RESEARCH ARTICLE

Radiation Exposure of Premature Infants Beyond the Perinatal Period

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ABSTRACT

OBJECTIVES: To determine the odds of premature compared with term infants exceeding the recommended radiation exposure threshold in the first year after discharge from birth hospitalization.

METHODS: In this observational retrospective cohort study, we compared the radiation exposure of premature and term infants between 2008 and 2015 in an urban hospital system. The primary outcome was crossing the radiation exposure threshold of 1 millisievert. We assessed prematurity's effect on this outcome with multivariable logistic regression.

RESULTS: In our study, 20 049 term and 2047 preterm infants met inclusion criteria. The population was approximately one-half female, predominantly multiracial or people of color (40% African American and 44% multiracial), and of low socioeconomic status. Premature infants had 2.25 times greater odds of crossing the threshold compared with term infants after adjustment for demographics (95% confidence interval [CI]: 1.66–3.05). Adjustment for complex chronic conditions, which are validated metrics of pediatric chronic illness, attenuated this association; however, premature infants still had 1.58 times greater odds of crossing the threshold (95% CI: 1.16–2.15). When the final model was analyzed by degree of prematurity, very preterm and extremely preterm infants were significantly more likely to cross the threshold (1.85 [95% CI: 1.03–3.32] and 2.53 [95% CI: 1.53–4.21], respectively), whereas late preterm infants were not (1.14 [95% CI: 0.73–1.78]).

CONCLUSIONS: Premature infants crossed the recommended radiation threshold more often than term infants in the year after discharge from birth hospitalization.

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Dr Hogan designed the study, conducted all analyses, drafted the initial manuscript, had full access to all the data in the study, and takes responsibility for the integrity of the data and the accuracy of the data analysis; Dr Bellin supervised and advised data analysis and critically reviewed the manuscript; Drs Douglas and Levin reviewed and revised the manuscript; Dr Esteban-Cruciani conceptualized the study and reviewed and revised the manuscript; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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Medical imaging is an integral part of inpatient pediatric medical care. With the increased use of imaging in the last decade, there has been heightened interest in the potential effects of ionizing radiation on children.[1] Children potentially have increased risk of developing a malignancy on the basis of increased sensitivity of their developing organs and their long life span, allowing for a longer lead time to the development of cancer.[2–5] However, the potential adverse effects of ionizing radiation on a growing child have been debated in the literature.[1,6–11] Although some authors support recommendations limiting pediatric radiation exposure as advocated by the Image Gently campaign, others suggest that such recommendations may result in the avoidance of necessary imaging by patients or referring physicans.[9,11,12] Policy makers, such as the Committee to Assess Health Risk from Exposure to Low Levels of Ionizing Radiation and the International Commission on Radiological Protection (ICRP), have taken the conservative approach, endorsing the linear, nonthreshold hypothesis.[13,14] The creators of the linear, nonthreshold hypothesis propose that the risk of malignancy exists even at low diagnostic doses.[15–17] On the basis of this theory, the ICRP established 1 millisievert (mSv) as the upper limit that an individual should be exposed to in 1 year.[14]

Authors of previous reports have quantitated the higher number of radiographs on premature infants admitted to the NICU.[18–23] In 1 study, 12% of very and extremely premature infants exceeded the yearly threshold of 1 mSv during their NICU admissions.[19] In addition, complications of prematurity frequently result in a lifetime of medical follow-ups, which in current practice often results in frequent exposures to ionizing radiation, especially when the child is hospitalized.[19] Although the radiation exposure has been quantified in the NICU, the radiation burden of premature infants after discharge from birth hospitalization has not been studied. The purpose of this study was to determine the odds of premature compared with term infants exceeding 1 mSv in the first year after discharge from birth hospitalization.

METHODS

Study Design and Data Source

We conducted a retrospective cohort study of patients managed within an urban medical system whose data were compiled in an electronic data warehouse, queried by Looking Glass Clinical Analytics (Streamline Health Solutions, Inc, Atlanta, GA). Looking Glass is a validated tool that is used for the creation of temporal cohorts.[24–26] The researchers at the data warehouse collect patient demographic characteristics and use data for all encounters within the Montefiore Medical System, including inpatient, emergency department, and outpatient encounters. All diagnoses from *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) and All Patient Refined Diagnosis Related Groups, as well as all procedure codes from ICD-9-CM, are searchable and can be used to define cohorts of patients.[27] All radiologic studies and their full text reports are searchable. The institutional review board at Albert Einstein College of Medicine approved this study.

Study Population

Children born within a Montefiore Medical Center hospital as identified by All Patient Refined Diagnosis Related Groups between January 1, 2008 and September 30, 2015 were available for inclusion in our study. Patients transferred to or out of a Montefiore hospital before discharge from birth hospitalization were excluded from analysis. We defined 2 cohorts of patients: premature infants (ICD-9-CM codes 765.22–765.28) and term infants (ICD-9-CM code 765.29).[28] We hypothesized that patients with a relationship with our health care system were more likely to receive medical imaging within our system. We therefore restricted our analysis to those patients who were most likely to obtain subsequent radiologic procedures in our system by requiring that all patients in the cohort have evidence of an ongoing relationship with Montefiore. We operationalized this by requiring at least 1 outpatient visit with a Montefiore provider, excluding laboratory- or imaging-only visits, at least once yearly for their first 3 years of life. Children who died in the first 3 years after birth were excluded.

Outcome Measures

The primary exposure was prematurity as defined by the ICD-9-CM code on birth hospitalization. The degree of prematurity was also evaluated as a predictor of radiation exposure: extremely preterm (<28 weeks' gestation; ICD-9-CM 765.22–765.24), very preterm (28–34 weeks' gestation; ICD-9-CM 765.25–765.27), and late preterm (34–37 weeks' gestation; ICD-9-CM 765.28).[29] The primary outcome was exposure of >1 mSv in the year after discharge from birth hospitalization per Institute for Clinical and Translational Research recommendations.[14]

Radiation Exposure

Cumulative medical radiation, dichotomized as >1 or <1 mSv, was the primary outcome variable. All radiographs and computed tomography (CT) images performed in the first 365 days after discharge from birth hospitalization were quantified. Each patient's burden of radiation was calculated by multiplying the number of each imaging study per patient with published age-appropriate mSv conversions.[30] Patients exposed to >1 mSv within 1 year of discharge were classified as being "over threshold." Radiation burden after discharge was chosen because a pediatric hospitalist or general pediatrician has the ability to affect medical radiation exposure after discharge, whereas the radiation burden of the NICU is under the purview of neonatologists. In the sensitivity analysis, we determined the proportion of patients to be above the threshold if 1 additional radiograph was added to a patient's radiation burden and the effect of restricting the analysis to primary care visits as opposed to any outpatient visits.

Covariates

Age, sex, race, and ethnicity were considered as demographic variables. Looking Glass is used to calculate a *z* score of socioeconomic status (SES) for each patient on the basis of census block, which is then normalized against statewide data.[31] SES was also included as a variable. Complex chronic conditions (CCCs) are validated metrics of pediatric chronic illness and were assessed for inclusion in the model.[32,33] CCCs are broken into 10 categories: neuromuscular, cardiovascular, respiratory, renal, gastrointestinal, hematology, immunodeficiency, metabolic, other congenital or genetic defect, and malignancy. The severity defining a CCC is such that it affects "several different organ systems or 1 system severely enough to require specialty pediatric care and probably some period of hospitalization in a tertiary care center."[33] CCCs as defined by Feudtner et al[33] in 2000 were used because the 2014 version included our primary predictor, prematurity, as a CCC. Birth year and number of well-child visits in the first year after discharge were also included in the model.

Analysis

Categorical comparisons of premature and term infants were summarized by using frequencies and percentages. The groups were compared by using χ^2 tests. Continuous variables were summarized with medians and interquartile ranges (IQRs) and evaluated by using Wilcoxon rank tests. A logistic regression assessing the primary outcome was conducted by using Stata version 14.1 (Stata Corp, College Station, TX). A priori, sex, race, and ethnicity were included in the model. Age at discharge was not included in the model because of its direct correlation with the degree of prematurity. Remaining variables, including CCCs, birth year, and number of well-child visits in the first year after discharge from birth hospitalization, were evaluated by using criteria of $P < .05$ for model inclusion in the backward stepwise variable selection method.

RESULTS

Demographics

In the studied population, we included 20 049 term and 2047 preterm infants. Our population was predominantly multiracial or people or color with low SES (Table 1). Median discharge age increased with the degree of prematurity. CCCs were significantly different between the groups when tracking along the degree of prematurity. CCCs were common, with 18% of term infants having at least 1 CCC as compared with 29% of late preterm, 53% of very preterm, and 81% of extremely preterm infants.

TABLE 1 Demographics of Term and Preterm Infants Discharged Between 2008 and 2015

	Term	Preterm	*P*
N	20 049	2047	—
Boys, *n* (%)	10 166 (50.7)	1075 (51.3)	.59
Race, *n* (%)			<.001
African American	7174 (40.0)	853 (41.7)	
Multiracial	8868 (44.1)	827 (40.4)	
White	1576 (8.8)	154 (7.5)	
Asian American	224 (1.1)	18 (0.9)	
American Indian or Alaskan native	77 (0.4)	9 (0.4)	
Native Hawaiian or other Pacific Islander	10 (0.1)	4 (0.2)	
Declined	2109 (10.5)	182 (8.9)	
Hispanic ethnicity, *n* (%)	4296 (30.2)	421 (27.0)	.01
Age at discharge, d (IQR)	2.6 (2.6 to 3.7)	11.7 (4.0 to 32.5)	<.001
Late preterm	—	5.8 (3.7 to 12.8)	
Very preterm	—	36.5 (23.7 to 51.5)	
Extremely preterm	—	91.6 (71.2 to 109.9)	
SES,[a] median (IQR)	−2.9 (−6.2 to −1.2)	−2.9 (−6.3 to −1.2)	.89
CCC, *n* (%)	3756 (18.7)	840 (40.1)	<.001

—, not applicable.

[a] SES defined by *z* score of average income in patient census block compared with median state income.

Radiation Burden

In the year after hospital discharge, ionizing radiation exposure was significantly different between term and preterm infants. The vast majority of the cohort received no radiation in the first year after discharge, or a low radiation burden (Table 2). However, significantly more preterm infants were exposed to >1 mSv of radiation in the first year after discharge (3.7% vs 1.7%; $P <$ .001). The proportion of infants that crossed the radiation threshold was higher within each group of premature infants (late preterm 2.4%, very preterm 5.1%, and extremely preterm 8.8%). Of the infants who crossed the threshold, 69% of term and 55% of preterm infants crossed because of a single CT examination ($P < .001$). The proportion of preterm infants with at least 1 chest, abdominal, or neck radiograph was approximately double that of term infants (Table 3, Supplemental Table 5). There were no significant differences in any individual type of CT exposure. However, the proportion of preterm infants exposed to any CT scanning was 2.2%, whereas term infants were significantly less at 1.5% ($P = .02$). Of the 345 term infants who crossed the radiation threshold, 72% crossed because of CT exposure alone, 21% crossed because of radiographs alone, and 6% crossed because of radiation from both radiographs and CT scans. In contrast, of the 78 premature infants who crossed the radiation threshold, 43% crossed because of CT exposure alone, 45% crossed because of radiograph exposure alone, and 11% crossed because of both CT and radiograph modalities.

Multivariable Analysis

Premature infants (<37 weeks' gestation) had 2.2 times greater odds of being above the radiation threshold compared with term infants in unadjusted logistic regression (Table 4). Adjusting for demographics did not significantly change this association (odds ratio [OR]: 2.25; 95% confidence interval [CI]: 1.66–3.05). However, adjusting for CCCs weakened the association of prematurity and exceeding the radiation threshold. After adjustment, premature infants were 58% more likely to be above the radiation threshold compared with term infants (OR: 1.58; 95% CI: 1.16–2.15). When the degree of prematurity was accounted for, very preterm and extremely preterm infants remained significantly more likely to be above the radiation threshold in relation

TABLE 2 Radiation Burden of Term and Preterm Infants in the First Year After Discharge From Birth Hospitalization

	Term	Preterm	*P*	Degree of Prematurity			*P*
				Late Preterm	Very Preterm	Extremely Preterm	
N	20 049	2047	—	1400	375	272	—
Radiation burden, *n* (%), mSv							
0	17 278 (86)	1525 (75)	<.001	1120 (80)	226 (71)	139 (51)	<.001
0–1	2424 (12)	444 (21)	—	245 (18)	90 (24)	109 (40)	—
1–5	313 (1.6)	64 (3.1)	—	30 (2.1)	16 (4.3)	18 (6.6)	—
5–10	13 (0.1)	11 (0.5)	—	3 (0.2)	3 (0.8)	5 (1.8)	—
10+	21 (0.1)	3 (0.1)	—	2 (0.1)	0 (0)	1 (0.4)	—

—, not applicable.

to term infants, whereas late preterm infants were not significantly different (Table 4). We believe that adjusting for CCCs is necessary because although many of the premature infant's CCCs were likely derived from their prematurity, a "fear of prematurity" may also have driven providers to obtain additional imaging. Therefore, we have classified prematurity as a confounder and not a mediator of the association with crossing the radiation threshold. There is no statistical test to determine if a variable is a confounder or a mediator; however, with our data, we found that the presence of CCCs predicted crossing the radiation threshold overall, as well as in most subcategories of CCCs (Supplemental Tables 6 and 7).

Sensitivity Analysis

Exploring the theoretical impact of an additional radiation study on each study participant revealed that adding 1 non-CT radiograph rarely caused a patient to newly cross the radiation threshold within 1 year. Adding 1 chest radiograph to every patient in the 22 146 person cohort only caused 7 infants (0.03% of the cohort) to newly exceed 1 mSv in 1 year. Adding 1 abdominal or pelvic radiograph increased the cohort's cross-threshold-radiation–population by 0.4% ($n = 74$) in term and 0.9% ($n = 19$) in preterm infants. In contrast, adding 1 CT scan of the brain, chest, or pelvis necessarily caused all patients in the cohort to exceed the radiation threshold.

A second sensitivity analysis was preformed to test the effect of restricting the analysis from patients with at least 1 outpatient visit per year for 3 years, to requiring that the outpatient visit was a primary care visit. We found that this more stringent definition eliminated 254 (1.3%) of term infants and 74 (3.5%) preterm infants from the analysis, accounting for 1.5% of the overall cohort. The removal of these patients did not significantly alter the primary outcome either by overall prematurity or by degree of prematurity.

TABLE 3 Exposure to at Least 1 Imaging Study in Term and Preterm Infants in the First Year After Discharge From Birth Hospitalization

	Term	Preterm	*P*	mSv[a]
N	20 049	2047	—	—
Radiographs, *n* (%)				
Chest	3602 (18)	634 (30)	<.001	0.08
Abdominal	597 (3.0)	124 (5.9)	<.001	0.34
Neck	248 (1.2)	61 (2.9)	<.001	0.12[b]
Pelvis	158 (0.8)	29 (1.4)	.01	0.35
Skull	99 (0.5)	9 (0.4)	.69	0.6
CT scans, *n* (%)				
Brain	360 (1.8)	48 (2.3)	.11	2.2
Facial bones	43 (0.2)	5 (0.2)	.82	0.5
Spine	15 (0.1)	2 (0.1)	.75	11.4
Chest	13 (0.1)	6 (0.2)	<.01	2.2
Abdominal and/or pelvis	12 (0.1)	4 (0.2)	.03	4.8
Hip	1 (<0.1)	0 (<0.1)	.75	7

—, not applicable.
[a] mSv estimates per Linet et al[30] except as indicated.
[b] mSv per Simpson et al.[34]

DISCUSSION

In this large, single center, retrospective cohort study, premature infants were significantly more likely to exceed the ICRP's radiation threshold of 1 mSv within 1 year after discharge from birth hospitalization as compared with term infants. With adjustment for demographics, premature infants were more than twice as likely to be >1 mSv within 1 year. As would be expected, adjusting for CCCs meaningfully diminished this association, but it remained significant, increasing the odds of crossing the threshold by 58%.

Adjustment for CCCs also attenuated the associations of crossing the threshold when adjusting for the degree of prematurity. The odds of very preterm and extremely preterm infants crossing the threshold was halved with CCC adjustment. Late preterm infants were not significantly different from term infants in any analysis.

Increased radiation exposure is more common in very preterm and extremely preterm infants in a seemingly dose-responsive relationship. CCC adjustment

TABLE 4 ORs of Exposure to >1 mSv of Medical Radiation in 1 Year Postdischarge From Birth Hospitalization

Risk Factor	No Adjustment >1 mSv OR (95% CI)	Adjusted for Demographics >1 mSv OR (95% CI)[a]	Full Model >1 mSv OR (95% CI)[b]
Any prematurity			
Term	Reference	Reference	Reference
Any prematurity	2.20 (1.71–2.82)	2.25 (1.66–3.05)	1.58 (1.16–2.15)
Degree of prematurity			
Term	Reference	Reference	Reference
Late preterm	1.41 (0.99–2.00)	1.34 (0.86–2.10)	1.14 (0.73–1.78)
Very preterm	3.03 (1.89–4.87)	3.05 (1.72–5.41)	1.85 (1.03–3.32)
Extremely preterm	5.50 (3.57–8.47)	5.62 (3.44–9.18)	2.53 (1.53–4.21)

[a] Adjusted for sex, race, and ethnicity.
[b] Adjusted for sex, race, ethnicity, and presence of CCC.

attenuates this association but does not eliminate it. This suggests that either the degree of prematurity drives physician ordering beyond other clinical diagnoses, or the CCC definition does not fully capture the extent of disease states that drive the association. Prospective studies would be required to fully investigate this question. In 2014, Feudtner et al[32] updated their CCC definition to include *International Classification of Diseases, 10th Revision* and other diagnoses not originally included in the definition. Although the majority of these were definitions that include technology dependence (ie, children dependent on ventilators or other durable medical equipment), a significant change to the definition was inclusion of prematurity as its own CCC. We chose to not use this updated definition because our analysis is dependent on the degree of prematurity. Using the updated definition would eliminate our primary predictor in this analysis.

Four percent of our very and extremely premature population crossed the threshold, as compared with Scott et al's[19] 12%. The majority of patients studied by Scott et al[19] were extremely premature infants, which is consistent with our finding of a 5 times greater odds of being above the threshold among extremely preterm infants compared with term infants. The cumulative exposure of extremely premature children is likely high in relation to other groups. We believe that extremely premature infants would benefit from additional study and clinical decision-making regarding diagnostic radiation exposure.

Using 1 mSv as the radiation threshold, we found that radiation exposure was primarily driven by CT imaging, with the majority of patients crossing this exposure because of a single CT. In addition, in our sensitivity analysis, we found that any patient exposed to an additional CT scan of the brain, chest, abdomen, or pelvis will be above the recommended early radiation burden. This is in stark contrast to the risks of obtaining an additional low-dose radiograph; there were only 7 patients in our cohort of >22 000 patients who exceeded the threshold with the addition of 1 chest radiograph. These data would support the need to focus surveillance efforts toward decreasing unnecessary CT scanning or employing other imaging modalities when possible (such as MRI scanning). A more targeted effort is more easily implementable and more likely to be successful. Although not reproduced in this limited cohort, the Image Gently campaign's focus on decreasing CT use has been effective, revealing increased ultrasound use and decreased CT use since the start of the campaign coupled with stable or decreased CT dose.[35]

There are a number of limitations to our study. Our data were obtained from a single medical system in the Bronx, New York, with a large minority population. Although not representative of the US population, we did not observe significant differences in exposure due to SES, race, or ethnicity. By using published averages of radiation exposure instead of actual measured exposures of each radiograph, we may have had an inaccurate measure of the radiation burden. This bias could have caused us to overestimate the burden of radiation exposure because the Image Gently "right sizing" of radiation exposure for pediatrics was implemented in 2010, after the publication of work by Linet et al.[30,36] In this study, we did not focus on radiation exposure during the birth hospitalization as others have[18,37] but rather on post-NICU radiation exposure. As such, we cannot offer true estimates of radiation burden over the first year of life. We expect that the degree of prematurity would also predict radiation burden in the first year of life, and not just the first year after discharge, but this is an area of potential future research.

Because this is a retrospective database study, we could not verify the patients received all of their radiographs within our system. We attempted to ameliorate this bias by requiring that patients have an outpatient visit at least once per year for the first 3 years of life in our health care system. This requirement might have biased our cohort to be healthier because it required all members of the cohort to survive until age 3; however, it was the best method to ensure a patient was consistently managed by our health care system and therefore more likely to receive the majority of their radiation exposure within our health system. We acknowledge that we may have underestimated the radiation burden of our cohort because of examination received at outside institutions. We believe this bias is small because <2% of our cohort was excluded when the inclusion criteria were restricted to primary care visits only. In addition, if the assumption is that premature infants were to receive subspecialty care in our hospital system and not their primary care, premature infants' radiographs would be more likely to be undercounted in relation to term infants, a finding that if measured would be supportive of our study's findings. Authors of further studies ought to include insurance claims data based on membership data for large cohorts of newborns to further validate our findings.

CONCLUSIONS

Premature infants, especially extremely premature infants, are significantly more likely to receive >1 mSv in the first year after discharge from birth hospitalization, exceeding national guidelines. Higher radiation exposure was primarily driven by CT scanning, rather than radiograph imaging. Use of the American College of Radiology appropriateness criteria[38] can aid in ensuring the appropriate ordering of imaging studies, decrease unnecessary imaging, improve awareness of radiation dose and its implications and guide use of alternative modalities.

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