Validation and Human Factors Evaluation of a New Device for Infant Weight Estimation

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Background

Weight is the foremost marker of health outcomes in infants. A weighing scale remains the universal gold standard for obtaining weight; however, in remote, resource-constrained settings access to functional scales can be limited. Even resource-replete settings suffer challenges with respect to weight assessment where it is difficult to remove, or account for the weight of, life-sustaining medical equipment. Though numerous proxies for weight have been evaluated, most use the meaures to dichotomize infants according to maturity at birth (e.g. low birth weight). Few studies offer equations for quantitative weight estimation and virtually none incorporate internal/external validation into their methodology. Using anthropometric data from over 2,000 US infants, we recently developed and validated a robust infant weight estimation method based on chest circumference (CC) and head circumference (HC).[1,2]

Objectives

To determine the predictive performance of, and human factors experience with, an inexpensive, paper-based tool that implements this method (babyTAPE) in a prospective, multi-center, observational, masked study.

Methods

POPULATION

- Premature and fullterm infants (0-90 postnatal days) capable of having measurements performed were stratified into nine age blocks with the goal of enrolling 20-60 infants/block.
- Infants were excluded from participation for any of the following:
  1. Known or apparent anatomical deformities
  2. Presence of external medical equipment that would impair the determination of actual weight
  3. In the opinion of the investigator or treating physician there were real or perceived contraindications for their inclusion
  4. Previous participation in the study

MEASUREMENT & EVALUATION

- Qualified raters measured length, weight, HC and CC for each infant using calibrated scales and measures.
- Raters also made measurements using masked versions of the Mercy babyTAPE.
- Finally, raters evaluated critical tasks associated with using the device for each set of measurements taken.

ANALYSIS

- Participant demographics and anthropometric measures were summarized using standard summary statistics.
- The predictive performance of the babyTAPE was established by comparing predicted weight and actual weight using statistics that include the mean error, mean squared error, concordance correlation coefficient, and proportion within 10% and 15% of actual.
- Between-user variability was characterized through estimation of the intraclass correlation (ICC).
- Descriptive statistics were used to define the human factors findings.

Results

- 486 infants (51.9% male) were enrolled, 481 had evaluable datasets.
- Infants averaged:
  - 36.8 ± 4.0 wk gestational age
  - 31.5 ± 28.6 d postnatal age
  - 50.1 ± 6.3 cm length
  - 3.519 ± 1.446 kg weight
- Infants spanned a range of z-scores for weight (-3.3 to 2.5), length (-4.5 to 2.7), and head circumference (-4.5 to 2.5).
- The correlations between the babyTAPE method predicted vs. actual weight (Figure 1, left) and the babyTAPE device predicted vs. actual weight (Figure 1, right) were both r=0.97.

Figure 1. Scatterplots depicting estimated vs. actual infant weight. Demming regression for method estimated weight slope 0.95 (95% CI 0.94, 0.97) and intercept 0.113 (95%CI 0.07, 0.16). Demming regression for device estimated weight slope 0.96 (95% CI 0.94, 0.98) and intercept 0.076 (95%CI 0.03, 0.12).

Results

- Mean error (percent error) across all participants was -70 gr (-1.3%).
- The fraction of young infants in whom the babyTAPE predicted weight within 10% and 15% of actual weight was 0.86 and 0.99.

HUMAN FACTORS

- Of 972 device measurements, there were a small number of cases where raters indicated trouble identifying correct anatomic landmarks, properly orienting the device, performing the measurement and reading the markings on the device. (Table)
  In all cases raters were confident or very confident in their measurements.

	Chest (N=486)	Head (N=486)
Trouble identifying the proper landmarks		
No	485 (99.8%)	486 (100.0%)
Yes	1 (0.2%)	0
Able to correctly identify the proper starting ends of babyTAPE		
No	1 (0.2%)	1 (0.2%)
Yes	485 (99.8%)	485 (99.8%)
Difficulty performing the measurements on this infant		
No	481 (99.0%)	483 (99.4%)
Yes	5 (1.0%)	3 (0.6%)
Markings on babyTAPE are easy to read		
No	4 (0.8%)	2 (0.4%)
Yes	482 (99.2%)	484 (99.6%)
Confidence of obtaining the same readings if repeated right now		
Not confident at all	0	0
Not confident	0	0
Not sure	0	0
Confident	44 (9.1%)	41 (8.4%)
Very confident	442 (90.9%)	445 (91.6%)

Conclusions

- The Mercy babyTAPE device was statistically equivalent to the method on which it was based and approximated infant weights with acceptable variance from the true weight.
- Human factors data suggest that the device is easy to use.
- The babyTAPE can be used to estimate weight in young infants when calibrated scales are impractical or unavailable.

References

[1] Ann Human Biol 2017;44:678-686
[2] Glob Pediatr Health 2017;4:1-9