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A multicenter prospective hospital-based surveillance to estimate the burden of rotavirus gastroenteritis in children less than five years of age in India

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ABSTRACT

Background: Rotavirus is the leading cause of severe, dehydrating diarrhea in children aged <5 years globally, with an estimated 25 million outpatient visits and 2 million hospitalizations attributable to rotavirus infections each year. The aim of this hospital-based surveillance was to summarize the local epidemiological and virological features of rotavirus and to estimate the disease burden in the population under surveillance in India.

Methods: During the 16 months surveillance period from April 2011 through July 2012, a total of 4711 children under the age of 5 years were admitted with acute diarrhea at 12 medical centers attached to medical schools throughout India. Stool samples were randomly collected from 2051 (43.5%) subjects and were analyzed for rotavirus positivity using commercial enzyme immunoassay kit (Premier Rotaclone Qualitative Elisa) at the respective study centers. Rotavirus positive samples were genotyped for VP7 and VP4 by reverse-transcription polymerase chain reaction (RT-PCR) at a central laboratory.

Results: During the study period, maximum number of rotavirus related hospitalizations were reported from December 2011 through February 2012. Out of the 2051 stool samples tested for rotavirus, overall 541 (26.4%) samples were positive for rotavirus VP6 antigen in stool. The highest positivity was observed in the month of December, 2011 (52.5%) and lowest in the month of May, 2011 (10.3%). We found that majority of the rotavirus positive cases (69.7%) were in children <24 months of age. The most common genotypes reported were G1 (38%), G2 (18%), G9 (18%), G12 (9%) and mixed strains (17%).

Conclusions: The results of this study confirm the significant burden of acute rotavirus gastroenteritis as a cause of hospitalizations in under five children in India.

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1. Introduction

Rotavirus infection, mostly caused by Group A viruses, is prevalent in human populations worldwide. Although the virus infects older individuals, the disease can be severe in immunologically naïve infants and young children. The burden of severe rotavirus illness and deaths falls heavily upon children in low and middle-income countries: more than 80% of rotavirus-related deaths are estimated to occur in lower income countries of Asia and sub-Saharan Africa [1].

India has an especially large population at risk of clinically significant rotavirus gastroenteritis (GE); of the 1.2 billion people, 11% are <5 years old. Worldwide in 2008, diarrhea attributable to rotavirus infection resulted in 453,000 deaths (95% CI 420,000–494,000) in children younger than 5 years representing 37% of deaths attributable to diarrhea and 5% of all deaths in children younger than 5 years. Five countries accounted for more than half of all deaths attributable to rotavirus infection: Democratic Republic of the Congo, Ethiopia, India, Nigeria, and Pakistan with India alone accounting for 22% of deaths (98,621 deaths) [2].

Typical clinical signs of infection include fever, projectile vomiting, and profuse watery diarrhea, which may significantly dehydrate the infected child. Moderate to severe dehydration in young children is more often associated with rotavirus infection than other enteropathogens. There are no specific medications for rotavirus GE, but rehydration with oral rehydration salts (ORS) has long been a standard therapy for acute infantile diarrhea. Severe dehydration can be life threatening and requires treatment in a clinic or hospital where the child can receive intravenous (IV) fluids and appropriate case management.

The purpose of this observational study was to carry out a hospital-based surveillance of rotavirus gastroenteritis in children ≤59 months of age and develop estimates of disease burden in the population under surveillance.

2. Methods

2.1. Study centers and duration

A prospective hospital-based surveillance was conducted at 12 medical centers attached to Medical Schools across India. From North India subjects were enrolled from Dayanand Medical College & Hospital, Ludhiana; Chhatrapati Shahuji Maharaj Medical University, Lucknow; Kalawati Saran Children Hospital, New Delhi; Post Graduate Institute of Medical Education and Research, Chandigarh and Sawai Man Singh Medical College, Jaipur. From South India, Gandhi Medical College, Hyderabad; JSS Medical College, Mysore; Kempegowda Institute of Medical Sciences, Bangalore and Kasturba Medical College & Hospital, Manipal were involved. From Western India, Goa Medical College, Goa recruited subjects. From Eastern part of India subjects were enrolled from Institute of Child Health, Kolkata and Kalinga Institute of Medical Sciences, Bhubaneswar (Fig. 1).

The 16 months surveillance study was conducted from April 2011 through July 2012.

2.2. Inclusion criteria

Children ≤59 months of age presenting with severe acute gastroenteritis (defined by the passage of ≥3 looser than normal stools with or without vomiting during the preceding 24 h period) and requiring hospitalization for at least 6 h were eligible for this study. An approved informed consent statement for obtaining stool samples was then read and signed by the parents/legally acceptable representatives of the subject, investigator and, when required, a witness. Upon obtaining consent, subjects were included in the study and their stool sample was obtained. Children older than 60 months, and those younger than 60 months but not requiring hospitalization for at least 6 h or whose parents did not consent for stool sampling were not included in the study.

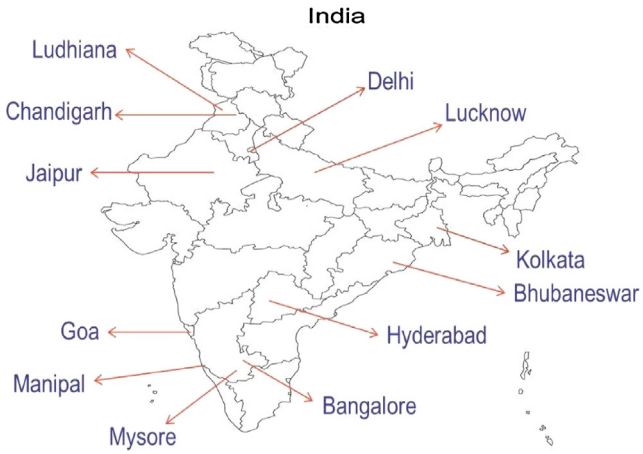

Fig. 1. Study centers across India.

2.3. Clinical assessment

Various parameters considered for clinical assessment of diarrheal severity were: time of onset, duration and maximum number of episodes of diarrhea and vomiting, intensity of fever and dehydration. These parameters were recorded in a Case Report Form. Severity of diarrhea was assessed using the Vesikari scoring system. As per the Vesikari Score Grading, a grade of 0–5 was considered as mild, 6–10 as moderate, 11–15 as severe and more than and equal to 16 as very severe [3].

2.4. Stool specimen collection

Approximately 5 ml of stool sample was collected in stool containers from the consenting subjects either on the day of presentation to hospital or within 48 h of hospital admission so as to avoid observing hospital-acquired infections. All the stool specimens were stored in a freezer at −20 °C until testing and sufficient care was taken to avoid freeze–thaw cycles.

2.5. Detection of rotavirus

All the collected stools samples were tested for rotavirus VP6 antigen using a commercial enzyme immunoassay kit (Premier Rota clone Qualitative EIA, Meridian Bioscience Inc., Cincinnati, USA) at the respective study centers, in duplicates and with appropriate controls. All the rotavirus VP6 antigen positive stool samples were sent for genotyping from the study centers to the Central Laboratory at Department of Gastrointestinal Sciences, Christian Medical College, Vellore under required controlled conditions.

2.6. Strain surveillance and characterization

Genotyping of all rotavirus positive stool samples was conducted at the Central Laboratory in Vellore. Genotyping was performed by using Reverse-Transcription Polymerase Chain Reaction (RT-PCR). Rotaviruses were classified into G- and P-types based on the variability in the genes encoding the two outer capsid proteins, VP7 and VP4, respectively. Viral RNA was extracted from stool specimens and reverse transcribed using random primers to

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