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Characterization of Thermal and Mechanical Indices from Serial Ultrasound Exams and Associations with Neonatal Anthropometry: The NICHD Fetal Growth Studies

Melissa M. Smarr, Ph.D.¹, Germaine M. Buck Louis, Ph.D., M.S.¹, Paul S. Albert, Ph.D.², Sungduk Kim, Ph.D.², Karin M. Fuchs, M.D.³, Jagtेशwar Grewal, Ph.D., M.P.H.¹, Mary E. D’Alton, M.D.³, and Katherine L. Grantz, M.D., M.S.⁴

¹Office of the Director, Division of Intramural Population Health Research, Eunice Kennedy Shriver National Institute of Child Health and Human Development, Bethesda, Maryland, USA

²Biostatistics Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute, Bethesda, Maryland, USA

³Department of Obstetrics & Gynecology, Columbia University Medical Center, New York, New York, USA

⁴Epidemiology Branch, Division of Intramural Population Health Research, Eunice Kennedy Shriver National Institute of Child Health and Human Development, Bethesda, Maryland, USA

Abstract

Objective: To determine if the number of maternal ultrasound scans where the highest thermal (TI) or mechanical (MI) indices recorded during obstetrical ultrasonology exceed 1.0 were associated with neonatal anthropometric measurements.

Study Design: A prospective cohort of 2,334 non-obese low risk pregnant women from 12 U.S. clinical sites underwent a total of six ultrasound scans, for which the highest TI and MI values were recorded. Neonatal anthropometric measurements were obtained within 12–24 hours of delivery. Multiple linear regression models adjusted for maternal race/ethnicity, body mass index, weight gain and gestational age were used to examine associations between the number of maternal ultrasounds during gestation with a TI or MI exceeding 1.0 and the mean change in neonatal anthropometry.

Results: Ultrasounds with TI or MI >1.0 were not associated with birthweight, neonatal length, nor head, chest and abdominal circumferences. TI >1.0 was negatively associated with neonatal mid-upper arm and mid-upper thigh circumferences. MI >1.0 was negatively associated with neonatal skinfold measurements of the anterior thigh and triceps, and neonatal circumferences of the mid-upper thigh and umbilicus.

Conclusions: Prenatal ultrasound examinations in which TI or MI intermittently exceeded 1.0 did not identify a pattern of alterations of birth size.

Keywords

birth weight; mechanical index; neonatal anthropometry; thermal index; ultrasound safety

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Introduction

The safety of clinically indicated antenatal ultrasounds has been established with little to no evidence of harm to the human fetus when equipment is used properly ¹. Still, ultrasound imaging involves the deposition of energy and pressure in the body, and the effects of exposure to thermal energy on fetal growth and development may depend on the scanning mode, exposure duration and the specific tissue being scanned ². Thermal energy exposure is assessed using the thermal index (TI), defined as the ratio of the emitted acoustic power to the power required to raise the temperature of tissue by 1°C. The non-thermal biological effects of ultrasound imaging (e.g., pressure, cavitation) are assessed using the mechanical index (MI), defined as the maximum value of the peak negative pressure divided by the square root of the acoustic center frequency. Clinical guidelines for obstetrical ultrasound technology and human health have been established and suggest that acoustic output should remain as low as reasonably possible (ALARA) ^{3,4}. In daily obstetric practice, a TI or MI 1.0 is a safety threshold for obstetrical ultrasounds ⁵. This criterion is in accordance with animal studies reporting hemorrhage in neonatal lung was as the result of intense output and MI was recommended to remain 1.0 ⁶.

Considering the widespread use of ultrasound for monitoring pregnant women and the potential for thermal energy from prenatal ultrasounds to be absorbed directly by fetal bone or conduct heat to surrounding fetal tissues ⁷, human studies of ultrasound exposures and fetal health are surprisingly lacking. Among the few epidemiologic research studies of prenatal ultrasound exposure and neonatal birth weight, equivocal findings are reported with one study reporting a positive association between ultrasound exposure and neonatal birth weight ⁸, while others reported negative associations ^{9,10}. To our knowledge, there has only been one study of repeated maternal exposure to ultrasounds and neonatal anthropometry (skinfolds and circumferences of the abdomen, chest and mid-upper arm) that found a lack of association ¹¹. Our objective was to explore the association of TI or MI >1.0, a recommended safety threshold, with neonatal anthropometry.

Methods

Study design and population

The NICHD Fetal Growth Studies - Singletons was a prospective cohort study that recruited 2,334 non-obese pregnant women from 12 U.S. clinical sites to establish a contemporary standard for fetal growth and, possibly, to further characterize by self-identified maternal race/ethnicity ¹². Specifically, the cohort included 612 (26%) non-Hispanic white, 611 (26%) non-Hispanic black, 649 (28%) Hispanic, and 460 (20%) Asian pregnant women. Eligibility criteria were designed for recruitment of low risk pregnant women and included: ages 18–40 years; pregravid body mass index (BMI) 19.0–29.9 kg/m²; viable singleton pregnancy; and planning to deliver at participating hospitals.

The current analysis excluded voluntary termination of pregnancies (n=7, <1%), miscarriages (n=23, 1%), fetal deaths (n=13, <1%), neonatal deaths without complete anthropometry measurements (n=5, <1%), women who moved away from the study catchment area (n=26, 1%), refused to continue prior to delivery (n=86, 4%), did not meet the inclusion criteria after enrollment (n=14, <1%), had unknown birth outcomes if the participant delivered at home or another hospital and medical records could not be obtained (n=11, <1%), or were lost to follow-up for other reasons (n=42, 2%), and n=148 (7%) as the result of one clinical site inadvertently using a different caliper when measuring neonatal skinfolds, prompting exclusion from the final analysis. The final cohort comprised 2,123 (91%) pregnant women and neonates. Human subjects' approval was obtained from all participating sites; women gave informed consent before data collection.

Data collection

Women were interviewed about lifestyle and medical and reproductive history upon enrollment and at each of the 5 study visits. In addition, maternal height and waist circumference were measured at baseline while weight was measured at each visit using a standardized protocol^{13,14}. Following an eligibility ultrasound at 10–13 weeks gestation, each woman was randomized to one of four follow-up schedules to capture ultrasound data across the full range of gestation while minimizing ultrasound exposure. As such, five additional ultrasounds were obtained for each woman within ± 1 week of the targeted gestational age¹². Fetal biometric measurements were performed at each visit according to standardized study procedures. Ultrasound examination included 2-D: crown-rump length (first trimester only), biparietal diameter, occipitofrontal diameter, orbital diameter, head circumference, abdominal circumference, femur length, humerus, radius, ulna, tibia, fibula length and cerebellar width; 3-D: fetus and gestational sac (first trimester only), arm fractional limb volume, thigh fractional limb volume, cerebellum, abdominal volume, and additional 3D if feasible: head volume, face volume, chest volume and pelvic volume; and additional measurements: nuchal translucency (first trimester only), fetal heart rate, uterine artery doppler, placental location, number of umbilical vessels & insertion site, amniotic fluid volume and fibroids. For all biometric measurements, three measurements were taken and for each measurement, two images were captured (one with and one without measurements); a total of six images were stored for each biometric parameter. Study scans were captured using Voluson E8s (GE Healthcare, Milwaukee, WI) with a transabdominal curved multifrequency volume transducer (real-time abdominal 4–8 MHz) and / or endovaginal multifrequency volume transducer (real-time intracavity 6–12 MHz). The study protocol specified that the study scan should be limited to 60 minutes and recommended maintaining low acoustic outputs at low levels with both TI and MI ≤ 1.0 , while obtaining high-quality images. Originally the TI was reported irrespective of machine setting (TIs - soft tissue or TIb – bone tissue); however, in accordance with the American Institute of Ultrasound in Medicine⁴, since all ultrasounds were performed at or greater than 10 weeks of gestation, machine settings were changed to ensure consistent reporting of TIb values. At the completion of each scan, sonographers reviewed all the acquired images and recorded the highest TI and MI values from the ultrasound (herein referred only as TI and MI). All measurements and images were captured in ViewPoint (GE Healthcare) and electronically transferred to the study's data coordinating center.

Study sonographers at each site underwent rigorous training prior to the performance of study scans. As previously reported, during the quality assurance (QA) process, 5% of study scans with triplicate images for each fetal measurement were randomly selected to be remeasured by the expert sonographer¹⁵. Scans were reviewed centrally and the highest observed TI and MI values were recorded. The QA demonstrated excellent (>0.90) reliability of biometric measurements between study sonographers and blinded expert reviewers¹⁵. However, agreement between the highest observed TI and MI reported by site sonographers and blinded expert reviewers was not previously assessed.

Birth weight (grams) and infant sex were abstracted from the neonatal medical record by research nurses following delivery. Standardized anthropometric measurements were completed by trained research staff within 12–24 hours of birth and included: birth length measured using a seca 416 Infantometer (SECA, Hamburg, Germany), upper arm and upper thigh length, circumference of the head, mid-upper arm, chest, abdomen (measured at a level midway between the xiphoid process and the umbilicus), and umbilicus (measured at a level just above the umbilicus) and mid-upper thigh were measured in centimeters by measuring tape; each measurement was taken to the nearest 0.1 cm^{13,16–24}. Neonatal skinfolds (abdominal flank, anterior thigh, subscapular and triceps) were measured in millimeters using Lange skinfold caliper (Beta Technology, Inc., Santa Cruz, CA); measurements were taken to the nearest 0.5 mm. Anthropometry was measured twice according to standard protocols prior to hospital discharge; measurements were performed three times if differences in measurements were beyond established limits^{14,25,26}. Averages of all replicate anthropometric measurements were used in the final analysis.

Statistical analysis

To assess agreement between reporting of the highest reported TI and MI values from the site sonographers and central review, Bland-Altman plots were examined. For each measurement, the standardized difference and mean were calculated between the site sonographers and the central reviewer. A mean difference of zero suggests perfect agreement between reported values; positive (negative) differences between values indicate that the site sonographer's reported highest TI and MI values were smaller (larger) than the value reported by the central reviewer.

Descriptive analyses included assessing missing data and measures of central tendency and variation. TI and MI values >2.0 (n=16 scans, <1%) were considered data entry errors and were removed from the current analysis. Additionally, there were n=4 (<1%) scans missing a TI or MI value, leaving 10,896 TI and MI values for 2,123 mother-neonate pairs. Furthermore, maternal baseline characteristics and neonatal outcomes were compared across categories of the total number of ultrasound scans per woman where TI or MI values exceeded 1.0 (0, 1 and ≥2 scans) using Wilcoxon-Mann-Whitney tests and Chi-square tests for continuous and categorical covariates, respectively.

Multiple linear regression models were used to estimate the mean change in neonatal birth weight and anthropometry endpoints relative to the number of maternal ultrasound scans where TI or MI exceeded 1.0 relative to women never having a scan with a TI or MI >1.0. Covariate selection for adjusted models first included maternal age, race, insurance and

gestational age, given they significantly differed by scans where TI or MI exceeded 1.0 and those identified using directed acyclic graphs. As such, further adjustment of neonatal anthropometry included maternal race, prenatal body mass index (BMI, weight in kg/height in m²), pregnancy weight gain (kg) and gestational age (weeks) at delivery.

In sensitivity analyses, we also assessed the influence of pregnancy (maternal/newborn) complications (e.g. preterm delivery, hypertensive diseases, gestational diabetes, and neonatal aneuploidy, anomalies, or death) in light of the former possibly influencing ultrasound settings given their effect on maternal or fetal size and observed differences in fetal growth by maternal race¹², respectively. We first did this by restricting the analysis to mother-neonate pairs without pregnancy complications and then stratified by race/ethnicity; this cohort was previously included in the development of the NICHD Fetal Growth Studies racial/ethnic standards of for fetal growth¹². All analyses were performed using SAS (version 9.4; SAS Institute Inc., Cary, NC) or R (version 3.1.2).

Results

Women were on average 28.2 ± 5.5 years of age with a pregravid BMI of 23.6 ± 3.0 kg/m², and with most (65%) women having private or managed care health insurance. The highest reported TI and MI across prenatal visits were not correlated (range: $-0.10 - 0.07$) with TI values ranging from 0.0–1.8 and MI values from 0.5 – 1.3. Overall, there were 1,793 (85%) women with 0 occurrences of a TI >1.0; 238 (11%) with 1 occurrence and 92 (4%) with 2 or more occasions where TI >1.0. For MI >1.0, there were 1,463 (69%) women with 0 occurrences; 454 (21%) with only 1 occurrence and 206 (10%) with 2 or more occasions where MI >1.0 (table 1). Women with 2+ ultrasound scans containing MI values >1.0 were older than women without any such scans [29.5 ± 5 years and 27.8 ± 5 years ($p < 0.0001$), respectively].

Neonates on average had a gestational age of 39 ± 2 weeks and a birth weight of $3,324 \pm 491$ grams; there was a slight excess of male births (52%) (Table 1). Means of several specific neonatal anthropometric measurements varied by the number of maternal ultrasound scans with TI or MI values >1.0. Mid-upper arm and mid-upper thigh circumference of neonates were smallest among women with 2 or more ultrasound scans with a TI >1.0 ($p < 0.01$), while the neonatal abdominal flank, anterior thigh and subscapular skinfolds tended to be largest among women with 2 or more ultrasound scans with a TI >1.0. Neonatal mid-upper thigh circumference, upper thigh length and anterior thigh skinfold measurements were generally smaller among mothers with 2 or more ultrasound scans with MI >1.0 ($p < 0.05$), Table 1.

Racial differences in the number of maternal ultrasound scans with TI and MI values were also observed. Specifically, Non-Hispanic Black women tended to have the highest prevalence (36%) of ultrasound scans exceeding the TI >1.0 threshold and Non-Hispanic White women the highest prevalence (42%) of ultrasound scans exceeding the MI >1.0 threshold (Table 1).

The number of maternal ultrasound scans during gestation where TI >1.0 and estimated mean changes in neonatal anthropometry assessed at birth are presented in Table 2. In

general, obstetric ultrasound scans with $TI > 1.0$ were not associated with neonatal birth weight, birth length, circumferences of the head, abdomen, umbilicus, and chest, nor triceps skinfolds, even after covariate adjustment. However, in comparison to women who never had scans with a $TI > 1.0$, women having 1 or 2+ elevated ultrasound scans had neonates with significantly smaller mid-upper arm circumferences [β (95% CI): 1 scan = -0.3 cm (-0.4 , -0.1); 2+ scans = -0.5 cm (-0.8 , -0.2)] and mid-upper thigh circumferences [β (95% CI): 1 scan = -0.39 cm (-0.7 , -0.1); 2+ scans = -0.6 cm (-1.1 , -0.2)]. Conversely, women having a scan with a $TI > 1.0$ were found to have neonates with significantly larger abdominal flank skinfolds [β (95% CI): 1 scan = 0.5 cm (0.3 , 0.7); 2+ scans = 0.7 cm (0.4 , 1.0)], subscapular skinfolds [β (95% CI): 1 scan = 0.2 cm (0.0 , 0.4); 2+ scans = 0.5 cm (0.2 , 0.8)], anterior thigh skinfolds [β (95% CI): 1 scan = 0.3 cm (0.0 , 0.6)], upper arm lengths [β (95% CI): 1 scan = 0.2 cm (0.0 , 0.4)] and upper thigh lengths [β (95% CI): 1 scan = 0.2 cm (0.0 , 0.4)] in comparison to women without elevated TI scans.

With regard to $MI > 1.0$ and neonatal outcomes, no significant associations were observed with birth weight, birth length, upper thigh length, circumference of the head, abdomen, chest, mid-upper arm nor abdominal flank and subscapular skinfolds even in adjusted models (Table 2). However, significant positive associations were observed between a $MI > 1.0$ and upper arm length (1 scan = 0.1 cm (0.0 , 0.2), though a negative association for 2+ elevated scans [-0.2 cm (-0.3 , -0.01)]. Other significant findings for 2+ scans with $MI > 1.0$ reflected reductions in 1 mid-upper thigh circumference [-0.8 cm (-1.1 , -0.5)], umbilical circumference [-0.5 cm (-0.9 , -0.1)], anterior thigh skinfold [-0.5 cm (-0.8 , -0.1)] and triceps skinfolds [-0.3 cm (-0.6 , -0.1)].

When the analytic cohort was restricted to the 1,731 (78%) women-neonates without pregnancy complications, the findings remained. Specifically, $TI > 1.0$ was significantly associated with both positive and negative changes in certain specific neonatal outcomes (Table 3), whereas $MI > 1.0$ tended to be negatively associated. The magnitude of change estimates associated with TI or $MI > 1.0$ remained robust in sensitivity analyses. In addition, the findings largely remained after stratifying by self-identified maternal race, though with more variability in effect estimates for all racial groups (Table 4). Significant associations for $MI > 1.0$ were limited to reductions in mid-upper arm and thigh but only among non-Hispanic White and non-Hispanic Black women.

Discussion

In this prospective cohort study, we found no consistent evidence that either a TI or $MI > 1.0$ on 1 or more prenatal ultrasound scans was associated with infants' birth size or anthropometry. This observation is particularly noteworthy for global measures of birth size such as weight, head circumference or length. A second key finding is that discrete characteristics of upper and lower limbs (circumferences, neonatal skinfolds, as well as length) may be associated with sporadic occurrences of a TI and $MI > 1.0$ rather than more significant changes in neonatal size such as birth length (distance from the soles of the feet to the top of the head), weight or head circumference. Corroboration of these results in sensitivity analyses increases our confidence that the observed associations were not due to pregnancy complications, anomalies or other conditions that would require additional

ultrasound scans than the standard antenatal care. A third key finding was that more associations with neonatal outcomes were observed for a TI >1.0 rather than MI >1.0, and that the former was associated with both significant increases and decreases in specific neonatal anthropometric measures whereas the latter was largely associated with decreases. A fourth and final finding was the relatively small estimated change for any of the neonatal outcomes for either a TI or MI >1.0 possibly a reflection of TI and MI within safety ranges for our cohort in comparison to other studies²⁵. Our findings are strengthened by the credentialing of sonographers, which yielded excellent reliability for fetal measurements⁴ and ultrasound data, including TI/MI, as well as by the longitudinal capture of exposures and completion of an in-depth anthropometric examination of neonates. Our observational study is exploratory in nature and alternative explanations should be considered relative to uncertain external validity or generalizability of findings to pregnant women who do not fit low risk antenatal profiles, the potential for residual confound, and the number of comparisons made. Still, at the $\alpha=0.05$ level we would only expect that 10 of our findings are explained purely by chance; we observed over 80 significant findings.

Interpreting our findings in the context of existing literature is challenging given the dearth of available information and with previous research largely relying on birth weight and not measured neonatal anthropometry^{8–10}. In the one previous epidemiological study to explore a potential association between repeated ultrasound exposure and neonatal outcomes, no association was observed between repeated maternal exposure to ultrasounds and neonatal anthropometry, including birth weight and length, among 2,743 Australian women with singleton pregnancies¹¹. We also did not observe a significant alteration in birth weight irrespective of the number of TI or MI >1.0 even after adjustment. Furthermore, the previous study also reported that mean head circumference was significantly smaller in neonates of women in the intensive group (who had undergone an additional ultrasound screening at 15 weeks) compared with neonates born to women in the regular ultrasound group (who did not receive an ultrasound scan prior to 19 weeks of gestation). Likewise, findings from the previous study suggested that neonates of women in the intensive group had smaller measures of skeletal size (as denoted by principal components grouping of length and circumferences of the head and chest) but not soft tissue (abdominal circumference and skinfold thicknesses from the triceps, parascapular and subscapular regions) compared with the regular group¹¹. We did not corroborate such findings, in fact, we observed no association between skeletal measures but found several associations with changes in soft tissue. Perhaps the differences in study findings can be explained by heterogeneity in study design and population, the number and timing of ultrasound scans and other aspects of clinical management. Still, these findings warrant further investigation of the potential effects of repeated ultrasound exposure and neonatal outcomes.

The biologic plausibility and clinical significance of our observed associations remain unclear, and warrants further inquiry. For example, it may be worth exploring how scans exceeding a TI or MI >1.0 may affect *in utero* fat deposition on both upper and lower limbs since such exposures were associated with small (<1 cm) reductions in neonatal anthropometric circumferences and skinfolds. One possible explanation is that changes in the amount of thermal energy deposited into the body during ultrasound scans varies with increasing gestational age and the mineralization of developing bone; the presence of bone

increases the likelihood of an increase in the absorbed energy by soft tissues adjacent to the bone¹. Still, we cannot not eliminate ‘reverse causation’ as a potential explanation in that leaner fetuses may require higher energy settings that would induce higher TI and MI values during prenatal imaging. It is also important to consider that depending on maternal habitus and / or fetal position, changes in machine settings may be required to achieve increased penetration and adequate visualization, and these adjustments may yield increased energy outputs which in turn explain variations in TI and MI values noted between scans. In addition, use of Doppler ultrasound increases energy outputs and may account for transient increases in MI and / or TI. We attempted to control for such confounding by adjustment for maternal pregravid BMI and gestational weight gain, given that an impaired acoustic window during an obstetric exam may differ by BMI status; suboptimal visualization rates have been shown to be higher among obese ($> 30 \text{ kg/m}^2$) pregnant women than pregnant women of normal weight ($< 30 \text{ kg/m}^2$)^{27–29}. Still, we cannot ignore the potential for observed associations to result from residual confounding.

Other important considerations in weighing our findings include choice of a study cohort that was specifically recruited to comprise low risk pregnant women, which may limit generalizability. Also, we have no information on total ultrasound dwell time for study scans, cumulative MI or TI exposure, or duration of exposure to TI or MI > 1.0 . Similarly, we have no data on the number of clinically-indicated scans our patients may have undergone in addition to their study scans. The low risk status of this cohort suggests that such exposures would likely be at a minimum. Finally, our findings should not be interpreted as safety data, as this is beyond the scope of this work.

In sum, our findings did not identify a pattern of altered fetal growth as measured by neonatal birth size and anthropometry among the 13% of women with a TI or MI > 1.0 in comparison to women without such occurrences. While there were some suggestions of small changes in limb adiposity, overall there was no consistent pattern with neonatal size or anthropometry. These findings may offer reassurance when repeated imaging is needed for clinical indications. Our findings await corroboration from research that captures duration of exposures and clinical indications over the course of pregnancy.

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Table 1. Description of analytic cohort by the number of maternal ultrasound exams where TI/MI >1.0 (n=2,123).

	Overall (n = 2123)	Thermal Index			Mechanical Index		
		None (n = 1793)	1 scan (n = 238)	2+ scans (n = 92)	None (n = 1463)	1 scan (n = 454)	2+ scans (n = 206)
<i>Maternal Characteristics</i> [§]							
Age (years) [¶]	28.2 ± 5.5	28.2 ± 5.4	28.2 ± 5.8	28.9 ± 6.1	27.8 ± 5.4	28.8 ± 5.7	29.5 ± 5.2
Pregavid BMI (kg/m ²)	23.6 ± 3.0	23.7 ± 3.0	23.2 ± 3.0	23.2 ± 2.8	23.6 ± 3.0	23.6 ± 3.0	23.5 ± 3.0
Maternal Race/Ethnicity ^{**¶}							
Non-Hispanic White, n (%)	564 (27)	502 (28)	48 (20)	14 (15)	325 (22)	152 (34)	87 (42)
Non-Hispanic Black, n (%)	548 (26)	427 (24)	85 (36)	36 (39)	375 (26)	127 (28)	46 (22)
Hispanic, n (%)	597 (28)	539 (30)	41 (17)	17 (19)	481 (33)	86 (19)	30 (15)
Asian, n (%)	410 (19)	321 (18)	64 (27)	25 (27)	278 (19)	89 (20)	43 (21)
Insurance ^{**¶}							
Private or managed care, n (%)	1370 (65)	1137 (64)	164 (69)	69 (75)	876 (60)	331 (73)	163 (79)
Other, n (%)	749 (35)	652 (36)	74 (31)	23 (25)	583 (40)	123 (27)	43 (21)
<i>Neonate Characteristics</i> [§]							
Gestational age at delivery (wks) ^{**¶}	39.3 ± 1.6	39.2 ± 1.6	39.5 ± 1.2	39.5 ± 1.4	39.2 ± 1.6	39.3 ± 1.5	39.5 ± 1.4
Birth Weight (g)	3324 ± 491	3321 ± 493	3346 ± 458	3315 ± 519	3317 ± 494	3335 ± 477	3348 ± 497
Lengths (cm):							
Birth length	50.1 ± 2.5	50.1 ± 2.6	50.2 ± 2.4	50.2 ± 2.4	50.1 ± 2.5	50.0 ± 2.4	50.2 ± 2.8
Upper arm length [*]	10.1 ± 1.1	10.1 ± 1.0	10.3 ± 1.2	10.2 ± 1.0	10.1 ± 1.0	10.2 ± 1.2	10.1 ± 1.1
Upper thigh length	10.4 ± 1.4	10.4 ± 1.4	10.6 ± 1.5	10.4 ± 1.2	10.4 ± 1.3	10.6 ± 1.5	10.3 ± 1.5
Circumferences (cm):							
Head	34.0 ± 1.5	34.02 ± 1.5	34.1 ± 1.5	34.0 ± 1.4	34.0 ± 1.5	34.1 ± 1.5	34.1 ± 1.8
Abdominal [‡]	33.1 ± 2.3	33.1 ± 2.3	33.0 ± 2.5	32.7 ± 2.2	33.0 ± 2.3	33.1 ± 2.4	33.2 ± 2.2
Chest	32.9 ± 2.1	32.9 ± 2.1	33.0 ± 2.4	32.8 ± 2.2	32.9 ± 2.1	33.0 ± 2.2	33.0 ± 2.1
Mid-upper arm ^{**¶}	10.5 ± 1.3	10.5 ± 1.3	10.4 ± 1.4	10.1 ± 1.4	10.5 ± 1.3	10.5 ± 1.4	10.5 ± 1.2

		Thermal Index			Mechanical Index		
	Overall (n = 2123)	None (n = 1793)	1 scan (n = 238)	2+ scans (n = 92)	None (n = 1463)	1 scan (n = 454)	2+ scans (n = 206)
Mid-upper thigh [*]	14.0 ± 2.0	14.1 ± 2.0	13.7 ± 2.1	13.5 ± 1.9	14.1 ± 2.0	14.0 ± 2.0	13.5 ± 2.3
Umbilical [‡]	31.2 ± 2.6	31.2 ± 2.6	31.2 ± 2.7	30.6 ± 2.8	31.3 ± 2.6	31.1 ± 2.6	31.0 ± 2.5
Skinfolds (mm):							
Abdominal flank ^{‡*}	4.3 ± 1.4	4.2 ± 1.4	4.7 ± 1.4	4.8 ± 1.3	4.2 ± 1.4	4.3 ± 1.3	4.3 ± 1.5
Anterior thigh ^{‡**¶}	6.1 ± 1.9	6.0 ± 1.9	6.4 ± 1.7	6.5 ± 1.7	6.1 ± 1.9	6.0 ± 1.9	5.8 ± 1.8
Subscapular ^{‡*}	4.5 ± 1.3	4.5 ± 1.3	4.6 ± 1.3	4.9 ± 1.3	4.5 ± 1.3	4.5 ± 1.3	4.4 ± 1.3
Triceps skinfold [‡]	4.9 ± 1.4	4.9 ± 1.4	5.0 ± 1.5	5.0 ± 1.3	4.9 ± 1.4	4.9 ± 1.4	4.8 ± 1.4
Sex							
Male, n (%)	1096 (52)	931 (52)	112 (48)	53 (58)	736 (51)	257 (57)	103 (50)
Female, n (%)	1013 (48)	850 (48)	124 (52)	39 (42)	714 (49)	196 (43)	103 (50)
Infant received care in NICU							
Yes, n (%)	224 (11)	188 (11)	29 (12)	7 (8)	159 (11)	41 (9)	24 (12)
No, n (%)	1880 (89)	1589 (89)	207 (88)	84 (91)	1286 (89)	412 (91)	182 (88)
Unknown, n (%)	4 (<1)	3 (<1)	0 (0)	1 (1)	4 (<1)	0 (0)	0 (0)
Any neonatal morbidities							
Yes, n (%)	105 (5)	88 (5)	12 (5)	5 (5)	69 (5)	23 (5)	13 (6.3)
No, n (%)	2003 (95)	1692 (95)	224 (95)	87 (95)	1380 (95)	430 (95)	193 (93.7)
Preterm Delivery							
Yes, n (%)	124 (6)	110 (6)	10 (4)	4 (4)	90 (6)	25 (6)	9 (4)
No, n (%)	1984 (94)	1670 (94)	226 (96)	88 (96)	1359 (94)	428 (94)	197 (96)

[§]Values are reported as mean ± SD unless noted as otherwise.

[‡]Excluded 148 measurements due to caliper error.

^{*}p < 0.05 in thermal index models.

[¶]p < 0.05 in mechanical index models.

[‡]Abdominal circumference was measured at a level midway between the xiphoid process and the umbilicus; umbilicus circumference was measured at a level just above the umbilicus.

Table 2.

Estimated mean change in neonatal anthropometry by the number of maternal ultrasound exams where thermal index or mechanical index >1.0 among 2,123 maternal-neonate pairs.

	Number of scans with TI>1.0				Number of scans with MI>1.0			
	Unadjusted Models		Adjusted Models		Unadjusted Models		Adjusted Models	
	1	2 +	1	2 +	1	2 +	1	2 +
Birthweight (g)	β (95% CI) 25 (-41, 92)	β (95% CI) -5.6 (-109, 95)	β (95% CI) 6.7 (-48, 62)	β (95% CI) 10 (-75, 95)	β (95% CI) 189 (-33, 70)	β (95% CI) 32 (-40, 104)	β (95% CI) -4.1 (-47, 39)	β (95% CI) -55 (-114, 4.7)
Lengths (cm):								
Birth length	0.1 (-0.2, 0.5)	0.1 (-0.5, 0.6)	0.0 (-0.3, 0.4)	0.0 (-0.5, 0.6)	0.2 (-0.1, 0.3)	0.3 (-0.1, 0.7)	0.1 (-0.2, 0.3)	-0.2 (-0.5, 0.2)
Upper arm	0.2 (0.1, 0.4)	0.1 (-0.1, 0.4)	0.2 (0.0, 0.3)	0.1 (-0.1, 0.4)	0.1 (0.0, 0.3)	-0.0 (-0.2, 0.1)	0.1 (0.0, 0.2)	-0.2 (-0.3, 0.0) [§]
Upper thigh	0.2 (0.0, 0.4)	0.0 (-0.3, 0.3)	0.2 (0.0, 0.4)	0.0 (-0.3, 0.3)	0.2 (0.0, 0.3)	-0.1 (-0.3, 0.1)	0.1 (0.0, 0.3) [¶]	-0.2 (-0.4, 0.0) [¶]
Circumferences [‡] (cm):								
Head	0.1 (-0.2, 0.3)	-0.1 (-0.4, 0.3)	0.0 (-0.2, 0.2)	-0.1 (-0.4, 0.2)	0.1 (-0.2, 0.3)	0.1 (-0.1, 0.4)	0.0 (-0.1, 0.2)	-0.1 (-0.3, 0.1)
Abdominal	-0.1 (-0.4, 0.2)	-0.4 (-0.9, 0.1)	0.0 (-0.3, 0.3)	-0.3 (-0.7, 0.2)	0.1 (-0.2, 0.3)	0.2 (-0.2, 0.5)	0.0 (-0.2, 0.3)	-0.1 (-0.4, 0.2)
Chest	0.0 (-0.3, 0.3)	-0.2 (-0.6, 0.3)	0.0 (-0.3, 0.3)	-0.1 (-0.5, 0.3)	0.1 (-0.1, 0.3)	0.1 (-0.2, 0.5)	0.0 (-0.2, 0.3)	-0.2 (-0.5, 0.1)
Mid-upper arm	-0.2 (-0.4, 0.0)	-0.5 (-0.8, -0.2)	-0.3 (-0.4, -0.1)	-0.5 (-0.8, -0.2)	0.0 (-0.1, 0.2)	-0.0 (-0.2, 0.2)	0.0 (-0.1, 0.1)	-0.2 (-0.4, 0.0)
Mid-upper thigh	-0.4 (-0.7, -0.1)	-0.6 (-1.1, -0.2)	-0.4 (-0.7, -0.1)	-0.6 (-1.1, -0.2)	-0.2 (-0.4, 0.1)	-0.6 (-1.0, -0.3)	-0.2 (-0.4, 0.0)	-0.8 (-1.1, -0.5)
Umbilical	-0.1 (-0.4, 0.3)	-0.6 (-1.2, -0.1)	0.0 (-0.3, 0.4)	-0.5 (-1.1, 0.1)	-0.2 (-0.5, 0.1)	-0.3 (-0.7, 0.1)	-0.2 (-0.5, 0.1)	-0.5 (-0.9, -0.1)
Skinfolds (mm):								
Abdominal flank	0.5 (0.3, 0.7)	0.6 (0.3, 0.9)	0.5 (0.3, 0.7)	0.7 (0.4, 1.0)	0.0 (-0.1, 0.2)	0.1 (-0.1, 0.3)	0.0 (-0.1, 0.2)	0.0 (-0.2, 0.3)
Anterior thigh	0.4 (0.1, 0.7)	0.5 (0.1, 0.9)	0.3 (0.0, 0.6)	0.4 (0.0, 0.9) [¶]	-0.1 (-0.4, 0.1)	-0.4 (-0.7, 0.1)	-0.2 (-0.4, 0.1)	-0.5 (-0.8, -0.1)
Subscapular	0.2 (0.0, 0.4) [¶]	0.4 (0.1, 0.7)	0.2 (0.0, 0.4)	0.5 (0.2, 0.8)	-0.0 (-0.2, 0.1)	-0.1 (-0.3, 0.1)	0.0 (-0.2, 0.1)	-0.1 (-0.3, 0.1)
Triceps	0.1 (-0.1, 0.3)	0.1 (-0.2, 0.4)	0.1 (-0.2, 0.3)	0.1 (-0.2, 0.5)	-0.0 (-0.2, 0.1)	-0.2 (-0.4, 0.1)	-0.1 (-0.3, 0.1)	-0.3 (-0.6, -0.1)

Note: Referent category comprises women who never had an ultrasound exam with a TI/MI > 1.0; beta coefficients measure the mean change in neonatal measurements for number of scans with TI/MI > 1.0 (1 or 2+) compared with scans having no TI/MI values > 1.0. Sample size varied by anthropometric parameter: birthweight (n=1975); length (n=1975); head circumference (n=1996); abdominal circumference, chest circumference, upper arm length and upper thigh length (n=1985); mid-upper circumference (n=1982); mid-upper thigh circumference (n=1984); umbilical circumference (n=1979); abdominal flank skinfold (n=1804); anterior thigh skinfold (n=1822); subscapular skinfold (n=1801); triceps skinfold (n=1821).

[‡] Abdominal circumference was measured at a level midway between the xiphoid process and the umbilicus; umbilical circumference was measured at a level just above the umbilicus.

[¶] Models were adjusted for maternal race, BMI, gestational weight gain and gestational age.

Bolded effect estimates and 95% CIs indicate statistical significance;
 $p < 0.05$ prior to rounding
 $p < 0.05$ prior to rounding.

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Estimated mean change in neonatal anthropometry by the number of maternal ultrasound exams where thermal index >1.0 among 1,731 maternal-neonate pairs with uncomplicated pregnancies, stratified by race/ethnicity – **sensitivity analysis.**

Table 3.

	Thermal Index Models*			
	All	White	Black	Hispanic
Birthweight (g)	β (95% CI)	β (95% CI)	β (95% CI)	β (95% CI)
1 scan	20 (–39, 78)	34 (–94, 161)	7.25 (–89, 104)	24 (–116, 163)
2+ scans	34 (–59, 127)	–74 (–323, 174)	45 (–111, 202)	150 (–41, 340)
Lengths (cm):				
Birth length				
1 scan	0.0 (–0.4, 0.3)	0.3 (–0.5, 1.1)	–0.3 (–0.9, 0.3)	0.4 (–0.4, 1.3)
2+ scans	0.0 (–0.6, 0.6)	1.0 (–0.6, 2.5)	0.0 (–0.9, 1.0)	–0.1 (–1.2, 1.0)
Upper arm				
1 scan	0.2 (0.0, 0.4) [†]	0.5 (0.2, 0.9)	0.0 (–0.3, 0.3)	0.4 (0.0, 0.8)
2+ scans	0.1 (–0.1, 0.4)	0.1 (–0.6, 0.9)	0.2 (–0.3, 0.7)	0.2 (–0.3, 0.6)
Upper thigh				
1 scan	0.2 (0.0, 0.4) [†]	0.7 (0.2, 1.1)	–0.2 (–0.5, 0.2)	0.2 (–0.3, 0.7)
2+ scans	–0.2 (–0.5, 0.2)	1.1 (0.2, 2.1)	–0.6 (–1.2, 0.0)[§]	–0.1 (–0.8, 0.6)
Circumferences (cm):				
Head				
1 scan	0.1 (–0.1, 0.3)	0.7 (0.2, 1.1)	–0.1 (–0.5, 0.2)	0.4 (–0.1, 0.9)
2+ scans	–0.1 (–0.5, 0.2)	0.5 (–0.4, 1.4)	–0.1 (–0.7, 0.5)	0.0 (–0.7, 0.6)
Abdominal				
1 scan	0.1 (–0.2, 0.4)	0.6 (0, 1.2)	–0.1 (–0.7, 0.4)	0.1 (–0.6, 0.8)
2+ scans	–0.2 (–0.7, 0.3)	1 (–0.2, 2.2)	–0.3 (–1.2, 0.6)	0.0 (–0.9, 0.9)
Chest				
1 scan	0.1 (–0.2, 0.4)	0.8 (0.2, 1.4)	0.0 (–0.4, 0.5)	0.1 (–0.6, 0.7)
2+ scans	–0.1 (–0.5, 0.3)	0.9 (–0.2, 2.1)	–0.1 (–0.9, 0.7)	0.1 (–0.7, 0.9)
Mid-upper arm				
1 scan	–0.3 (–0.4, –0.1)	0.2 (–0.1, 0.6)	–0.5 (–0.9, –0.2)	–0.5 (–1.0, –0.1)
				–0.2 (–0.6, 0.2)

Birthweight (g)	Thermal Index Models*				
	All	White	Black	Hispanic	Asian
	β (95% CI)	β (95% CI)	β (95% CI)	β (95% CI)	β (95% CI)
2+ scans	-0.6 (-0.9, -0.3)	0.0 (-0.8, 0.7)	-0.8 (-1.3, -0.2)	-0.6 (-1.2, 0.0)[§]	-0.5 (-1.1, 0.0)
Mid-upper thigh					
1 scan	-0.4 (-0.7, -0.1)	0.2 (-0.4, 0.8)	-0.7 (-1.3, -0.2)	-0.7 (-1.4, 0.0)	-0.3 (-0.9, 0.3)
2+ scans	-0.8 (-1.3, -0.3)	-0.4 (-1.6, 0.9)	-1.2 (-2.2, -0.2)	-0.7 (-1.6, 0.2)	-0.5 (-1.3, 0.4)
Umbilical					
1 scan	0.2 (-0.2, 0.6)	0.7 (-0.1, 1.5)	0.2 (-0.4, 0.9)	-0.3 (-1.1, 0.6)	-0.1 (-0.8, 0.7)
2+ scans	-0.2 (-0.8, 0.4)	0.3 (-1.4, 1.9)	-0.5 (-1.5, 0.6)	0.3 (-0.8, 1.4)	-0.6 (-1.7, 0.5)
Skinfolds (mm):					
Abdominal flank					
1 scan	0.5 (0.2, 0.7)	0.1 (-0.4, 0.6)	0.5 (0.1, 1.0)	1.2 (0.7, 1.7)	0.3 (-0.1, 0.8)
2+ scans	0.7 (0.3, 1.0)	0.7 (-0.3, 1.7)	0.0 (-0.8, 0.7)	1.4 (0.7, 2.1)	0.7 (0.0, 1.3)
Anterior thigh					
1 scan	0.3 (0.0, 0.7)	0.3 (-0.3, 0.9)	0.0 (-0.6, 0.7)	1.3 (0.6, 2.0)	0.1 (-0.5, 0.7)
2+ scans	0.5 (0.0, 1.0)	0.1 (-1.2, 1.4)	0.1 (-1.0, 1.2)	0.8 (-0.1, 1.8)	1.1 (0.2, 2.0)
Subscapular					
1 scan	0.2 (0.0, 0.4)	0.3 (-0.1, 0.7)	0.3 (-0.2, 0.7)	0.6 (0.2, 1.1)	0.0 (-0.4, 0.3)
2+ scans	0.5 (0.2, 0.9)	0.1 (-0.7, 0.9)	0.3 (-0.5, 1.0)	0.9 (0.3, 1.5)	0.7 (0.1, 1.3)
Triceps					
1 scan	0.0 (-0.2, 0.3)	-0.3 (-0.7, 0.2)	-0.1 (-0.6, 0.3)	0.3 (-0.2, 0.7)	0.3 (-0.1, 0.8)
2+ scans	0.1 (-0.3, 0.5)	-0.3 (-1.3, 0.6)	-0.1 (-0.8, 0.6)	0.4 (-0.3, 1.0)	0.4 (-0.3, 1.1)

Note: Referent category comprises women who never had an ultrasound exam with a TI>1.0; beta coefficients measure the mean change in neonatal measurements for number of scans with TI>1.0 (1 or 2+) compared with scans having no TI values > 1.0.

* Models were adjusted for maternal race, BMI, gestational weight gain and gestational age.

[‡] Abdominal circumference was measured at a level midway between the xiphoid process and the umbilicus; umbilicus circumference was measured at a level just above the umbilicus.

Bolded effect estimates and 95% CIs indicate statistical significance;

[¶] $p > 0.05$ prior to rounding;

[§] $p < 0.05$ prior to rounding.

Estimated mean change in neonatal anthropometry by the number of maternal ultrasound exams where mechanical index >1.0 among 1,731 maternal-neonate pairs with uncomplicated pregnancies, stratified by race/ethnicity – **sensitivity analysis.**

Table 4.

	Mechanical Index Models [*]			
	All	White	Black	Hispanic
Birthweight (g)	β (95% CI)	β (95% CI)	β (95% CI)	β (95% CI)
1 scan	-15 (-60, 30)	-24 (-109, 60)	-32.06 (-114, 50)	23 (-75, 121)
2+ scans	-28 (-93, 36)	-40 (-146, 66)	-92 (-228, 45)	97 (-79, 272)
Lengths (cm):				
Birth length				
1 scan	0.0 (-0.2, 0.3)	0.5 (-0.1, 1.0)	-0.3 (-0.7, 0.2)	0.0 (-0.5, 0.6)
2+ scans	-0.2 (-0.6, 0.2)	-0.7 (-1.3, 0.0)	-0.4 (-1.3, 0.4)	-0.3 (-1.4, 0.8)
Upper arm				
1 scan	0.1 (0.0, 0.2)	0.0 (-0.2, 0.3)	0.0 (-0.2, 0.3)	0.2 (-0.1, 0.4)
2+ scans	-0.1 (-0.3, 0.0)	-0.2 (-0.5, 0.1)	-0.3 (-0.7, 0.1)	0.3 (-0.1, 0.8)
Upper thigh				
1 scan	0.2 (0.0, 0.3)	0.2 (-0.1, 0.5)	0.1 (-0.2, 0.4)	0.1 (-0.2, 0.5)
2+ scans	-0.3 (-0.5, -0.1)	-0.4 (-0.7, 0.0)	-0.4 (-0.9, 0.1)	0.1 (-0.5, 0.7)
Circumferences (cm):				
Head				
1 scan	0.0 (-0.2, 0.2)	0.2 (-0.1, 0.5)	-0.1 (-0.4, 0.2)	0.0 (-0.3, 0.3)
2+ scans	-0.2 (-0.4, 0.0)	-0.6 (-0.9, -0.2)	-0.1 (-0.6, 0.5)	0.2 (-0.4, 0.8)
Abdominal				
1 scan	0.0 (-0.2, 0.2)	0.3 (0.0, 0.7) [†]	-0.3 (-0.8, 0.1)	0.1 (-0.4, 0.6)
2+ scans	-0.1 (-0.4, 0.3)	-0.1 (-0.6, 0.4)	-0.1 (-0.9, 0.7)	0.3 (-0.6, 1.1)
Chest				
1 scan	0.0 (-0.3, 0.2)	0.2 (-0.2, 0.6)	-0.2 (-0.6, 0.2)	0.0 (-0.5, 0.4)
2+ scans	-0.2 (-0.5, 0.1)	-0.3 (-0.8, 0.1)	-0.1 (-0.8, 0.5)	0.4 (-0.4, 1.2)
Mid-upper arm				
1 scan	0.0 (-0.2, 0.1)	-0.1 (-0.3, 0.2)	-0.2 (-0.5, 0.1)	0.2 (-0.2, 0.5)
2+ scans	-0.2 (-0.4, 0.1)	-0.3 (-0.6, 0.0)[§]	0.0 (-0.5, 0.5)	0.1 (-0.5, 0.7)

Birthweight (g)	Mechanical Index Models [*]				
	All	White	Black	Hispanic	Asian
	β (95% CI)	β (95% CI)	β (95% CI)	β (95% CI)	β (95% CI)
Mid-upper thigh					
1 scan	-0.2 (-0.5, 0.0)[§]	0.0 (-0.4, 0.4)	-0.7 (-1.2, -0.2)	0.1 (-0.4, 0.6)	-0.4 (-0.9, 0.1)
2+ scans	-0.9 (-1.2, -0.6)	-1.3 (-1.8, -0.8)	-1.0 (-1.9, -0.2)	-0.2 (-1.1, 0.6)	-0.5 (-1.1, 0.2)
Umbilical					
1 scan	-0.3 (-0.6, 0.0)	-0.1 (-0.7, 0.4)	-0.1 (-0.7, 0.4)	-0.5 (-1.1, 0.1)	-0.5 (-1.1, 0.2)
2+ scans	-0.6 (-1.1, -0.2)	-0.9 (-1.6, -0.2)	-0.3 (-1.3, 0.6)	-0.3 (-1.3, 0.7)	-0.5 (-1.4, 0.3)
Skinfolds (mm):					
Abdominal flank					
1 scan	0.0 (-0.1, 0.2)	0.1 (-0.2, 0.5)	0.1 (-0.3, 0.5)	0.1 (-0.3, 0.5)	-0.2 (-0.5, 0.2)
2+ scans	0.1 (-0.2, 0.4)	0.1 (-0.4, 0.5)	0.8 (0.1, 1.4)	0.0 (-0.7, 0.7)	-0.2 (-0.7, 0.3)
Anterior thigh					
1 scan	-0.1 (-0.4, 0.1)	-0.3 (-0.7, 0.1)	0.1 (-0.5, 0.6)	0.4 (-0.1, 0.9)	-0.4 (-0.9, 0.1)
2+ scans	-0.4 (-0.7, -0.1)	-0.7 (-1.2, -0.2)	-0.2 (-1.1, 0.7)	-0.1 (-1.0, 0.7)	-0.3 (-1.0, 0.4)
Subscapular					
1 scan	0.0 (-0.2, 0.1)	0.1 (-0.2, 0.3)	0.0 (-0.4, 0.3)	0.0 (-0.3, 0.3)	-0.3 (-0.6, 0.1)
2+ scans	0.0 (-0.3, 0.2)	-0.1 (-0.5, 0.2)	0.3 (-0.4, 0.9)	0.0 (-0.5, 0.6)	0.0 (-0.5, 0.4)
Triceps					
1 scan	-0.2 (-0.3, 0.0)	-0.2 (-0.5, 0.1)	-0.1 (-0.5, 0.2)	-0.1 (-0.5, 0.2)	-0.3 (-0.7, 0.1)
2+ scans	-0.3 (-0.6, -0.1)	-0.4 (-0.8, -0.1)	0.0 (-0.7, 0.6)	-0.2 (-0.8, 0.4)	-0.2 (-0.8, 0.3)

Note: Referent category comprises women who never had an ultrasound exam with a MI > 1.0; beta coefficients measure the mean change in neonatal measurements for number of scans with MI > 1.0 (1 or 2+) compared with scans having no MI values > 1.0.

^{*} Models were adjusted for maternal race, BMI, gestational weight gain and gestational age.

[‡] Abdominal circumference was measured at a level midway between the xiphoid process and the umbilicus; umbilicus circumference was measured at a level just above the umbilicus.

Bolded effect estimates and 95% CIs indicate statistical significance;

[¶] $p > 0.05$ prior to rounding;

[§] $p < 0.05$ prior to rounding.