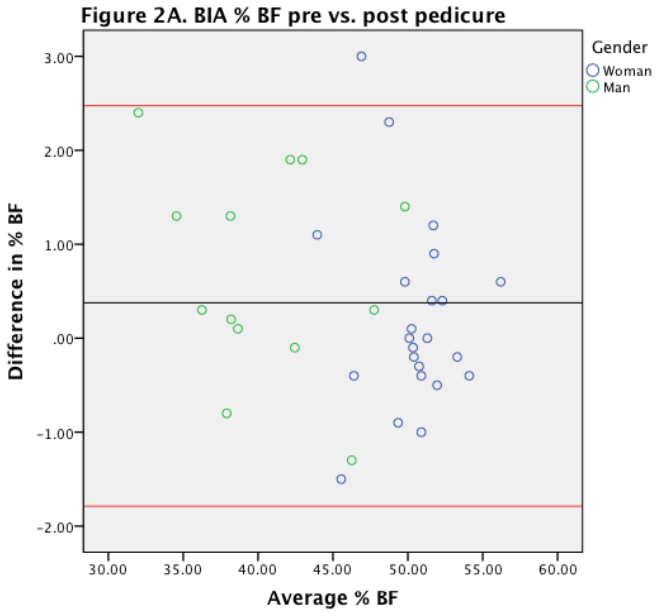
[a] Test statistic

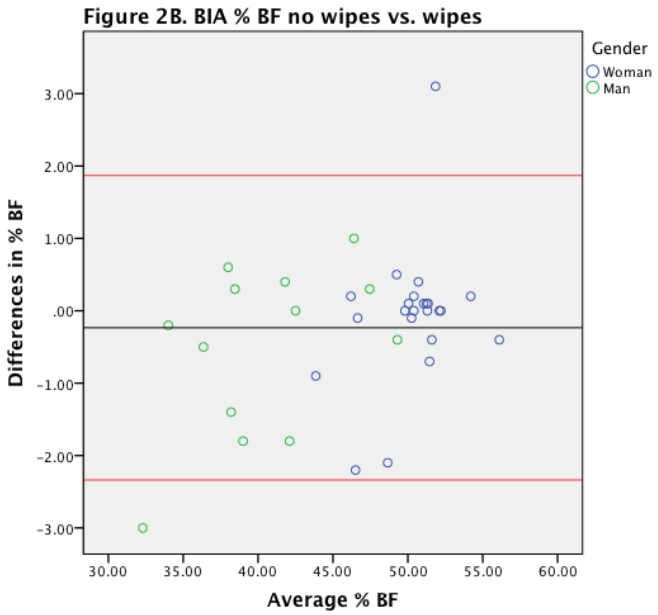
[b] Effect size

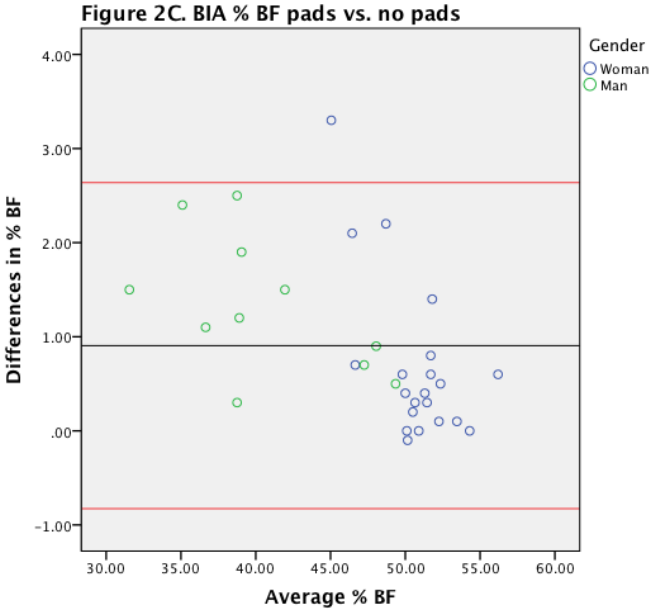
The Wilcoxon signed-rank tests revealed that the intervention with axillary pads was the only one that resulted in a highly statistically significant difference in %BF measurements ($p < .001$). Percent body fat values were higher for all participants using axillary pads than without pads. The effect size, r, for the axillary pads intervention is considered extremely large when measured against Cohen's criteria, where an effect size ≥ 0.5 is considered as large (49). The effect size for this intervention is also much larger than the other three interventions analyzed in this study. The other three interventions did not have a statistically significant effect.

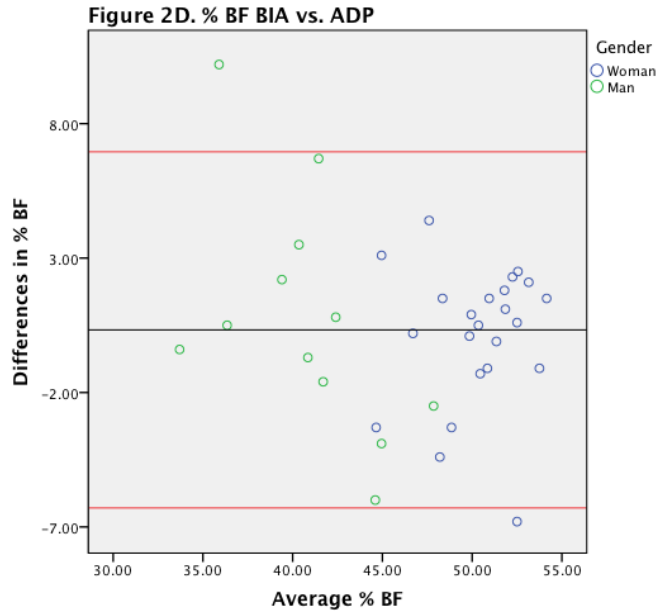
Bland-Altman plots can be seen in **Figure 2 (A-D)** below.

Figure 2. A-D: Bland-Altman plots of the different interventions, showing mean and ± 2 standard deviations









For each one of the plots, it appears that the majority of the data sets observed fall within the limits set at ± 2 standard deviations. All four figures show a tendency for the females in the study to have higher body fat percentages compared to the males. There appears to be a clustering of values from female participants who have 50-55 %BF. The differences in %BF in all measurements obtained only using BIA (pre and post pedicure, with and without wipes, and with and without axillary pads) had a much lower variance than when %BF measurements obtained by BIA were compared with those obtained by ADP. The standard deviation of %BF values measured by BIA and ADP was significantly higher than that of the other three interventions.

Figure 2C depicting the graph of %BF measurements obtained during the axillary pad intervention showed a fixed bias, or a systematic difference between the measurements. The mean difference, 0.92, is much closer to 1 than 0. This is not the case for the other interventions. This observation is echoed by the results of the Wilcoxon signed-rank test described below. Unlike **Figure 2C**, **Figure 2A** and **2B** did not reveal to have systematic differences. With the exception of **Figure 2C**, there appears to be a consistent outlier on either side of the standard deviations plotted on all figures. Similar to **Figure 2A** and **2B**, **Figure 2D** also did not depict systematic differences, despite the large spread.

Results from the regression analysis performed on %BF values obtained using BIA (with electrolyte wipes and no pads) can be seen in **Table 3 on the next page**.

Table 3. Multiple regression analysis of % BF measurements obtained from BIA using InBody electrolyte wipes and no axillary pads

Parameter	B	Standard error of B	p	95% Confidence interval	
				Lower bound	Upper bound
Intercept	22.32	6.46	.002	9.13	35.51
Age (years)	-0.05	0.05	.37	-0.16	0.06
Gender					
Female	10.76	1.26	<.001	8.20	13.33
BMI (kg/m^2)	0.48	0.14	<.001	0.20	0.76
Severity score					
3	-0.67	1.43	0.64	-3.59	2.24
4	0.31	1.35	0.82	-2.44	3.06

** Unlisted values for male and severity score 5 are not listed because the values have been incorporated into the intercept*

Multiple R^2: 0.74 (Adjusted R^2: 0.69)

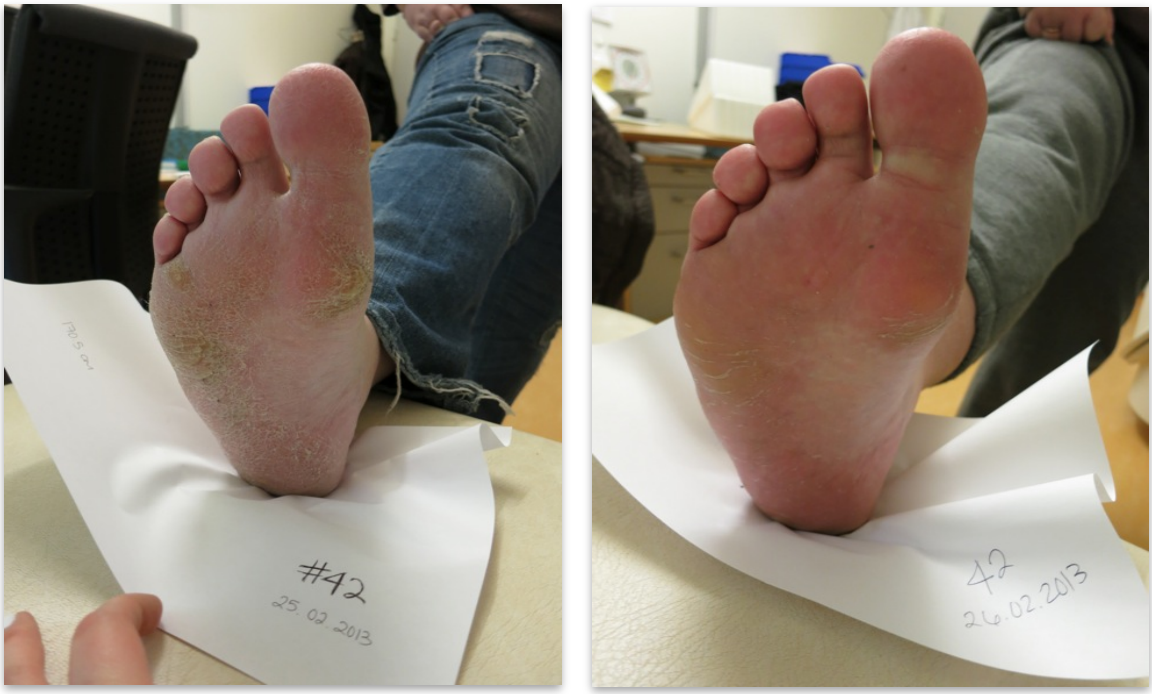
Residual Standard Error: 3.48 with 31 degrees of freedom

F-statistic: 20.62 with 4 and 3 degrees of freedom, (p <.001).

Linear regression analysis revealed that with a one-unit increase in BMI, %BF increased by 0.5 percent points. We can conclude that BMI is significant in predicting %BF because the p-value reported is < .001, which is less than the cutoff. Age and severity score of callosities do not appear to be significant factors. However, gender proved to be an important factor as well, with a (p < .001). On average, the females in this study had a %BF that was 11 percent points higher than the males. Overall, the regression model fitted with age, BMI, gender, and severity score of callosities accounted for 74% of the variability in the data collected. The results from the omnibus F-test performed on this data revealed that the model involving the predictors discussed is suitable fit for predicting %BF. When the regression analysis was re-done fitted with only gender and BMI, the results showed that these two variables alone could explain 72% of the variability in the data.

As mentioned earlier, further regression analyses were performed on the differences for each one of the interventions using the same predictor variables described above. The results from the omnibus F-tests performed for all interventions: pre and post pedicure, wipes vs. no wipes, axillary pads vs. no axillary pads, and the comparison of ADP and BIA proved to be statistically insignificant at ($p < .05$). For the differences in % BF values before and after the pedicure, the regression model fitted with age, BMI, gender, and severity score only accounted for 9.3% of the variability in the data collected. For the differences in % BF values with and without InBody electrolyte wipes, the variables described above explained 6.1% of the variability in the data. For the differences in % BF values obtained through ADP and BIA, the predictor variables discussed accounted for 5.6% of the variability in the data. The regression analysis performed on the difference in %BF using axillary pads and no pads revealed that the predictor variables were able to explain 29% of the variability in the data. Despite a significantly larger variability explained in this model, none of the predictor variables were significant at ($p < .001$), however, gender and BMI were significant at ($p < .05$) in predicting %BF.

Figure 3. Before and after pedicure foot picture of a study participant



Discussion

The assessment of body composition in severely obese adults remains challenging. The need for a practical, valid, and reliable method to assess body composition especially for the morbidly obese is warranted. BIA is user-friendly, noninvasive, relatively inexpensive, portable, and can be used on a wide range of subjects, however, its validity and reliability is still disputable. Overall, based on our findings, it seems that multiple-frequency BIA is a valid method for estimating %BF in severely obese adults; the results obtained from BIA in our study population are comparable with those obtained by BodPod. Our results also show that plantar callosities and the use of InBody electrolyte wipes do not have a statistically significant effect on BIA measurements. Arm posture, however, was revealed to be of statistical significance when measuring %BF in morbidly obese individuals using the BIA method. Further examination of the arm and trunk contact and how this may affect the reliability of BIA measurements is warranted. Clinical significance is not contingent upon statistical significance; our findings, regardless of statistical status, are of clinical importance and should be taken into consideration in clinical settings as well as future research involving BIA.

Reliability

Few studies have looked at the reliability of BIA on severely obese individuals. Studies that have looked at BIA's reliability have often recommended further evaluation on the standardization of BIA measurements (31, 34). Several factors have been found to affect BIA's body composition values (31, 34). The present study assessed the impact of body (arm) position and skin hydration status on BIA measurements. Arm position was assessed using axillary pads, while hydration status of the skin was assessed using InBody electrolyte wipes and pedicure to remove callosities.

Plantar callosity removal (pedicure)

BIA is becoming an increasingly popular method for assessing body composition in clinical settings. Thus, knowledge on this topic is of high clinical importance, especially since hydration status is a key component of BIA and the presence of callosities might influence the rate of water retention. As far as we know, the effect of plantar callosities on BIA measurements has never been examined. We wanted to explore the impact of plantar callosities on the reliability of BIA measurements because the presence of callosities suggests that the skin is not normally hydrated. This condition potentially causes systematic errors to arise during BIA measurements, where the skin on the palms and the soles of the feet come into contact with metal electrodes (40).

To our surprise, the removal of callosities did not have a statistically significant effect on %BF. The results of our regression analysis performed on %BF measurements before and after callosity removal showed that the severity of callosities do not affect body composition measurements obtained using the BIA method. One reason could be because the calluses we observed in our study participants had a tendency to form *around* the heel of the foot as well as *the sides* of the foot, and not so much on the plantar region. The InBody 720 platform only uses the plantar area of the foot to read measurements; the calluses present on the sides and around the heel of the foot are not involved in the measurement. Therefore, the removal of calluses might not have made much of an impact. To the best of our knowledge, no known objective classification system measuring the severity of callosities is available. Despite the lack of such a system, we had a highly experienced podiatrist that was well qualified to make callosity assessments of our study participants' feet. The podiatrist had decided to evaluate the severity of callosities using a scale from 1-5 (5 being most severe) and had given initial assessments of the study participants' feet using photographs. The photographs might not have been adequate to fully determine the severity of the calluses. Further statistical analyses were performed on participants belonging to a scale of 4 and/or 5 to see if higher severity would have an effect on %BF measurements, but the findings were insignificant and inconclusive. Despite statistical insignificance, since the results of our intervention revealed that callosities do not affect the reliability of BIA measurements, we can

recommend clinicians and other BIA users to use BIA for body composition measurements despite the presence of callosities.

InBody electrolyte wipes

Hard and/or dry skin is a condition that was listed as a factor that could affect BIA measurements (31, 34). The InBody 720 manual only recommends the use of electrolyte wipes if an error reading arises. InBody electrolyte wipes are neither widely available nor often used in clinical practice. Moreover, very little information is available on its effectiveness in moistening hard, dry skin. Thus, determining the effect of these electrolyte wipes are also of clinical importance. Since our study recruited adults with moderate to severe callosities, we felt that we should provide electrolyte wipes to each study participant to test the effect of their usage. Even though we had hypothesized that the usage of electrolyte wipes would have an impact on the BIA measurements, our results showed otherwise. Our analysis on the difference in %BF measured with electrolyte wipes confirmed that electrolyte wipes do not have an effect on BIA measurements. Based on our findings, we can conclude that electrolyte wipes do not need to be used on a routine basis during measurements even on individuals with callosities.

Axillary pads

This study aimed at evaluating the impact of using custom-made axillary pads on the measurement of percent body fat using BIA. The axillary pads were made out of Plastazote® foam, an inert, noninvasive material that is water resistant and non-conductive (50). These pads were created by the Trøndelag Orthopedic Workshop and specifically designed for this project so that the arm posture would be held at a precise, standardized 15° angle. As discussed in the introduction, the InBody 720 manual does not specify the significance of holding the arms at a 15°angle, nor provide instructions on how this is to be standardized and performed. In daily practice, we have witnessed that clinicians do not always adhere to these guidelines and have measured their patients using various arm-torso angles, from acute angles formed at about 15° up to right angles (90°). Furthermore, we also speculated that arm posture might be of high significance because the excessive skin under the arms of morbid obese individuals may touch the trunk and interfere with the measurement. Despite manual's instructions to hold arms out

at a 15° angle, the arm and trunk region might not be sufficiently separated to provide proper measurements of the respective body segments. We believed that improper measurements of these segments would therefore lead to inaccurate measurements of overall body composition. Therefore, we hypothesized that the use of axillary pads would have an impact on the reliability of BIA measurements. Knowledge on the importance of arm posture, especially when measuring the body composition of severely obese individuals using BIA is not only relevant for clinical practice, but also for future studies involving BIA.

The evaluation of the effect of axillary pads on BIA measurements was warranted, as several authors expressed the need for further studies to be conducted on the impact of body position on BIA measurements (51, 52). Shafer and colleagues (2009) conducted a study on the reliability and validity of segmental multiple-frequency BIA on a group of healthy adults with varying BMI. They recommended further assessment be performed on the estimate of resistance of the trunk region. The segmental multiple-frequency BIA instrument they used was similar to that used in our study, where the electrode placements on the hands and feet are distally located. The placement of the electrodes had given indirect, inadequate estimates of the resistance of the trunk. Shafer and colleagues (2009) argued further that the fat mass distribution in the obese, particularly, affects trunk resistivity, which in turn, might have caused the inaccurate measurements of the body torso. Their overall findings suggest that inaccurate body torso measurements might have affected their measurement of overall body composition using BIA.

Our findings confirm our hypothesis; %BF was significantly higher when the BIA measurement was performed with axillary pads than without (mean difference of 1.04%). Similar to Shafer and colleagues' study, our results suggest that arm posture affected the overall measurement of body composition using BIA. The significance of our findings is further strengthened by the result of our linear regression of the differences in %BF for the axillary pads intervention fitted with the predictor variables, where these variables were not shown to be highly significant in explaining the differences. BMI and gender

were able to explain some of the differences; however, we believe that %BF is ultimately higher using axillary pads because the pads prevented the excess skin and adipose tissue from the arms to come into contact with the trunk, and therefore allowed for a more precise, accurate measurement of body composition. The axillary pads also allowed the BIA measurements to be more standardized. The results obtained from our axillary pad intervention are also of great clinical significance because it helped fill the gap in knowledge on the importance of body position during BIA measurements and the need for standardization.

Validity

BIA vs. ADP

Many studies have assessed the validity of BIA against DEXA (36, 38, 51) while others have examined body composition estimates obtained by BIA and ADP and compared these estimates with DEXA (28, 53). Those who have compared the validity of BIA with DEXA have found that BIA consistently underestimates %BF in the severely obese (21, 22, 51). Studies comparing BIA, ADP, and DEXA have also concluded that BIA tends to underestimate %BF and that these methods should not be used interchangeably in the severely obese (53). Very few studies have assessed the validity of body composition estimates from BIA, in morbidly obese individuals, and compared the estimates with those obtained from ADP (54).

The results of this study revealed that BIA has strong validity when used to measure body composition in severely obese adults. Percentage body fat values reported by BIA and ADP were not statistically significant different. This finding is consistent with that reported by Horie and colleagues (2008); who found that BIA and ADP's body fat estimations did not differ significantly and had good accuracy and precision (54). However, their assessment of limits of agreement using Bland-Altman plots showed that they had a wide limit of agreement; thus, they concluded that standard BIA equations were inadequate for estimating body fat in severely obese patients. The limit of agreement performed in this study on the comparison of %BF values between ADP and BIA also depicted a large spread in agreement. Beck and colleagues (2012) conducted a

similar study in forty-one healthy patients (BMI 22 ± SD 3.5) and found that BIA and ADP had a good within-day and between-day correlation and therefore demonstrated good within- and between-day agreement, despite a mean difference of 3.1% (55). Due to the high mean difference, the authors recommended ADP and BIA not to be used interchangeably. The results of our study showed that the differences in %BF were not statistically significant (mean difference of 0.33%); meaning that both BIA and ADP can be clinically used to measure body composition in the morbidly obese. However, using BIA and ADP interchangeably should be done with caution as our study reveals an inconsistency in findings with other similar studies. Further studies are needed to confirm our findings.

Feasibility of ADP in morbid obesity

Air displacement plethysmography has been widely utilized in various population groups, including in the severely obese, and is often employed because it is user-friendly and has strong validity (25, 28). Petroni and colleagues (2003) assessed the feasibility of ADP using BodPod in nine morbidly obese patients and reported that ADP was a suitable method for assessing body composition in patients with BMI >40 kg/m^2 (56). However, the results of this study do not support their findings. Although 35 out of 36 of our participants were successfully measured using ADP, there was one participant who was not physically able to enter into the chamber. This male participant had a BMI of 48.7 and a height of 195 cm, and was not able to sit inside the chamber with the doors closed. The seat was too small for him, and his thighs were too long for the chamber door to properly close. Several of the participants who were successfully measured using ADP had commented on the tight space inside the chamber and expressed uncertainty prior to measurement. Based on our findings, we recommend that further studies conduct a reevaluation of the feasibility of ADP in the morbid obese demographic. The size of the BodPod chamber should be reassessed and altered so that it can fit people of all sizes.

Study limitations

The majority of the interventions assessed in this study have never been done before. The target population of morbidly obese individuals with severe callosities was unknown. As a result, sample size calculations were difficult to perform; a small sample size can be considered a limitation to our study. In-depth detail of study participants' medical history was also not available. Therefore, with the exception of the exclusion criteria, other medical conditions that may have altered the body composition measurements were not taken into consideration. Despite our efforts, the standardization of all procedures was challenging. For instance, no instructions were given on how to apply the electrolyte wipes. Some participants were successfully able to apply the electrolyte wipes while standing on the platform, while others had to lean on an object or sit down to apply the electrolyte wipes and then take a few steps to get to the InBody 720 platform. This lack of instruction made it difficult for this study to standardize the measurement procedure. Furthermore, how moistened the hands and feet were and/or needed to be during measurement is not known. Procedures on how to standardize this aspect of the study had not been discussed previously. The actual arm-torso angle when the patient was instructed to hold a 15° without pads was also not evaluated, nor standardized because the InBody 720 manual does not specify how this should be performed. Four measurements of earlier participants also had to be excluded from statistical analysis because the weight of the axillary pads on BIA for these measurements was not properly adjusted. However, since our findings for this intervention are statistically significant at ($p < .001$), we believe that excluding their measurements did not affect the outcome of the intervention.

The measurements pre and post pedicure were also done over a span of two days for ethical reasons. We had speculated that the amount of time required for each participant to be measured before and after the pedicure in one day in a fasted state would be much too long and thus, unethical. This decision, however, should not affect the validity or reliability of BIA measurements because BIA has been shown to have good between-day agreement (55). Appointments that suited the participant, the podiatrist, the availability of the instrument, and ethics surrounding the time frame needed to perform

all of the measurements made it difficult for this intervention to be conducted only in one day. However, the consecutive two-day participation requirement made it difficult for this study to recruit participants. Additionally, due to scheduling difficulties, not all of the measurements were done in the morning. Patients had to come having fasted whenever it was feasible for all parties involved; thus, the timing of the measurements was not standardized. The time of day when the measurements were taken could have affected the results.

Lastly, our inclusion criteria might have been too relaxed. As mentioned earlier, feet severity was assessed using photographs. According to the podiatrist's evaluation, all of the participants who were recruited had feet that had moderate to severe callosities and needed a pedicure to remove the calluses. The podiatrist had described that feet severity was difficult to analyze based on photographs alone, but that upon examining them the day of pedicure, she confirmed that her initial evaluations on the feet were correct. As previously discussed, a known objective classification system measuring the severity of callosities is unavailable; thus, we had one extremely qualified podiatrist assess the severity of the callosities of all of the study participants. However, as described callosities were not always present in areas where the feet made contact with the BIA electrodes. Future studies should involve an initial screening by the podiatrist before inclusion, and include patients with callosities formed specifically on areas touching the BIA electrodes. However, the fact that regression analyses showed that callosity severity was not a predictor of %BF, strengthens our finding that the presence/absence of callosities does not impact significantly on %BF assessed through BIA.

Recommendations for further study

This study's findings on the validity of BIA compared to ADP did not confirm the results from previous studies, where BIA overestimated %BF in the severely obese (54, 55). Further validity studies should be performed to strengthen our findings. We also recommend assessments to be made on the size and the feasibility of ADP on morbidly obese individuals. Axillary pads, or another form of standardization for arm posture should be regulated and implemented on BIA body composition measurements.

Standardization and better clarification of the techniques used to measure these individuals are warranted to strengthen the reliability of BIA measurements.

Conclusion

Overall, although not all of the results of this study are statistically significant, the findings from the interventions conducted are clinically relevant. The results from the interventions testing the impact of InBody electrolyte wipes and the effect of callosity removal (pedicure) were statistically insignificant, but they reveal clinically relevant findings: electrolyte wipes do not need to be used during measurements, and the presence of calluses does not seem to affect the outcome of body composition measurements. Through this intervention, our study has found BIA to be reliable against factors involving skin hydration of the hands and feet. The assessment of the validity of BIA compared to ADP also suggests that BIA is a valid instrument for assessing body composition of the severely obese. This finding implies that both BIA and ADP are valid methods for performing body composition measurements on the morbid obese population. However, the feasibility of using the ADP method on this demographic should be reevaluated since not all of the participants in our study were able to be measured using ADP.

The intervention examining the effect of the custom-built axillary pads is of utmost clinical significance. Our finding, that %BF was higher when BIA measurements were performed using the axillary pads, suggests that arm posture is of extreme importance when measuring body composition through BIA in morbidly obese individuals. This finding, therefore, encourages further assessment to be done on the standardization of arm posture during BIA measurements, particularly on the morbid obese population.

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Appendix 1. Informed consent form (English version)

Request for participation in a clinical trial

The impact of plantar callosities, arm posture, and use of electrolyte wipes on the reliability of body composition measurements by BIA in morbidly obese adults

Background and purpose

This is a request for you to participate in a research study to examine the reliability of a bioelectrical impedance analyzer (BIA). There are many different models of these scales that are available - from those that are simple, inexpensive, and are sold primarily to the general public, to the sophisticated machines used by clinicians and researchers. A BIA is essentially an advanced scale. What makes it special is its ability to distinguish fat mass from lean mass (muscle, bone). Values obtained from these measurements are important for those who want to know what body mass consists of. Nutritionists and physical trainers, for example, can use this data to recommend a diet or exercise regimen that would allow a person to lose weight without losing muscle mass.

In this study, we would like to test the reliability of one of the most advanced impedance machines available on the market, the InBody720. Therefore, we will be evaluating measurements obtained using this machine while paying special attention to the role of callosities may have on these measurements. This machine is used daily in St. Olav University Hospital's Obesity Outpatient Clinic. You have been asked to participate in this study because you are a patient of the Obesity Outpatient Clinic. For the purposes of this study, we are only recruiting obese patients. The Regional Center for Morbid Obesity (RSSO) at St. Olav's University Hospital is responsible for this study.

What does the study involve?

The study entails that you meet up at the Obesity Outpatient Clinic at St. Olav's University Hospital on two consecutive days having fasted. You will be weighed using BIA during both days. During Day 1, you will also be measured using another machine called the BodPod. The BodPod is also an advanced scale but measures body volume in addition. Following BIA and BodPod measurements on Day 1, you will receive a pedicure from the podiatrist who will remove the calluses and hard skin under your feet. This can take up to 1 hour. We will make an appointment with the podiatrist situated 200 m away from the Obesity Outpatient Clinic for you so that the pedicure can take place after the measurements have been taken. The cost of the pedicure is covered by this study. Participation in this study involves no blood tests or other examinations. Study personnel will take pictures of your feet before and after the treatment.

What will happen to the measurements and your personal information?

Measurement results will be analyzed by a graduate student in collaboration with researchers at RSSO, St. Olav's University Hospital and Faculty of Medicine, NTNU.
Photographs of the soles of your feet are taken to evaluate skin quality, but can also be used in articles and seminars accompanying the study. The information documented about you will only be used in accordance with the purpose of the study as described above. All the data will be processed without name, personal identification number or other directly recognizable type of information. A code number links you to your data through a list of names. Only authorized personnel associated with the project have access to the list of names and can get back to you. For control purposes, the name list stored securely until 1 Dec. 2017. Then the list is deleted. The project leader, Bård Kulseng will be responsible for data during this period. Authorities that could have access to data material would include the project manager and the committee for misconduct in research. It will not be possible to identify you in the results of the study when these are published.

Voluntary participation

Participation in the study is voluntary. You can withdraw your consent to participate in the study at any time and without stating any particular reason. This will not bear any consequences for your further treatment in the Outpatient Clinic. If you wish to participate, sign the declaration of consent on the last page. If you wish to opt out of the study or have questions concerning the study, please may contact Magnus Strømmen at the RSSO by phone at 91 70 10 10.

Further information on the study can be found in Chapter A. Further information about, data privacy, finance and insurance can be found in Chapter B. The declaration of consent follows Chapter B.

Chapter A – Further explanation of what the study involves

Criteria for participation

This study is aimed at patients at the Obesity Outpatient Clinic who have moderate to extensive hard/thick skin on the soles (callosities).

Examinations that study participants must undergo

You must meet up at the Outpatient Clinic having fasted for two consecutive days by appointment.

Examinations will occur in this order:

- *Impedance measurements:* Using only undergarments, you will be standing on an advanced scale that will measure you for approximately two minutes per measurement. It is important that you stand still while the test is conducted. The measurements will be done several times during both days.

- *BodPod measurements:* These measurements will only be taken on Day 1. Using only undergarments, you will sit inside a chamber for several minutes while sitting still and breathing normally.

- *An appointment with the podiatrist:* We will schedule the appointment for you to remove the calluses under your feet. We will bear the expenses associated with your treatment.

- Photographs of your feet will be taken during Day 1 and Day 2.

Although each test will only take several minutes, you should expect to spend 1-2 hours to complete these examinations on Day 1, and around 30 minutes on Day 2. You will also receive a breakfast coupon that can be used at St. Olav's cafés during both days upon completion of the measurements.

Potential advantages and disadvantages

If you choose to participate, you will receive body mass (composition) measurements using some of the most advanced measurement methods that are available in Norway. The BodPod machine used in this study is considered as the most reliable machine in practical use and is the only one available in Norway. You will also receive a free pedicure and free breakfasts for two days. Many of our patients at the Outpatient Clinic struggle with calluses under the feet and are prone to complications associated with callosities and may benefit from receiving the pedicure. We are not aware of any disadvantages or risks associated with participating in this study.

Chapter B – Data privacy, funding, and insurance

Data privacy

Information collected on you will primarily be weight data (body weight, fat mass, fat-free mass), height, weight, and age. We will also document the pictures we take of your feet.

Releasing material and data to other parties

If you agree to participate in the study, you also consent to testing and non-identifiable data (described above) to be given to the graduate student to perform the analyses and her supervisors at St. Olav's Hospital and Faculty of Medicine at NTNU.

Right to access and material storage

If you agree to participate in the study, you are entitled to have access to the information registered about you. You also have the right to correct any mistakes in the information we have registered. If you withdraw from the study, you can request to have your collected data deleted, unless the information has already been used in analyses or in scientific publications.

Funding and Insurance

The study is funded by research grants from Helse Midt-Norge (The Central Norway Regional Health Authority) and NTNU. Patients are covered by the Norwegian National Insurance Scheme (pasientskadeerstatning) , jf Pasientskadeloven §1.

Information about the outcome of the study
You will receive a copy of your test results. The outcome of the study will be published in a scientific journal and will be linked via our website: www.stolav.no/overvekt. It may also be used in seminars.

Consent for participation in the study

I hereby confirm that I am willing to participate in the study.

(Signed by the study participant, date)

I hereby confirm that I have given information about the study.

(Signed, role in the study, date)

Appendix 2. Informed consent form (Norwegian version)

Forespørsel om deltakelse i forskningsprosjektet

Betydningen av fotkallositeter, arm positur, og bruk av elektrolytt servietter for påliteligheten av kroppsmassemåling utført med bioelektrisk impedans analyse hos sykelig overvektige voksne

Bakgrunn og hensikt

Dette er en henvendelse til deg om å delta i en forskningsstudie for å undersøke påliteligheten av impedansmaskiner. Det finnes mange ulike modeller av slike maskiner, fra de helt enkle og rimelige solgt primært til private for bruk på baderommet, til avanserte maskiner brukt av klinikere og forskere.

En impedansmaskin er i grunnen en avansert badevekt. Det som gjør den spesiell er at den skiller mellom fettmasse og fettfri masse (muskler, knokler). Slik gir den verdifull informasjon for mennesker som ønsker å vite hva kroppsmassen består i, eksempelvis ved dietter eller trening hvor det er vesentlig å gå ned i vekt uten å tape særlig muskelmasse.

I denne studien ønsker vi å teste påliteligheten ved en av de mest avanserte impedansmaskinene på markedet. Denne er i daglig bruk ved Obesitaspoliklinikken på St. Olavs Hospital. Mer eksakt ønsker vi å undersøke betydningen hard hud under føttene har for måleresultatet.

Du blir spurt om å delta fordi du er pasient ved Obesitaspoliklinikken. I denne studien henvender vi oss kun til overvektige.

Ansvarlig for studien er Regionalt senter for sykelig overvekt ved St. Olavs Hospital.

Hva innebærer studien?

Studien innebærer at du må møte fastende fra morgenen ved Obesitaspoliklinikken på to påfølgende dager. Begge dagene vil du bli veid med impedansmaskinen. Den ene dagen vil du i tillegg bli testet i en annen maskin kalt BodPod. Dette er også en slags avansert vekt, men som i tillegg måler volumet av kroppen.

På Dag 1 vil du i tillegg få behandling hos fotterapeut. Fotterapeuten vil da fjerne hard hud under føttene dine (pedikyr). Dette kan ta opptil 1 time. Vi vil gjøre avtale med fotterapeuten for deg slik at dette kan taes etter testingen på Dag 1. Fotterapeuten holder til 200 m unna Obesitaspoliklinikken. Behandlingen dekkes av prosjektet og skal derfor ikke koste deg noe.

Å delta i studien innebærer ingen blodprøver eller andre undersøkelser. Men det vil bli tatt bilder av føttene dine før og etter behandlingen hos fotterapeut.

Mulige fordeler og ulemper

Fordelene med å delta er at du vil få en grundig måling av kroppsmasse utført med BodPod. Maskinen er regnet som den mest pålitelige i praktisk bruk og er den eneste i Norge. En annen fordel er at du får gratis fotpleie. Mange av våre pasienter sliter med hard hud under føttene og er utsatt for komplikasjoner grunnet dette.

Vi er ikke kjent med at det er ulemper eller risiko knyttet til å delta i studien.

Hva skjer med informasjonen om deg?

Måleresultatene vil bli analysert av en mastergradsstudent i samarbeid med forskere ved Regionalt senter for sykelig overvekt, St. Olavs Hospital og Det medisinske fakultet, NTNU. Fotografi av fotsålen taes for å vurdere hudens kvalitet, men vil også kunne brukes i artikler/foredrag som følger av studien.

Informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger og prøver gjennom en navneliste.

Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg. Av kontrollhensyn blir navnelisten oppbevart forsvarlig frem til 1. des. 2017. Deretter blir listen slettet. Det er prosjektleder Bård Kulseng som er ansvarlig for datamaterialet i denne perioden. Instanser som kan tenkes å kontrollere grunnlagsmaterialet er f.eks. forskningsansvarlige og Uredelighetsutvalget for forskning.

Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Frivillig deltakelse

Det er frivillig å delta i studien. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Dette vil ikke få konsekvenser for din videre behandling i poliklinikken. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke uten at det påvirker din øvrige behandling. Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte Magnus Strømmen ved Regionalt senter for sykelig overvekt på telefon 91 70 10 10.

Ytterligere informasjon om studien finnes i kapittel *A*.
Ytterligere informasjon om personvern og forsikring finnes i kapittel B
Samtykkeerklæring følger etter kapittel B.

Kapittel A- utdypende forklaring av hva studien innebærer

Kriterier for deltakelse

Studien henvender seg til pasienter ved Obesitaspoliklinikken og som har moderat til omfattende hard/tykk hud på fotsålene.

Undersøkelser du må gjennom

Du må møte fastende i Obesitaspoliklinikken to påfølgende dager etter nærmere avtale. Dette skal du gjennom:

- *Impedansmåling:* Dette er i praksis å stå på en slags avansert vekt. Det er viktig at du står rolig mens testen kjøres, noe som vil ta omtrent to minutter. Testen vil bli gjort gjentatte ganger begge dagene. Veiingen vil bli gjort i undertøy.

- *BodPod-måling:* Denne testen kjøres kun en av dagene. Den innebærer at du sitter inne i et kammer et par minutters tid. Testen kjøres i undertøy.

- *Time hos fotterapeut:* Vi bestiller time for deg. Behandlingen hos fotterapeut er betalt av oss.

- *Fotografi av fotsålene.* Bilder kan bli tatt både på Dag 1 og Dag 2.

Selv om hver enkelt test i seg selv kun tar et par minutters tid, må du i verste fall påregne 1-2 timer for å få alt dette unnagjort. Timen hos fotterapeut på Dag 1 kommer i tillegg. Du vil også få betalt frokost av oss etter målingene er unnagjort.

Mulige fordeler

Om du velger å delta vil du få målt din kroppsmasse ved hjelp av de mest avanserte målemetodene som finnes tilgjengelig i Norge i dag. Du vil også få gratis fotpleie.

Mulige ulemper

Vi kjenner ikke til at det er ulemper knyttet til å delta.

Kapittel B - Personvern, biobank, økonomi og forsikring

Personvern

Opplysninger som registreres om deg er først og fremst vektdata (kroppsvekt, fettmasse, fettfri masse). Dernest registrerer vi fotografier av fotsålen.

St. Olavs Hospital ved administrerende direktør er databehandlingsansvarlig. Studien er godkjent av Regionalt komité for medisinsk og helsefaglig forskningsetikk.

Utlevering av materiale og opplysninger til andre

Hvis du sier ja til å delta i studien, gir du også ditt samtykke til at prøver og avidentifiserte opplysninger (beskrevet ovenfor) utleveres til masterstudenten som skal gjøre analysene og hennes veiledere ved St. Olavs Hospital og Det medisinske fakultet ved NTNU.

Rett til innsyn og sletting av opplysninger om deg og sletting av prøver

Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du trekker deg fra studien, kan du kreve å få slettet innsamlede prøver og opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner.

Økonomi

Studien er finansiert gjennom forskningsmidler fra Helse Midt-Norge og NTNU.

Forsikring

Pasientene omfattes av Norsk pasientskadeerstatning, jf Pasientskadeloven §1.

Informasjon om utfallet av studien

Du vil få kopi av dine egne måleresultater. Utfallet av undersøkelsen blir publisert i et vitenskaplig tidsskrift og vil bli lenket til via vår hjemmeside: www.stolav.no/overvekt.
Det kan også bli kunngjort i foredrag.

Samtykke til deltakelse i studien

Jeg er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)