Sociodemographic and Dietary Risk Factors for Natural Infant Intussusception in the United States

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ABSTRACT

Background: In 1999, a US case-control study demonstrated a strong association between intussusception and a rotavirus vaccine (Rotashield). However, because most (87%) cases were not temporally associated with vaccination, we reanalyzed these data to assess risk factors for intussusception cases unrelated to Rotashield.

Patients and Methods: Case-patients were infants with intussusception between November 1998 and June 1999. Controls were matched by age and hospital of birth. Sociodemographic and feeding practice data were collected through parent and provider interviews. Conditional logistic regression was used to identify risk factors for intussusception, controlling for exposure to Rotashield <21 days before intussusception.

Results: Four hundred twenty-nine cases and 1763 controls were enrolled. Among case-patients, 372 (87%) had not received Rotashield within 21 days before intussusception. After adjusting for recent Rotashield administration, factors associated with intussusception included male sex (odds ratio [OR] 1.7; 95% confidence interval [CI] 1.3–2.2), Hispanic (OR 2.1; 95% CI 1.4–3.2) or black (OR 1.8; 95% CI 1.2–2.7) race/ethnicity, and Medicaid enrollment (OR 1.5; 95% CI 1.1–2.0). Feeding practices modified the risk of intussusception. Interaction was found between introduction of solid food (ISF) and type of formula consumption. Using breast milk as the referent group, infants with ISF for at least 5 weeks who consumed soy milk–based formula had a lower risk (OR 0.26; 95% CI 0.1–0.7) and infants without ISF who consumed cow's-milk formula had an increased risk (OR 2.33; 95% CI 1.4–3.9).

Conclusions: Risk of intussusception among US infants varies based on sociodemographic characteristics and feeding patterns.

Key Words: epidemiology, intestinal diseases, intussusception, risk factors

(*JPGN* 2010;51: 458–463)

Intussusception is the most common cause of acute intestinal obstruction in infants, occurring when 1 segment of bowel invaginates, or telescopes, into the distal bowel, leading to venous congestion and bowel wall edema. Few cases spontaneously resolve, whereas most, if untreated, progress to arterial obstruction, which can result in bowel necrosis, perforation, and possibly death (1).

Received November 9, 2009; accepted January 6, 2010.

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The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention.

The authors report no conflicts of interest.

DOI: 10.1097/MPG.0b013e3181d3273f

In most cases, the cause of intussusception is not known. A wide range of viruses and bacteria, and some parasites, have been identified in patients with intussusception; however, only adenovirus infection has been significantly associated with intussusception (2). The incidence of intussusception among infants younger than 1 year of age is ~40 to 50/100,000 in most reports (3,4). Rates as high as 300/100,000 have been reported in some populations (2), and several studies have identified differences in rates by race/ethnicity (2,5). Intussusception rates also vary markedly by age during the first year of life. Few cases occur before 2 months of age, and the peak incidence is between 4 and 6 months of life. The rates of intussusception in the United States and some other developed countries have declined in the last decade for reasons that are not known (3,6–8). The variation in intussusception rates by age, region, and race/ethnicity suggests that genetic, cultural, dietary, or environmental factors may have a role in the development of intussusception.

In 1998, a rhesus-human reassortant oral rotavirus vaccine (Rotashield, Wyeth Lederle Vaccines, Philadelphia) was recommended in the United States for routine immunization of infants at 2, 4, and 6 months of age. Nine months after vaccine introduction, an increasing number of reports of intussusception temporally associated with Rotashield vaccination led to the suspension of vaccine use in the United States (9). A nationwide case-control study subsequently confirmed an association between Rotashield and intussusception, with the greatest risk within 3 to 7 days following the first dose.

The US Rotashield case-control study identified approximately half of all of the intussusception cases estimated to have occurred in the United States during the study period. In that study, Murphy et al (10) identified that Rotashield vaccination was strongly associated with intussusception. However, 87% of the cases identified in the study were not temporally associated with Rotashield (10). Thus, we reanalyzed these data to focus on cases of natural intussusception that were not temporally associated with Rotashield vaccination to assess risk factors for natural intussusception (10,11).

PATIENTS AND METHODS

Selection of Case-patients and Controls

Details of the methods have been previously described (10). In summary, intussusception case-patients and their matched controls were selected in the 19 states where 80% of the Rotashield was distributed. Within these states, investigators selected hospitals that discharged 75% of the intussusception case-patients from the previous 3 years.

Case-patients

Investigators in the original study enrolled infants at least 1 month to younger than 12 months of age, hospitalized with intus-

susception during the study period (November 1, 1998 to June 30, 1999) and who had the diagnosis confirmed by radiologic procedure, surgery, or autopsy.

Controls

Four control infants for each case-patient were randomly selected from among infants born on the same day and in the same hospital as the case-patient.

Data Collection

Data for both case-patients and controls were collected from providers and parents or guardians, including the following variables: Rotashield exposure; sociodemographic factors, including sex, race/ethnicity, mother's level of education, Medicaid status, other young children living at home with the infant, and child care practices; dietary practices, including nonsolid food consumption (breast milk, cow's milk formula, soy milk formula, or other formula), introduction of solid food other than cereal (ISF) (no introduction, introduction within previous month, or introduction beyond 1 month); and previous diagnosis of milk allergy or lactose intolerance.

Statistical Analysis

Using conditional logistic regression, we estimated the matched odds ratio (OR) and confidence intervals (CI) for intussusception by individual sociodemographic and dietary characteristics. We then used a multivariate model to test the independence of these associations. In the initial (full) model, variables were included if they had a P value ≤ 0.2 in the univariate analysis.

Because our objective was to assess risk factors for natural intussusception (ie, unrelated to Rotashield vaccination), we controlled for exposure to first, second, or third doses of Rotashield within 21 days of the reference date (date of hospitalization for case-patients; age-equivalent date in controls). Risk of intussusception is unlikely after 21 days of vaccine receipt because intestinal replication of the virus does not occur (10). Each dose was added to the model by exposure window (1–7, 8–14, and 15–21 days) (10). Because the analysis and data for the association between Rotashield and intussusception have been described previously, these data are not presented here (10). The initial multivariate model was simplified and reduced by removing the least significant variable with P value >0.05, provided its removal did not change ORs for the remaining variables by more than 10%. This procedure was repeated in turn with the next least significant variables until a final model was reached.

Variables included in the final model were Rotashield exposure, sex, race/ethnicity, mother's level of education, Medicaid status, breast milk/formula consumption, and ISF. The model was tested to satisfy requirements for convergence and fit and ensure that no multicollinearity existed among the independent variables. The variance inflation factor for each independent variable was <10. Interactions were investigated and tested using likelihood ratio tests. For significant interactions we used Statistical Analysis System (SAS) Interactive Matrix Language and the covariance matrix of the estimated model parameters to compute interaction ORs and their 95% confidence. Analyses were completed using SAS version 9.2 (SAS Institute, Cary, NC).

RESULTS

The Rotashield case-control study included 429 infants with intussusception and 1763 matched controls. Among the included infants, 372 (87%) infants with intussusception and 1673 (95%) matched controls had not received Rotashield within 21 days before intussusception (case-patients) or the reference date (controls). Case-patients vaccinated with Rotashield within 21 days before intussusception were significantly ($P < 0.001$) younger (mean 20 weeks) than case-patients not vaccinated in this time period (mean 30 weeks).

Infants with intussusception were disproportionately boys and black, Hispanic, or other race or ethnicity (Table 1). Case-patients were more likely to have mothers with a lower level of education than controls and were more often a recipient of Medicaid health coverage or subsidized health care. Before the onset of intussusception, case-patients less often had ISF and were less likely enrolled in home-based child care than controls. Other than the Rotashield vaccine, no differences in vaccination rates existed between case-patients and controls (data not shown) (10).

In the multivariate model, after adjusting for receipt of Rotashield, we identified a significantly increased risk of intussusception among male infants (OR 1.7; 95% CI 1.3–2.2), Hispanic or black infants (OR 2.1; 95% CI 1.4–3.2 and OR 1.8; 95% CI 1.2–2.7, respectively), and infants who received Medicaid health care benefits (OR 1.5; 95% CI 1.1–2.0) (Table 2).

The effect of nonsolid food (breast milk, cow's milk, or other type of formula) on risk of intussusception was significantly different among infants with any ISF (ie, <5 weeks or >5 weeks before intussusception onset) compared with those without ISF ($P = 0.003$) (Table 3). Compared with breast-feeding, consumption of cow's-milk–based formula was associated with more than a 2-fold increased risk of intussusception among infants without ISF and was not associated with intussusception among infants with any ISF. Use of soy milk–based formula was not associated with intussusception among infants without ISF or with only recent ISF (<5 weeks), but appeared protective against intussusception among infants with ISF 5 or more weeks before the reference date (Table 3).

No interaction was found between age and race/ethnicity, age and breast milk/formula consumption, or Medicaid status and race/ethnicity. The age (in months) distribution of breast milk/formula consumption was similar when stratified by ISF (Fig. 1). The interquartile ranges were similar for recent (within 5 weeks), sustained (>5 weeks), or no ISF (2.6, 2.9, and 2.7, respectively). Similarly, when distributed by month of age, no difference in pattern emerged for breast milk/formula consumption and ISF when stratified by race/ethnicity, Medicaid status, sex, or education levels (data not shown).

DISCUSSION

In our analysis, we identified an association between intussusception and sociodemographic and dietary factors that provide further insight into several observations from previous studies of the epidemiology of intussusception. Compared with whites, Hispanics and blacks had a 2-fold increased risk of intussusception, after adjusting for other potential confounders. Whether differences in factors like genetic, dietary, or environmental could explain this increased risk remains unclear. These findings are consistent with previous observations that rates of intussusception among US infants are higher among Hispanics (45/100,000) and blacks (37/100,000) than among whites (27/100,000) (3). Differences in rates of intussusception by race/ethnicity have also been identified in other populations (2,5). Greenberg et al (5) found ethnic variation between Bedouin and Jewish populations in Israel and suggested the difference to be potentially related to reporting biases. Furthermore, socioeconomic status and subsequent differences in access to health care or health care–seeking behavior have been correlated with variation in intussusception rates (2,12–14).

TABLE 1. Characteristics of infants with intussusception and their age-matched controls*

Infant characteristic†	Cases	Controls	Unadjusted OR (95% CI)	P
	No. (%)			
Sex	n = 429	n = 1763		
Male	262 (61.1)	890 (50.5)	1.6 (1.3–1.9)	<0.001
Race or ethnic group	n = 412	n = 1748		
Hispanic	110 (26.7)	353 (20.2)	2.3 (1.6–3.4)	<0.001
Black	81 (19.7)	271 (15.5)	2.0 (1.4–2.8)	<0.001
Other or mixed	45 (10.9)	178 (10.2)	1.5 (1.0–2.1)	0.040
Non-Hispanic white§	176 (42.7)	946 (54.1)	1.0	
Mother's level of education	n = 410	n = 1735		
Less than high school	103 (25.1)	312 (18.0)	2.3 (1.6–3.4)	<0.001
High school graduate or some college or technical school	230 (56.1)	936 (54.0)	1.7 (1.2–2.2)	0.001
College graduate§	77 (18.8)	487 (28.1)	1.0	
Type of health insurance	n = 413	n = 1744		
Medicaid or subsidized	182 (44.1)	593 (34.0)	1.7 (1.3–2.2)	<0.001
Private insurance§	231 (55.9)	1151 (66.0)	1.0	
Other young children living at home with infant	n = 417	n = 1756		
≥1 additional child <5 y old	177 (42.5)	691 (39.4)	1.1 (0.9–1.4)	0.230
No additional child <5 y old§	240 (57.5)	1065 (60.6)	1.0	
Child care	n = 416	n = 1748		
Home-based	43 (10.3)	261 (14.9)	0.7 (0.5–0.9)	0.018
Center-based	47 (11.3)	171 (9.8)	1.1 (0.8- 1.6)	0.546
Other	3 (0.7)	17(1.0)	0.7 (0.2–2.3)	0.530
No child care§	323 (77.6)	1299 (74.3)	1.0	
Breast milk/formula consumption	n = 417	n = 1758		
Cow's-milk–based formula	286 (68.6)	1077 (61.3)	1.2 (0.9–1.6)	0.180
Soy milk–based formula	34 (8.2)	209 (11.9)	0.7 (0.5–1.1)	0.130
Other formula	12 (2.9)	93 (5.3)	0.6 (0.3–1.1)	0.100
Breast milk for most feedings§	85 (20.4)	379 (21.6)	1.0	
Introduction of solid food	n = 388	n = 1653		
≥5 wk before reference date	121 (31.2)	613 (37.1)	0.7 (0.5–0.9)	0.010
<5 wk before reference date	65 (16.8)	295 (17.9)	0.8 (0.6–1.1)	0.190
No solid food before reference date§	202 (52.1)	745 (45.1)	1.0	
Diet allergy	n = 382	n = 1652		
Milk allergy/lactose intolerance¶	16 (4.2)	81 (4.9)	0.8 (0.5–1.5)	0.520

CI = confidence interval; ISF = introduction of solid food; OR = odds ratio.

* Some data presented here were previously published in reference [10]. 429 infants with intussusception and 1763 matched controls were used for analysis. Univariate analysis was conducted using these denominators unless specified. Cases were matched by age and the hospital where the infant was born. Because of rounding not all of the percentages sum to 100. ORs and *P* values were calculated using the referent group.

† 57 (13%) case-infants and 90 (5%) control-infants were exposed to Rotashield within 21 days of intussusception (case-infants) or reference date (control-infants). Unadjusted ORs for receipt of Rotashield reported previously in reference [10].

§ Referent group used for OR.

¶ Previous diagnosis by provider before reference date.

In the original Rotashield study, Murphy et al (10) found a strong risk of intussusception in association with Rotashield vaccination regardless of diet type. However, we found that the risk of natural intussusception was modified by the type of milk consumed and the timing of solid food introduction by infants. Previous studies have shown that dietary and weaning practices vary in the United States and can substantially alter the gut morphology (1,15–24). Among infants without ISF, those consuming cow's-milk–based formula had more than a 2-fold increased risk of intussusception compared with breast-fed infants. The biological plausibility for cow's-milk–based formula to affect the infant gut differently from breast milk exists. Intestinal damage caused by cow's-milk consumption is well documented among infants with cow's-milk protein allergy, which is estimated to occur in 2% to 5% of infants. In these infants, the immune system generates antibodies against cow's-milk and damages the intestinal mucosal surface (25). Conversely, among infants with ISF for at least 5 weeks, soy formula was associated with a significantly lower risk of intussusception compared with breast-feeding. For reasons that are unclear, the protective effect of the combination of soy formula and solid foods for at least 5 weeks before reference date was greater than the sum of their separate protective effects. Currently, indications for soy milk formula over cow's-milk formula are rare and only recommended in infants with galactosemia, hereditary lactase deficiency, or when a vegetarian diet is preferred by the guardian (26). Infants who received soy formula preferentially may have had other unidentified cofactors that contributed to their decreased risk of intussusception. Our results raise more questions than provide answers; we cannot provide a unified theory to explain

TABLE 2. Adjusted OR in the case-control analysis*

Infant characteristics	Adjusted OR (95% CI)	Adjusted *P*
Sex		
Male	1.7 (1.3–2.2)	<0.001
Female†	1.0	
Race or ethnic group		
Hispanic	2.1 (1.4–3.2)	0.001
Black	1.8 (1.2–2.7)	0.004
Other	1.5 (1.0–2.4)	0.052
Non-Hispanic white	1.0	
Type of health insurance		
Medicaid or subsidized	1.5 (1.1–2.0)	0.014
Private, military, self-paid, or other†	1.0	
Mother's level of education		
Less than high school	1.4 (0.9–2.2)	0.130
High school graduate	1.4 (1.0–1.9)	0.074
College graduate†	1.0	
Introduction of solid food	§	
Breast milk/formula consumption	§	

CI = confidence interval; OR = odds ratio.
* Adjusted ORs were calculated for infants with complete data available: 382 cases and 1657 controls. Each variable displayed was included in the final model. OR and *P* value for each variable adjusted for receipt of Rotashield <21 days before reference date and each other.
† Referent group.
§ Interaction present between introduction of solid food and breast milk/formula consumption. Please see Table 3 for calculated OR.

our findings on diet and intussusception, and additional studies would be required to elucidate this complicated interaction.

The limitations to the analysis warrant cautious interpretation. Data for case-patients and controls were collected from parent and provider interviews. This form of data collection is subject to recall bias and potentially diminished the quality of information for the study. The average time that elapsed between the case hospitalization and the provider interview was ~140 days for cases and 169 days for controls. We also chose to retain the case-control match for our analysis. By controlling for Rotashield vaccination rather than excluding infants who received Rotashield, we potentially included case-patients who were distinctly different from ''native'' intussusception cases. We retained infants receiving Rotashield because the larger sample size increased the statistical power of the study and allowed for better control of age. The alternative study design was to exclude all of the Rotashield vaccinated case-patients and controls from analysis. However, Murphy et al (10) showed that Rotashield recipients were more likely to be white, have private health insurance, and have more highly educated mothers, all of the factors associated with lower risk of intussusception. Therefore, excluding case-patients and controls who received Rotashield would have resulted in a study less representative of the general population with findings of compromised validity. The Rotashield study was hospital based and did not include case-patients managed exclusively in outpatient or short-stay settings, where cases of intussusception may also be managed (27). Although cases and controls were matched by hospital, we cannot exclude the possibility of a bias from differences in health care–seeking patterns by race/ethnicity between cases and controls. Although our observation of an association of intussusception with the type of diet is intriguing, we cannot be confident that the infants designated in a particular feeding group were exclusively fed breast milk, soy milk, or cow's-milk formula, or had other prior exposure to other feeding types. Previous experience with other feeding types

TABLE 3. Interaction between introduction solid food and breast milk/formula consumption*

Subgroups	Cases/controls	OR	95% CI	*P*
>5 wk before reference date				
Median age: 8.2 mo†				
Breast milk§	22/99	1.00	—	—
Soy milk–based	9/89	0.26	(0.1–0.7)	0.007
Cow's-milk–based	82/378	0.86	(0.5–1.5)	0.577
Other	7/46	0.60	(0.2–1.6)	0.316
<5 wk before reference date				
Median age: 6.5 mo†				
Breast milk§	13/52	1.00	—	—
Soy milk–based	11/28	1.33	(0.5–3.9)	0.605
Cow's-milk–based	39/208	0.75	(0.3–1.7)	0.487
Other	1/7	0.76	(0.08–7.7)	0.818
No introduction				
Median age: 4.8 mo†				
Breast milk§	31/184	1.00	—	—
Soy milk–based	11/78	0.76	(0.4–1.7)	0.494
Cow's-milk–based	158/449	2.33	(1.4–3.9)	0.001
Other	2/32	0.48	(0.1–1.8)	0.271

CI = confidence interval; OR = odds ratio.
* Data were available for 386 cases and 1650 controls. Variables were matched for age and the hospital where the case was born. ORs are adjusted for receipt of Rotashield <21 days before reference date, sex, race/ethnicity, level of education, and insurance status. Interaction statistically significant ($P = 0.003$).
† Median age for controls.
§ Referent category.

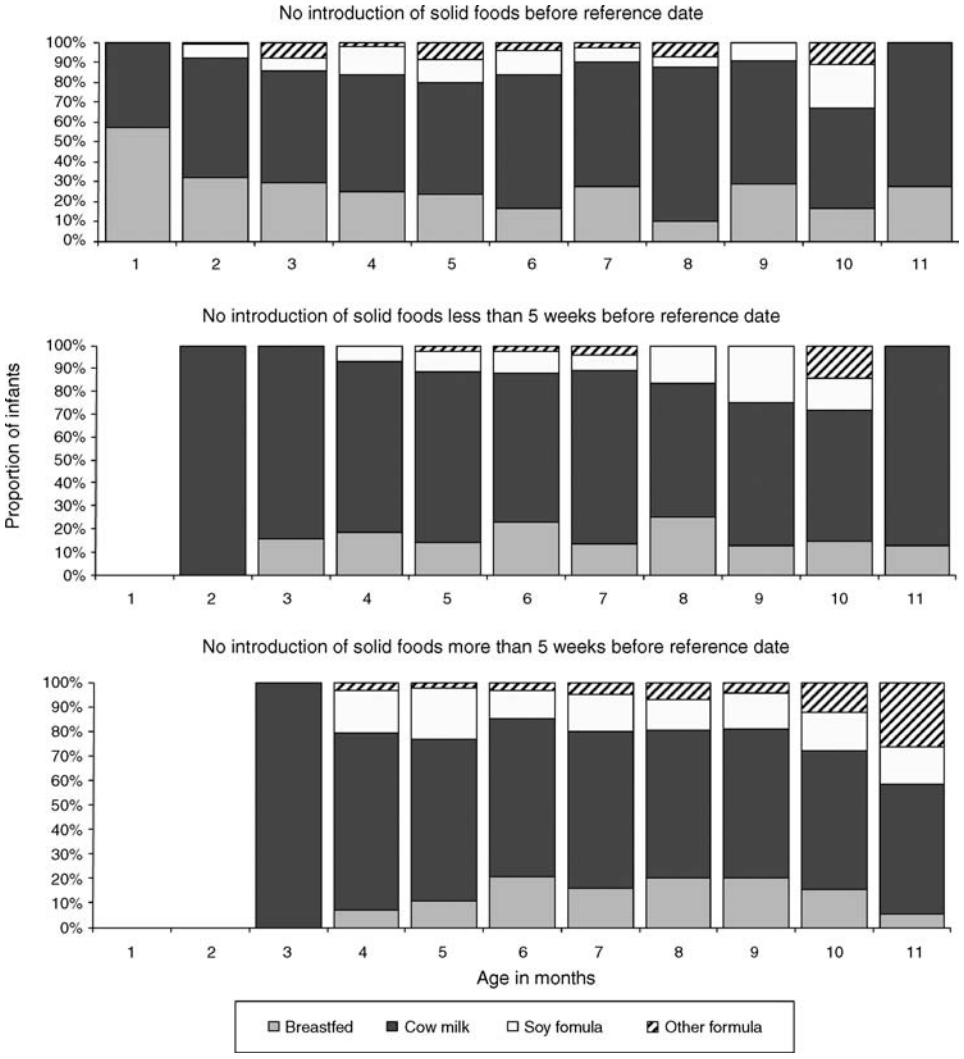

FIGURE 1. Percent of controls consuming breast milk/formula by month of age. Stratified by timing of introduction of solid food before reference date. Infants were included in the study if their age was >1 month and <12 months at the reference date. Reference date for controls defined as the date when their age in days was the same as their matched intussusception case, when the case was hospitalized. Data were available for 1650 controls. No adjustment was made for Rotashield exposure. Introduction of solid food is defined as solid food other than cereal.

could be relevant because infants with cow's-milk allergic enterocolitis can develop similar symptoms after switching to soy formula.

CONCLUSIONS

Our results reinforce previous observations that risk patterns for intussusception in infants are associated with sociodemographic characteristics and dietary practices that cross race and ethnicity, and markers of access to medical care and education. These results provide new avenues for research into the trends in intussusception incidence. The role of diet in the pathogenesis of intussusception is intriguing and additional investigation is warranted.

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