VALIDATION OF A NEW AIR DISPLACEMENT PLETHYSMOGRAPH FOR THE DETERMINATION OF INFANT BODY COMPOSITION

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Abstract

For both clinical and research purposes, it is of great importance to be able to assess infant body composition. However, a safe, simple, non-invasive, and accurate method of estimating infant body composition is not currently available. The "PEA POD", a new air displacement plethysmograph specially designed to measure the body volume of infants, has been developed by the same research team that developed the BOD POD, which measures body volume in adults. Body density can be calculated from the measurement of body volume and body mass. From body density, the body fat mass (FM) and fat free mass (FFM) compartments can be estimated. The purpose of this research study is to validate the accuracy of FM and FFM measurements in infants based on the PEA POD, as compared to the results obtained with estimating FM and FFM from measurement of total body water (TBW). TBW will be calculated using the back extrapolation method with an ^{18}O tracer. Twenty-five healthy, term infants between two weeks and two months of age and 25 healthy low birth weight infants will be measured by both methods and the results compared. If the PEA POD produces results not significantly different from those based on TBW, it will provide further evidence of this device's potential usefulness in both clinical and research applications.

1. SCIENTIFIC BACKGROUND AND SCOPE OF PROJECT

1.1. The need for better tools to assess the body composition of infants

There are many pediatric research and clinical situations in which the assessment of body composition is important. In studies of infant growth, unlike the measurement of weight gain only, knowing body composition allows further insight into the nature of the gain. For example, how infant body composition is affected by the composition of the diet, such as breast milk versus infant formula, and changes in dietary patterns, such as the introduction of complementary foods, are important areas of study. In research involving infants recovering from malnutrition, measuring both weight gain and change in body composition allows a better understanding of the effectiveness of various re-feeding protocols.

Clinically, knowledge of body composition allows for a more accurate assessment of nutritional status than weight alone. Serial measurements of body composition can provide the clinician with information regarding how nutritional status is changing in response to medical or dietary interventions. Among hospitalized pediatric patients, malnutrition can cause an increase in morbidity, mortality and length of hospital stay.

Despite the usefulness of body composition data, they are not often collected as part of research or clinical practice because of the lack of an appropriate measurement tool.

In order to be practical in either a clinical or research setting, a body composition measurement technique should be simple to use, precise, accurate, reliable, non-invasive and relatively inexpensive.

The measurement of the physical density of the human body is a common method for determining body composition in adults. Prediction equations have been established which relate percent fat to body density [1]. Density is determined by dividing the mass of the subject by body volume. While the accurate assessment of body weight is relatively easy due to the availability of precise scales, the assessment of body volume is more challenging. Great precision is required in measuring body volume if it is to be useful in the estimation of body composition. For example, a 10 kg infant with a body volume of 9,500 ml, would be estimated to have 20.0% body fat, based on the Brozek prediction equation [1]. However, just a 1% error in the body volume measurement (95 ml) produces a 24.3% body fat result, an 18% difference. For an accurate body fat result, it is generally accepted that body volume should have no more than a .25% error. Achieving this degree of accuracy is especially difficult in infants.

The most commonly used technique for measuring body density in adults, underwater weighing, is obviously not appropriate for use in infants and children. Since the 1960's, researchers have attempted to devise instruments for measuring the body volume of infants [2,3,4,5,], but not have produced values with an acceptable level of within-subject variability.

Other technologies applied to the measurement of body composition of infants include total body electrical conductivity (TOBEC) and dual energy x-ray absorptiometry (DEXA). Both of these methods require costly equipment and require the infant to lie motionless, usually under sedation, for an extended period of time. The validity of TOBEC in estimating the body composition of infants has not been clearly established and DEXA has the additional disadvantage of exposing the infant to radiation. These drawbacks preclude TOBEC and DEXA from having widespread use in measuring infant body composition.

The measurement of body volume also allows for the further breakdown of body composition into four compartments: total body fat, total body protein, total body water, and total body minerals. An estimate based on a four-compartment model does not have the error associated with variations in the overall density of the FFM used in a two-compartment model. Total body mineral is estimated from the literature [6,7], and total body water can be measured by use of the stable isotope oxygen-18. Because the densities of each compartment are known values, the total body fat and total body protein compartments can be calculated by solving simultaneously the equations related to total body mass and total body density. Being able to examine body composition in this way is especially useful in young infants, as their growth rate is rapid and the relative proportion of the components of FFM change with growth [8].

1.2. The PEA POD

The PEA POD is a small plethysmograph suitable for measuring the body volume of infants. Its design is based on the same principles as its predecessor, the BOD POD. Developed in 1994, the BOD POD has been shown to accurately and precisely measure body density in adults [9,10].

Commercially available since 1995, about $^{18}0$ BOD PODs have been sold to research and medical institutions around the world. The BOD POD has been the primary device by which we assess body composition for our research studies involving postpartum women. In comparison to hydrostatic weighing, it is much simpler, quicker and at least as accurate in measuring body volume. It is also better tolerated and more convenient for the research subject.

The PEA POD is a dual chambered device made of 15" diameter acrylic tubing. In simplified terms, body volume is measured via a precisely controlled, volume-perturbing element, which is mounted between the two chambers, leading to small and complementary pressure fluctuations in the two chambers. The interior volume of the sealed chamber may be estimated by measuring the increase in pressure resulting from the volume change created by the volume-perturbing element. If a subject is introduced, exactly the same amount of volume perturbence will produce an increased pressure response, because the volume of the chamber is reduced by the volume of the subject. The increase in the pressure response provides a measure of subject volume. A two-point calibration with chamber empty and with known reference volume allows scaling and translation of this function to read output to the nearest 1 ml. The infant need only lie in the chamber for approximately 60 seconds in order to obtain a valid measurement. Thoracic gas volume of the infant (lung volume) is estimated.

The PEA POD has been shown to measure the volume of inanimate objects, ranging in size from 3-12 liters, reliably and accurately. In comparison to water displacement, the volume measurement varied by 0.23-0.59%. The standard error of the mean (SEM) from 5 repeated trials ranged from 0.02-0.06%. A SEM of 0.06% corresponds to a 0.2 percentage point difference in the body fat estimate (Table I).

We have collaborated with the developers of the PEA POD, Life Measurements Measurement International (LMI), in testing the feasibility of using the device in measuring the body volume of human infants. Six infants from 3-8 weeks of age, and 3.5-6.6 kg were tested. None of the infants was disturbed by the procedure, and in fact they all seemed to be calmer than expected while in the chamber.

We hypothesize that the muffled nature of the mother's voice while the infant was in the chamber was an experience similar to being in the womb.

TABLE I. RESULTS OF MEASURING THE VOLUME OF INANIMATE PHANTOMS (BY WATER DISPLACEMENT AND PEA POD).

RESULTS OF PHANTOM VOLUME TESTING							
Water Displacement			Infant PEA POD				
Phantom	Mean (mL)	SD (mL)	SD Error (% of mean)	Mean (ml)	Mean Error (%) [(observed phantom)/ phantom] x 100	SD (ml)	SD Error (% of mean)
1	3,212	13	0.40	3,229	0.59	2	0.06
2	6,454	17	0.26	6,480	0.42	2	0.03
3	9,692	22	0.23	9,724	0.33	2	0.02
4	12,925	12	0.09	12,957	0.26	5	0.04

The purpose of the research study presented here is to assess the validity of this new device. Appropriate validation trials must be conducted in order to establish the precision, reliability, and accuracy of the PEA POD in estimating body composition. If the PEA POD produces results not significantly different from those based on TBW, it will provide further evidence of this device's potential usefulness in both clinical and research applications.

2. METHODS

2.1 Overview

Twenty-five healthy term infants and 25 healthy low birth weight infants (LBW) will be recruited for study. The infants will be tested for volume and mass using the plethysmograph and associated scale, thus providing a whole body density measurement. The same infants will also be tested for TBW using the back extrapolation method with ^{18}O as the isotopic tracer [11]. The density data derived from the plethysmograph will be used independently to predict body composition (2-compartment model) and also in combination with TBW to predict body composition based on a 4-compartment model [12]. The main outcome variables will be the precision, reliability and accuracy of the PEA POD in assessing body composition.

2.2 Recruitment and consent

Term infants will first be recruited for study. If the study results show the PEA POD to be valid in measuring body composition in this population, the exact procedures will be repeated within a population of low birth weight infants. To be eligible, full term infants (37-43 weeks gestation) must be no more than 8 weeks of age.

Infants will be recruited via flyers at the local birthing center, mother-and-baby store, mother's groups and La Leche League. The study protocol will be explained to the parent of the study subject and informed consent obtained.

2.3 Study protocol

3. INFANT ANTHROPOMETRY

On day 1 of the study, body volume and mass will be measured using the plethysmograph. Two successive measurements will be conducted. If the two body volume measurements vary by more than .25% from each other, a third measurement will be done. Infant length will be measured to the nearest 0.1 cm using an infant length board. On day 2 and day 7 of the study, body volume will again be measured, as in the above protocol.

4. TOTAL BODY WATER DETERMINATION

On day 1, upon completion of the plethysmographic measurements, at least 2 ml of urine will be obtained and frozen for later analysis of background ^{18}O concentration. The amount of ^{18}O to be administered will be calculated based on giving the infant 0.5 g/kg body weight of 10% ^{18}O. The actual dose will be weighed to the nearest 0.01 g. Among the breastfed infants, the dose will be mixed with approximately 10 ml of the mother's own expressed milk. For formula fed infants, the dose will be mixed with approximately 10 ml of ready-to-feed infant formula. In either case, the dose will be administered via a 10 cc syringe to which a short length of feeding tube has been attached. The infant will be "finger fed" accordingly. In our experience most young infants will accept a feeding of this nature. The feeding apparatus will be weighed before and after dose administration in order to calculate actual dose given.

Additional urine samples will be collected 24, 48, and 72 hours post dose, in addition to days 5, 6 and 7. The exact time of dosing and each urine sampling will be recorded.

There are generally two methods for estimating the dilution space; plateau and back extrapolation. Because of the high rate of water turnover during infancy, the back extrapolation method has been shown to be more accurate [11].

As explained by Davies and Wells (EJCN), "Calculation of the dilution spaces using the back-extrapolation method involves determination of the time-zero regression intercept of a plot of log isotope enrichment of body fluids against time. From this inferred isotopic concentration, the pre-dose isotopic enrichment is subtracted, and the weight of dose given is divided by the resulting concentration to calculate the dilution space for the tracer [11]. Because a small amount of exchange of the isotope with non-aqueous oxygen occurs, the dilution space is slightly larger than the amount of TBW. Therefore, the ^{18}O dilution space is divided by 1.01 to give TBW. Percent body fat is then estimated based on the hydration factor of FFM in early infancy.

5. CALCULATION OF OUTCOMES

Precision, or within-subject measurement error, will be determined by calculating the coefficient of variation of the duplicate body volume measurements conducted on each infant on each measurement day.

Reliability, or day-to-day variability, will be calculated by determining the net difference between mean body volume measurements obtained on day 1 and day 2. Paired t-test will be used to determine if this value is significantly different from zero.

The *accuracy* of the %FM results obtained from the PEA POD will be based on two comparisons. First, using a two-compartment model, the PEA POD results will be compared with body volume as calculated from TBW results obtained with the ^{18}O tracer. Second, using the ^{18}O tracer to estimate TBW, and the PEA POD to estimate body density, a four-compartment model of body composition will be compared with published values[12].

6. SAMPLE SIZE JUSTIFICATION

In order to detect a true population correlation between the measurement of body volume via TBW and PEA POD with a minimum correlation coefficient of 0.6, at a significance level of 0.05 and 80% power, 16 subjects are needed.

Assuming a generously high rate of dosing failure (i.e., infant spits up or vomits soon after dose administration, or refuses to consume the dose) of 30%, and an attrition rate of 10%, the actual sample size necessary is about 23. Thus, our target sample size of 25 infants for each study (term and LBW) should be adequate.

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