Rotavirus Diarrhea and its Determinants Among Under-Five Children Admitted in a Tertiary Care Hospital of Southern Haryana, India

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Abstract

Objective To estimate the prevalence of rotavirus diarrhea and its demographic, social, and clinical characteristics among children less than five years of age admitted in a rural tertiary care institute.

Methods This prospective hospital-based observational study was carried out during February 2016 to June 2019. Diarrheal admissions of children aged 0–59 mo were screened and those who met the inclusion criteria were included in the study. Sociodemographic and clinical information was collected using a case report form. Stool samples were collected within 48 h of admission and transported in cold chain every month to the referral laboratory situated at Christian Medical College for testing.

Results Among the children admitted with acute diarrhea, 148 (11.02%) were positive for rotavirus in the study. As per Vesikari scoring system, around three fourth (76.2%) of children were having severe or very severe diarrhea. Severity of diarrhea was more among rotavirus positive cases as assessed by the Vesikari scoring system. The rotavirus diarrhea showed a peak during November to February.

Conclusion Rotavirus diarrhea is an issue of public health importance, particularly due to its association with the severe diarrhea. As evidenced from similar settings in the world, rotavirus vaccine introduction and increased coverage is the most important strategy towards prevention and control of rotavirus diarrhea.

Keywords Acute gastroenteritis, Vesikari score, Enzyme-linked immunosorbent assay (ELISA), Rotavirus infections

Introduction

Diarrhea is one of the leading causes of death among under-five children and responsible for 9% of global under-five mortality [1]. Rotavirus infection is responsible for around two fifth (39%) of the mortality due to diarrhea and a large proportion of these deaths occur in developing countries [2]. India alone contributes for 22% of the worldwide rotavirus deaths [3]. Rotavirus infection caused 21357.6 (13150.8–

33967.0) deaths among under-five children in Indian settings as noticed in the Global Burden of Disease study [4]. In India, rotaviral diarrhea contributes nearly 24% of cases among children under-two years of age and 13% of episodes among children aged 2–5 y [5]. Every year 11.4 million cases of rotavirus diarrhea occur in India which in turn lead to 872,000 hospitalizations among under five children [6].

The Indian National Rotavirus Surveillance Network has reported the rotavirus positivity among under five children who are hospitalized due to diarrhea to be about 40% [7]. Rotavirus was also found to be responsible for substantial disease magnitude in children < 5 y of age in Kolkata, where a study reported the positivity among outpatients to be about 48% [8, 9]. The study institute is a recently established and sole tertiary care institute situated in district Nuh (earlier Mewat) of Haryana state and no hospital or community-based study pertaining to rotavirus diarrhoea was conducted in this area. The current study aims to report the prevalence of rotavirus diarrhea and its demographic, social, and clinical correlates among children less than five years of age admitted in this rural tertiary care institute of southern Haryana, India.

Material and Methods

The present prospective observational study was carried out in hospital setting as part of a multicenter study to estimate the effectiveness and impact assessment of a newly introduced rotavirus vaccine among children less than five years of age hospitalized with acute gastroenteritis (AGE) in SHKM Government Medical College & Hospital, Nuh, Haryana, between February 2016 to June 2019 [10]. The institutional ethics committee approval was obtained before commencing the study.

An under-five child admitted in the study facility due to acute gastroenteritis as a primary complaint was eligible for enrolment into the study. If the child had any chronic medical condition explaining the onset of diarrheal illness, he/she was not considered for enrolment [11]. The Vesikari scoring system was used to ascertain the severity of diarrhea [12]. Diarrheal episode was labelled mild if the score was ≤ 5 ,

moderate for 6 to 10 score, severe if the score was between 11 and 15, and very severe if the score was $\geq$ 16.

The inclusion criteria determining the eligibility for enrolment into the surveillance constituted the age criterion (< 5 y), collection of sample within 48 h of admission in the study facility and treatment of the child with intravenous or oral fluid either in casualty department for a minimum of 6 h or after admission to the study facility.

The exclusion criteria for the study were unwillingness of the parent/caregiver or guardian to give informed written consent and if the child was admitted in the study facility following referral from another facility and was treated in the other facility for more than 24 h.

The hospital wards were visited by the study staff on a daily basis to screen the cases of under five children hospitalized with acute gastroenteritis which were recorded in a logbook. If a child fulfilled the eligibility and inclusion criteria, a written informed consent was sought from the parent/caregiver before enrolling the child in the surveillance. Sociodemographic and clinical data were collected using a case report form. Screw-top containers were used to collect a stool sample from the child within 48 h of enrollment. Stool samples were labelled with unique identity number and stored at -20°C .

Stool samples were transported in cold chain every month to the referral laboratory situated at Christian Medical College (CMC), Vellore along with the case report forms for necessary testing and data entry. Any issues pertaining to quantity or quality were recorded at referral laboratory immediately after receiving stool samples. Completeness of the monthly case report forms was checked by referral laboratory before data entry and in case of any errors or missing fields found, clarification and responses were sought from study staff using data clarification forms. The stool samples were tested for rotavirus antigen at the referral laboratory using commercially available enzyme-linked immunosorbent assay (ELISA) kits and genotyped using methods described in published literature [13–15]. The results of testing were reported back to the study site periodically.

Data so collected were entered in Microsoft Excel worksheet and to describe the study participants, analyses of sociodemographic, clinical, and treatment variables were performed using descriptive statistics. Tests were performed assuming significance level of 5%, thus an association was considered significant if the 'p' value is less than 0.05. Variables were depicted as percentage (%) and analyzed using odds ratio statistic.

Results

Over a 3-year period, 1442 children were admitted to the hospital due to acute gastroenteritis, out of which 1359 children who met the inclusion criteria were enrolled in the surveillance. The testing of stool samples for rotavirus was done for 1343 (98.8%) patients. The mean age (SD) of the study participants was 11.1 (9.68) mo, and subjects aged less than or equal to 2 y accounted for 92.8% of all enrolled children (Table 1).

Proportion of males was higher than females among enrolled children. Study area being the most backward district of Haryana, most of the mothers of admitted children were illiterate (85.9%) [16]. Around half of the households were using borewell/open well/covered well as a source of drinking water followed by tap to house (26.6%) and community tap (21.9%). About one-fifth of children were admitted in winter season (20.6%) i.e., November to February (Table 1).

Around 73.5% children were having mild to moderate dehydration while 11.3% participants had severe dehydration. One third of the children (33.3%) received oral rehydration salt (ORS) before admission. About three-fifth children (60.4%) had fever along with diarrhoea at the time of admission. Most of (96.5%) the children required intravenous (IV) fluids. Out of 1343 children with acute diarrhea, 148 (11%) were positive for rotavirus in the study. As per Vesikari scoring system, around three-fourth (76.2%) children were having severe or very severe diarrhea. Thirty-four (2.5%) children died during the course of treatment (Table 1).

Table 2 compares sociodemographic and clinical correlates of under five children with diarrhea based on rotavirus positivity. Rotavirus diarrhea rate did not vary significantly by age, sex, mothers' literacy and source of drinking water. Rotavirus positivity rate was significantly higher during winter months (P value < 0.001). Rotavirus diarrhea children were more likely to have higher frequency of stool ($P < 0.01$) and vomiting ($P < 0.05$) during a 24-h period. Rotavirus positive cases were having more severe diarrhea episodes as compared to children with other cause diarrhea ($P < 0.05$). Proportion of children vaccinated with all three doses of rotavirus vaccine was significantly higher among children who had other cause diarrhea as compared to rotavirus diarrhea (P value < 0.05). Duration of hospital stay, and outcome did not differ significantly among rotavirus-positive and rotavirus-negative group.

Discussion

The present study was undertaken in the lone tertiary care institute situated in a rural area of district, Nuh. The district Nuh has been declared as the most backward district of Haryana state and also listed in 108 most backward districts of India identified by National Institute for Transformation of India (NITI) Aayog. Its backwardness is mainly attributed to poor health indicators and low level of literacy [16]. National Family Health Survey-4 conducted during 2015–16 reported that only 13.1 % children aged 12–23 mo are fully immunized in district Nuh [17].

Several studies have reported rotavirus to be the leading cause of severe diarrhea among under-five children in India with the prevalence ranging from 30%–50% [18–20]. While the current study reported a positivity of 11%, previous studies from the National Rotavirus Surveillance Network have noticed the prevalence of rotavirus infection among children less than 59 mo of age to be about 39% and another paper by Bahl et al. detected 23.5% prevalence [18, 21]. Rotavirus positivity of approximately 20% was reported in a review of 46 epidemiological studies among under-five children seeking inpatient care for acute gastroenteritis [20]. The low rotavirus positivity rate reported by the present study as compared to previous studies might be due to the fact that majority of the present study enrollment occurred after

introduction of vaccine in immunization programme of our state Haryana on 11th April 2016, so protective effect of vaccine might have led to less rotavirus positivity among children admitted with diarrhea in our hospital [10, 22]. A performance feedback report pertaining to Rotavirus Sentinel Surveillance by World Health Organization has reported a decline of rotavirus diarrhea from 40% in 2014 to 25% in 2015 among countries in east and southern Africa after introduction of rotavirus vaccine from the year 2014 [23, 24].

The results depict that children under two years of age are at increased risk of rotavirus diarrhea which corroborate with findings of published studies which report high risk of rotavirus diarrhea in infants [25–27]. According to the scientific working group of World Health Organization, rotavirus infections show a peak incidence at 9 to 12 mo and majority of cases occur in children between 6 to 24 mo [28].

The present study has showed a peak in rotavirus diarrhea in November to February which is quite similar to reports of other studies conducted in north India [13, 21, 29]. This result differs from a study which reported no seasonal variation in south India and different months of March and April in north India [14]. Rotavirus diarrhea was also significantly associated with fever and vomiting which is similar to clinical presentation highlighted in a review [30].

The Vesikari scoring system was used to assess severity of gastroenteritis in the present study. Proportions of very severe and severe diarrhea episodes were significantly higher among rotavirus-positive children compared to rotavirus negative subjects. These observations corroborate with findings of Delhi based study and other studies [18, 31, 32].

The authors could not find any association of rotavirus positivity with dehydration and duration of stay in hospital while other studies reported higher proportion of severity among children infected with rotavirus [33, 34]. The findings of the present study may differ from those of earlier studies, because firstly, the authors evaluated only inpatient children, whereas many earlier studies also assessed outpatients and secondly, most of the published studies were conducted before availability of rotavirus vaccine free-of-

cost under national immunization programme. The present study had some limitations. Since the study was conducted in a hospital setting hence the results are not likely to be representative of the true disease magnitude in the community. Also, other etiological agent causing diarrhea were not explored in the current study.

Conclusion

The present study concludes that a rotavirus positivity of 11.02% among hospitalized children with diarrhea even after rolling out of vaccine in the National Immunization Programme, is an issue of public health importance, particularly due to its association with the severe diarrhea. Thus, improvement in three doses rotavirus vaccine coverage is the most important strategy towards prevention and control of rotavirus diarrhea. Simultaneously health education of the family members and community at large regarding good hygiene and sanitation can play an important role in declining the rotavirus infection.

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Authors' Contributions AKG and SC conceptualized and designed the study; SC and AKG collected the data and drafted the paper; AD and AKG supervised the laboratory work and provided critical inputs; VT and NPN cleaned and analyzed the data. All authors approved the final manuscript. SC will act as guarantor for this paper.

Ethical Clearance The study was approved by the institutional ethics committee of SHKM Government Medical College, Nalhar, Haryana.

Conflict of Interest None.

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Table 1 Sociodemographic and clinical profile of children under five years admitted with acute gastroenteritis (n=1359)

Variable	Number of children (n=1359)	Percent (%)
Age category		
<= 2 y	1261	92.8
> 2 y	98	7.2
Gender		
Male	846	62.3
Female	513	37.7
Mother's education		
Illiterate	1168	85.95
Primary	150	11.04
Secondary	32	2.35
Higher secondary and above	9	0.66
Source of drinking water		
Bore well/covered well/open well	699	51.4
Community tap	298	21.9
Tap to house	361	26.6
Not specified	01	0.1
Season		
Winter season (Nov–Feb)	280	20.6
Other seasons (Mar–Oct)	1079	79.4
ORS status before admission		
Received ORS before admission	453	33.3
Not received ORS before admission	905	66.6
Do not know	1	0.1
Fever		
Yes	821	60.4
No	538	39.6
Dehydration status		
No dehydration	202	14.9

Some dehydration	999	73.5
Severe dehydration	153	11.2
Shock	5	0.4
ORT status		
Received ORT during hospital stay	1310	96.4
Not received ORT during hospital stay	49	3.6
IV fluids status		
Received IV fluids during hospital stay	1311	96.5
Not received IV fluids during hospital stay	48	3.5
Vesikari score		
Mild	61	4.49
Moderate	263	19.35
Severe	774	56.95
Very severe	261	19.21
Duration of hospital stay		
< 3 d	479	35.2
>= 3 d	880	64.8
Rotavirus status		
Rotavirus positive	148	11.02
Rotavirus negative	1195	88.98
Outcome		
Recovered	1202	88.5
Died	34	2.5
Referred	25	1.8
Left against medical advice	98	7.2

Table 2 Association of sociodemographic and clinical variables with rotavirus positivity among under five children admitted with acute gastroenteritis

Variable	Rotavirus negative (n=1195)	Rotavirus positive (n=148)	OR (95% C. I.)	P value
Age category				
<= 2 y	1107 (88.92%)	138 (11.08%)	Ref	
> 2 y	88 (89.80%)	10 (10.20%)	0.91 (0.46–1.79)	0.789
Gender				
Male	745 (89.01%)	92 (10.99%)	Ref	
Female	450 (88.93%)	56 (11.07%)	1.01 (0.71–1.43)	0.966
Mother's education				
Mother illiterate	1030 (89.18%)	125 (10.82%)	Ref	
Mother educated	165 (87.77%)	23 (12.23%)	1.15 (0.71–1.84)	0.567
Source of drinking water				
Bore well/covered well/open well	624 (90.17%)	68 (9.83%)	0.78 (0.55–1.09)	
Community tap/house tap	571 (87.71%)	80 (12.29%)	Ref	0.151
Season				
Winter season (Nov-Feb)	198 (72.26%)	76 (27.74%)	5.31 (3.72–7.59)	
Other seasons	997 (93.26%)	72 (6.74%)	Ref	< 0.001*
Fever				
Yes	711 (87.67%)	100 (12.33%)	1.42 (0.99–2.04)	
No	484 (90.98%)	48 (9.02%)	Ref	0.059
Dehydration status				
Dehydrated	1008 (88.34%)	133 (11.66%)	1.64 (0.94–2.87)	
No dehydration	187 (92.57%)	15 (7.43%)	Ref	0.079
Hospital stay				
< 3 d	406 (86.75%)	62 (13.25%)	Ref	
>= 3 d	789 (90.17%)	86 (9.83%)	0.71 (0.50–1.01)	0.057
Maximum episode of stool/day				
<= 4	262 (93.57%)	18 (6.43%)	Ref	
> 4	933 (87.77%)	130 (12.23%)	2.03 (1.21–3.38)	0.007*
Maximum episode of vomiting/day				
<= 4 or no vomiting	889 (90.07%)	98 (9.93%)	Ref	
> 4	306 (85.96%)	50 (14.04%)	1.48 (1.03–2.13)	0.034*

Vesikari score				
Mild and moderate	299 (92.57%)	24 (7.43%)	Ref	
Severe and very severe	896 (87.84%)	124 (12.16%)	1.72 (1.09–2.72)	0.019*
Rotavirus vaccine				
Vaccinated received: Only 1 dose [#]	276 (88.75%)	35 (11.25%)	0.92 (0.60–1.40)	0.692
Vaccinated received: Only 2 doses [#]	136 (87.74%)	19 (12.26%)	1.01 (0.59–1.72)	0.965
Vaccinated- received: All three doses	189 (94.03%)	12 (5.97%)	0.46 (0.24–0.86)	0.015*
Not vaccinated	594 (87.87%)	82 (12.13%)	Ref	
Outcome				
Recovered	1057 (88.53%)	137 (11.47%)	Ref	
Died	25 (92.59%)	2 (7.41%)	0.62 (0.14–2.63)	0.515
Others [#] (Referred/Left against medical advice)	113 (92.82%)	9 (7.38%)	0.61 (0.30–1.24)	0.174

*Statistically significant