

ABSTRACT

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Title: Evaluation of the Protective Association of the Rotavirus Vaccine in Bogota, Colombia

Key words: Rotavirus Vaccine, Evaluation, Effectiveness, Latin America.

Participating Institutions: Charité – Universitätsmedizin Berlin Involved and Universidad Nacional de Colombia. Supervisor: Dr. Natasha Howard, London School of Hygiene & Tropical Medicine.

General Objective: To analyze the association between exposure with Rotarix and outcome of diarrhea, and AGE hospitalization in Bogota, Colombia, based on the data collected for Bogota in the 2010 GREESP nationwide study.

Specific Objectives: To attempt to recreate in Bogota the protective association found for rotavirus vaccination against 1) all-cause diarrhea and 2) AGE hospitalizations, as observed within the nationwide population survey.

Methods: The present study was a sub-study nationwide GREESP group, and used the same data collection and analysis methods. Briefly a cross-sectional survey given in five chosen districts in Bogota, Colombia to 1822 children aged between 2 and 24 months old collected information about the children's rotavirus vaccination status, diarrhea and AGE hospitalization history, as well as basic socio-economic and demographic information. Data obtained was analyzed using Epi Info Version 3.5.3. Crude, stratified and multivariate logistic regression models were developed to analyze the associations between rotavirus vaccination exposure and any-diarrhea episode or AGE hospitalization, to determine the protective association of the vaccine against

the given clinical outcomes. Associations were adjusted for possible confounders and potential effect modifiers were identified.

Findings: Rotarix vaccination coverage in Bogota amounted to 96.3% (among 1270 children holding vaccination cards). *1-dose of Rotarix* was associated with 38% lower odds of diarrhea (OR= 0.62; CI 95% 0,43 - 0,88), and *any-dose vaccination* with 63% lower odds of AGE hospitalization (OR= 0.37; CI 95% 0,14 - 0,99). 2-doses of Rotarix were associated with 21% lower odds of diarrhea (OR= 0.79; CI 95% 0.35-1.81) and 15% lower odds of AGE hospitalization (OR= 0.85; CI 95% 0.57-1.26) compared to unvaccinated children.

Discussion and Conclusion: This investigation could not replicate the vaccine's protective associations in Bogota, as observed by the GREESP group. Although protective associations were obtained for most of the studied relationships, significant results were only found for *1-dose of Rotarix* and diarrhea, and *any-dose vaccination and AGE hospitalization*. Factors that could explain the differences in the findings obtained included the study's inherited limitations, and Bogota's special characteristics affecting the association between vaccination and clinical outcomes. Factors affecting the validity of the results included information and selection bias, a low study power, lack of vaccination card as an inclusion criterion, software limitations, and genetic variability of the virus in Bogota. Specific variables modifying the effect of the vaccine in Bogota were also identified. Even though Rotarix showed protective associations for any-diarrhea episodes and AGE hospitalization, the key message of this investigation is that the protective association of Rotarix is closely dependant and affected by the population's characteristics receiving the vaccine.