Standardization of Research-Quality Anthropometric Measurement of Infants and Implementation in a Multicenter Study

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Abstract

Malnutrition is one of the earliest clinical manifestations of cystic fibrosis (CF) and is associated with poorer pulmonary and cognitive outcomes and survival later in life. Infant growth can be a responsive measure for clinical research in this age group if obtained and characterized accurately. We report here the methods to standardize and implement research-quality anthropometric measurement of infants with cystic fibrosis in the Baby Observational Nutrition Study multicenter trial. Clin Trans Sci 2015; Volume 8: 330–333

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Introduction

Malnutrition is one of the earliest clinical manifestations of cystic fibrosis (CF) and is associated with poorer pulmonary and cognitive outcomes and survival later in life.^{1–5} The strongest data associating nutritional status in infancy and later clinical status has been derived from the controlled clinical trial of CF newborn screening (NBS) conducted in the state of Wisconsin from 1985 to 1994.⁶ As this newborn screening program progressed, it was noted that 60% of CF infants returned to their birth weight Z score by age 2 years compared with 40% who failed to catch-up.⁷ There are many reasons why infants with CF have malnutrition and/or fail to achieve catch up growth. Despite the clinical importance of early growth patterns in the first year of life, these have not been studied in a sample representative of the US CF population.

Early in life, accurate anthropometric measurements are important because management decisions are made based on them; they are also a critical component of accurate clinical research in infants. Roche and Sun state that “the assessment and interpretation of child growth requires standardized measurement procedures, trained personnel, the use of appropriate, regularly calibrated instruments and the collection of reliability data.”⁸ However, a comparison of studies in which infant anthropometrics were utilized revealed that in most reports the number of examiners was small and methodology was inadequate.⁹ Reliability and reproducibility data are crucial for the interpretation of anthropometric assessments of growth and nutritional status in children.⁸

The Cystic Fibrosis Foundation Therapeutics Development Network (CFF-TDN) is a group of 77 sites across the US whose goal is to study outcome measures and interventions for people with CF.¹⁰ We designed the Baby Observational Nutrition Study (BONUS) to demonstrate that growth can be effectively characterized in infants in a safe, feasible manner for use as a primary endpoint in a multicenter study.¹¹ We had the secondary aim of identifying factors that are associated with worse growth during the first year of life. We report here the methods for standardization and implementation of research-quality anthropometric measurement of infants in the BONUS multicenter trial.

Methods

We developed a multistep process to assure that anthropometric measurements were of high quality and that fidelity was maintained throughout the 30-month long study. We established standard operating procedures (SOPs) for measurement of weight, length and head (occipitofrontal) circumference (see Supporting Information Appendix S1, Appendix S2, and Appendix S3). These SOPs defined each measurement and the equipment needed, calibration procedures, methods, and acceptable variances. They were reviewed and accepted by the CFF-TDN. Calibration equipment was distributed to each site. Didactic training and review of the SOPs was performed either directly at an investigators’ meeting or by Webinar. Each site was required to have a minimum of two certified anthropometrists. Anthropometrists were certified after receiving standardized training in the SOPs, passing one of two unique versions of a didactic test based on the training content, and satisfactorily performing each of the three measurements (weight, length, and head circumference) on a healthy infant. Measurements were videotaped and reviewed by one of the staff members (CCM or SC) using a standardized scoring system (Table 1). Performance was reevaluated annually. At sites that experienced transition of staff, each new anthropometrist was required to undergo the same certification. Parents provided informed consent for infants to participate in the larger BONUS protocol as per each institution’s ethics board’s requirements.

Results

Twenty-eight US centers participated in the study. Anthropometric training was a requirement of site activation and the approval process. The initially selected 25 centers completed the anthropometric certification process from November 2011 through September 2012. Three additional centers were added to the study at a later time; their anthropometric certification was completed by March 2013. The number of certified personnel at each center differed, depending on the site’s staffing capacity and needs. At 14 centers, there were 2 anthropometrists trained and certified; at 12 centers, there were 3 anthropometrists trained and certified; at 2 centers, there were 4 anthropometrists trained

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Calibration of scale
Was standard weight used and was result within 10 grams?
Was calibration done twice?
Calibration of length board
Was the standard length used and was result within 0.2 cm?
Was calibration done twice?
Technique for weighing baby
Was baby naked?
Was weight done twice?
Were the two weights within 100 grams of each other?
Technique for length measurement
Was a helper present?
Was the head held in the proper position?
Were socks removed?
Was at least one leg extended fully?
Was length measured twice?
Were the length measurements within 0.7 cm of each other?
Technique for head circumference measurement:
Was the proper tape used (i.e., not a paper tape)?
Were headbands and barrettes removed?
Was the tape placed in the proper position?
Was the measurement done twice?
Were the head circumference measurements within 0.5 cm of each other?
Were appropriate infection control policies used or described?

Table 1. Criteria for evaluating anthropometric measurement performance.

and certified prior study initiation. Overall (across all centers) 72 persons were initially certified prior study initiation and site activation; 44 were research coordinators and 28 were dietitians.

Certification was a two-step process with the didactic testing preceding the evaluation of practical skills. The following difficulties were encountered with the initial certification process: (1) institutional barriers (i.e., institutional policy at

some sites required a specific informed consent to be obtained prior to videotaping an infant for the purpose of the practical evaluation); (2) identifying a healthy infant to measure for evaluation (explaining to the parent (s) that the videotaping was not a study procedure for the infant but was a requirement for the anthropometrist to demonstrate appropriate measurement techniques); (3) time restrictions (as videotaping required extra time in a busy schedule for both the parents of the baby and the anthropometrist); (4) technological challenges (i.e., downloading video file to Accellion, the secure file sharing platform).

Changes in staff during the course of the study reflected the following: (1) 25 certified anthropometrists left sites during the course of the study; (2) an additional 17 persons were trained (thus a total of 89 persons underwent the initial certification process). At 4 sites, due to unexpected staff changes during the study, there was only one certified person present to perform anthropometric measurements; these sites were instructed to identify a second person to be certified.

During the initial phase of certification, one individual did not pass the didactic test and was required to take it on two occasions. Four anthropometrists had to repeat their practical (videotaped) evaluation for not performing the measurements properly. Reasons included: using incorrect equipment, such as a paper tape rather than the nonstretchable tape provided to measure head circumference (single instance) or using the appropriate equipment incorrectly (three instances). As expected, the technique to determine length was the most difficult measurement to perform. Calibration issues were not a problem.

To ensure that there was minimal decline in fidelity of the measurement procedures, anthropometrists were required to recertify on an annual basis, planned to occur 1 year after the initial certification date at each individual site. Therefore, recertification dates were spread out throughout the calendar year. Anthropometrists were not required to repeat the didactic test. The new video was submitted to the dedicated TDNCC reviewer for evaluation.

Three of the 28 sites chose to participate in the study for only 1 year and thus did not require recertification. Twenty-three of the remaining 25 centers successfully recertified. Although the sites were very compliant about recertification IT was time consuming and led to significant delay at some sites (Figure 1).

In addition to the certification process, the TDNCC required sites to submit the completed Equipment Verification (calibration) Logs for scales used to measure weight and infantometers used to measure infant length on a quarterly basis. These logs included the following: date and time of calibration, equipment serial number, calibration values, abnormalities observed, action taken, name and signature of the person performing calibration. Most common findings of logs not being fully completed were the following: (1) absence of serial number due to equipment being attached to the exam table making the number inaccessible; (2) absence of calibration values for the period of time when visits occurred and measurements were performed.

Figure 1. Time to anthropometrist recertification.

Discussion

CF is caused by dysfunction of the CF transmembrane regulator (CFTR) ion channel. We have entered an era when modulation of CFTR is now possible for the majority of patients with CF. As we move toward treating younger and younger patients with these interventions we will need robust endpoints to follow. Fortunately, survival has increased and thus is no longer a feasible endpoint for clinical trials. The surrogate endpoints of forced expiratory volume in 1 second (FEV₁) to describe lung function and body mass index (BMI) to describe nutritional status have been used in most clinical trials. While pulmonary function is a critical outcome since most deaths are due to respiratory failure, these tests are not feasible to perform in young infants. Chest x-rays are insensitive and chest CT scans require anesthesia and radiation exposure.

Infancy is a time of rapid growth; healthy infants double their birth weight by 4 months of age and triple it by a year of age.¹² Thus, infants with CF who have an underlying condition associated with nutrient malabsorption and in some cases increased caloric expenditure are especially vulnerable during this time of high metabolic demand. This liability can be turned into an asset by recognizing that infant growth can be a responsive measure for clinical research in this age group as long as it can be characterized accurately. Key aspects of standardizing anthropometric measurements include the selection and calibration of the equipment; the use of standardized measurement procedures by all personnel; high-quality training conducted by experts, and frequent standardization sessions.¹³ Although the methodology of large studies of fetal and newborn growth¹⁴ and longitudinal infant anthropometrics to define normal infant growth have been published,¹⁵ to our knowledge this is the first description of remote learning and standardization of anthropometric measures in a research consortium focusing on infants with an underlying disease.

We describe some of the barriers to implementing and sustaining a standardized methodology for anthropometric measurements across multiple sites. These include institutional barriers and privacy concerns when demonstrating technique on a healthy infant, time constraints, and technology challenges. The common finding of changes in staff during the study underscores the importance of creating a continuous and sustainable system for certification. Although most centers performed recertification in a reasonable time frame, delays in recertification may have been due to time constraints or resistance to demonstrating what nurses and coordinators may consider to be a routine part of care. Nonetheless, although infrequent, we found errors in measurement that required correction. Investigators for the INTERGROWTH-21st Project, one of the large multicenter studies to describe infant growth, report that overall measurement of infant weight, length, and head circumference appears to have improved with the introduction of anthropometry protocols and that these methods have been adopted as part of routine clinical care.¹³ Thus, we speculate that an additional benefit of this training may be to improve accuracy of measurement of infant growth at the Cystic Fibrosis Centers that participated in the BONUS anthropometric certification.

Conclusion

Through the multicenter Baby Observational Nutrition Study of infants with CF, we have demonstrated that anthropometric training to produce research-quality measurements can be effectively standardized and remote certification can be successful in a multicenter study.

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Supporting Information

Additional supporting information may be found in the online version of this paper.

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