Evaluation of intussusception after oral monovalent rotavirus vaccination in South Africa

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Background and aims

Post-licensure studies have shown an association between rotavirus vaccination and intussusception. We assessed the risk of intussusception associated with Rotarix® (RV1) administration, at six and 14 weeks of age, in an upper-middle income country, South Africa.

Methods

Active prospective surveillance for intussusception was conducted in eight hospitals from September 2013–December 2017. Retrospective case enrolment was done at one hospital from July 2012–August 2013. Demographic characteristics, symptom onset and rotavirus vaccine status were ascertained. Using the self-controlled case-series method, we estimated age-adjusted incidence-rate ratios within 1–7, 8–21, and 1–21 days of rotavirus vaccination in children aged 28–275 days at onset of symptoms. In addition, age-matched controls were enrolled for a subset of cases (n=169), and a secondary analysis performed.

Results

There were 346 cases included in the case-series analysis. Post-dose one, there were zero intussusception cases within 1–7 days, and five cases within 8–21 days of vaccination. Post-dose two, 15 cases occurred within 1–7 days, and 18 cases within 8–21 days of vaccination. There was no increased risk of intussusception 1–7 days after dose one (no cases observed) or dose two (relative incidence (RI): 1·71; 95% confidence interval (CI) 0·83–3·01). Similarly, there was no increased risk 8–21 days after the first (RI: 4·01; 95% CI 0·87–10·56) or second dose (RI: 0·96; 95% CI 0·52–1·60). Results were similar for the case-control analysis.

Conclusions

The risk of intussusception in the 21 days after the first or second dose of RV1 was not higher than the background risk among South Africa infants.