

Is there Increased Risk of Intussusception Post-ROTAVIRUS VACCINATION?

A Multicenter, hospital-based, post-marketing, active surveillance study at 27 hospitals across 10 states in India was conducted between 2016-2019. All infants (age: 28-365 days, n=589) with intussusception (radiologically or surgically confirmed) were included in self-controlled case series analysis. Rotavirus (Rotavac, Bharat Biotech International) vaccination status was ascertained by means of vaccination records.

> The relative incidence (incidence during the risk window vs. all other times) of intussusception within risk windows of 1 to 7 days, 8 to 21 days, and 1 to 21 days after vaccination was evaluated.

> In a subgroup of patients, a matched case-control analysis was performed, with matching for age, sex, and location.

ACADEMIC P.E.A.R.L.S

Pediatric Evidence And Research Learning Snippet



Intussusception after Rotavirus Vaccine Introduction in India

Reddy et al. N Engl J Med 2020 (Nov);383:1932-40. DOI: 10.1056/NEJMoa2002276

Table 1. Relative Incidence of Intussusception in Risk Windows after the First, Second, and Third Doses of Rotavirus Vaccine.*

Dose and Risk Window	No. of Cases	Relative Incidence (95% CI)
Dose 1		
Days 1-7	2	0.83 (0.00-3.00)
Days 8-21	2	0.35 (0.00-1.09)
Days 1-21	4	0.52 (0.08-1.27)
Dose 2		
Days 1-7	4	0.86 (0.20-2.15)
Days 8-21	15	1.23 (0.60-2.10)
Days 1-21	19	1.13 (0.61-1.94)
Dose 3		
Days 1-7	15	1.65 (0.82-2.64)
Days 8-21	22	1.08 (0.69-1.73)
Days 1-21	37	1.24 (0.81-1.82)

Table 2. Matched Odds of Intussusception in Risk Windows after Rotavirus Vaccination in Case-Control Pairs of Indian Infants.*

Dose and Risk Window	No. of Cases	No. of Controls	Matched Odds Ratio (95% CI)
Dose 1			
1-7 days	1	1	1.00 (0.12-78.49)
8-21 days	1	5	0.00 (0.00-1.51)
1-21 days	2	6	0.00 (0.00-1.51)
Dose 2			
1-7 days	1	1	1.00 (0.01-78.49)
8-21 days	3	3	1.00 (0.07-13.79)
1-21 days	4	4	1.00 (0.13-7.46)
Dose 3			
1-7 days	6	3	2.50 (0.41-26.25)
8-21 days	7	7	1.00 (0.26-3.74)
1-21 days	13	10	1.40 (0.49-4.42)

- ✓ Of total 589 included infants, 377 received rotavirus vaccination.
- ✓ There was no increase in incidence of intussusception after first, second or third dose of vaccine in any risk window in self-control or case-control analysis.
- ✓ Similar studies from Western countries showed a low-risk of intussusception while studies from Africa did not show any risk (similar to present study).

Conclusion: In this post-marketing, active surveillance study, it was found that Rotavac, an oral rotavirus vaccine produced in India, was not associated with intussusception in the population studied

EXPERT COMMENT



- Pre-marketing surveillance of new rotavirus vaccines did not show any increase in risk of intussusception and present post-marketing study further provides confidence for safety of rotavirus vaccination.
- High antibodies of maternal milk, co-administration of oral polio vaccine, malnutrition and presence of gut pathogens are possible reasons for no risk of intussusception post-vaccination in developing countries.
- With changing socioeconomics and decrease in oral polio vaccination, risk of intussusception may change in India in future.

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Reference

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