

Effectiveness of Pentavalent Rotavirus Vaccine (RV5) in US Clinical Practice

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Background:

A complete 3-dose series of RV5 prevented 94-96% of severe rotavirus disease in clinical trials, but the effectiveness of complete or partial immunization in clinical practice has not been evaluated. We assessed the effectiveness of RV5 using 3 control groups, including an immunization registry.

Methods:

During February-June 2008, children with acute gastroenteritis (AGE) aged 15 days –23 months were recruited from TCH ER. Fecal specimens were collected and tested for rotavirus using an EIA (Rotaclone®). Immunization data were obtained from the parent record, health care providers, and/or the Houston-Harris County Immunization Registry (HHCIR). Vaccine effectiveness (VE = 1 - odds ratio) was calculated using RV5 immunization rates among rotavirus-positive AGE patients and 3 control groups: rotavirus-negative AGE patients; concurrently enrolled acute respiratory infection (ARI) patients; and age-matched children from HHCIR.

Results:

Of 205 AGE patients with a fecal specimen, 90 (44%) tested positive for rotavirus. The median age of rotavirus-positive AGE patients (76 weeks) was greater than rotavirus-negative AGE (46 weeks, $p < 0.001$) and ARI patients (37 weeks, $p < 0.001$), but the groups were otherwise similar. Age adjusted VE for a 3-dose RV5 series was 85-89%; partial immunization had a lower but substantial VE. Immunization data for 44% of rotavirus cases were available from HHCIR; the estimated 3-dose VE was similar (82% [19%, 96%]).

Table 1. Effectiveness of RV5 by dose and type of control

	Rotavirus Positive Cases		ARI Controls	Rotavirus Negative Controls	
Number of Doses ^a	n=79	n=206	VE (95% CI)	n=108	VE (1 – Odds Ratio) (95% CI)
0 doses	67 (85%)	91 (44%)	1.0 Ref	47 (44%)	1.0 Ref
1 dose	5 (6%)	43 (21%)	65% (<0%, 89%)	16 (15%)	65% (<0%, 89%)
2 doses	2 (3%)	28 (14%)	72% (<0%, 94%)	13 (12%)	82% (15%, 96%)
3 doses	5 (6%)	44 (21%)	85% (55%, 95%)	32 (30%)	89% (70%, 96%)

^a Using the most current vaccination data from parent, provider or immunization registry

Conclusions:

In this first post-licensure evaluation in US children, RV5 was highly effective at preventing rotavirus disease. Immunization registries are a valuable source of data for VE evaluations.