Prevalence and clinical profile of rotavirus associated diarrhea in a tertiary care center in North India: A descriptive hospital-based study

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ABSTRACT

Background: Rotavirus is the leading cause of severe diarrhea in infancy and childhood period especially in developing countries causing several deaths. **Objective:** This study was conducted to determine hospital-based prevalence, clinical profile, demographic data, and treatment outcome of rotavirus diarrhea in children under 5 years of age attending a tertiary care hospital in North India. **Materials and Methods:** A total of 210 patients, under 5 years of age, presenting with a complaint of watery diarrhea were enrolled in the study. Their stool samples were analyzed by latex agglutination test for rotavirus antigen. Significant values of variables were determined using t-tests and Chi-square tests as appropriate. **Results:** Out of 210 patients, 108 (51.4%) were tested positive for rotavirus. While 170 (80.9%) patients with gastroenteritis were hospitalized, 92 (54.1%) of the hospitalized patients had rotavirus gastroenteritis (RVGE). RVGE was maximum in the season of December (100%), January (92.8%), and February (93.7%). None of the exclusive breastfed patients were tested positive for rotavirus. 75% of the patients with RVGE were top fed and 25% were on mixed feeding. In this study, 79.5% of the patients who were malnourished had RVGE. 54.6% of the patients with RVGE had some dehydration while 35.2% had severe dehydration. The average duration of gastroenteritis (±standard deviation [SD]) in patients with RVGE was 4.30 (±0.91) days. **Conclusion:** The result of the current study reflects that rotavirus is an important cause of severe diarrhea in infants and young children and hence emphasizes the need for the introduction of rotavirus vaccine in the existing national immunization schedule.

Key words: *Latex agglutination test, Rotavirus gastroenteritis, Rotavirus*

Rotavirus is an important causative agent of acute diarrhea in infants and young children worldwide [1]. Among the leading causes of death, diarrhea is the second most common cause of child death [2]. Approximately 40% of hospitalizations in cases of acute diarrhea in under 5 year children are caused by rotavirus and every year nearly half a million children die due to rotavirus infections [3]. According to Global Enteric Multicenter Study, the four most common pathogens responsible for moderate-to-severe diarrhea among children in sub-Saharan Africa and South Asia were rotavirus, *Cryptosporidium*, enterotoxigenic *Escherichia coli*, and *Shigella* [4].

In developing countries of Asia, Africa, and Latin America where hygiene and sanitary measures are suboptimal, and access to health-care facilities are meager, mortality rate due to rotavirus-associated diarrhea is high [5]. Rotavirus diarrhea accounts for 2,000,000 outpatient visits, 457,000–884,000 hospitalizations, and 122,000–153,000 deaths in under-5 children in India, annually. There is a huge economic impact of rotavirus diarrhea. It is estimated that India spends Rs 2.0–3.4 billion (US$ 41–72 million) annually in medical costs to treat rotavirus diarrhea [6]. Besides improvement in hygiene and sanitation, vaccination plays an important role to decrease the incidence of severe rotavirus-associated diarrhea requiring admission in the hospital, thereby decreasing the disease burden. Two live-attenuated rotavirus vaccines (Rotarix® and RotaTeq®) have demonstrated very good safety and efficacy profiles in large clinical trials in the Western industrialized countries and Latin America [7-12]. In 2009, the World Health Organization recommended that rotavirus vaccine be included in all national immunization programme [6].

The objectives of this study were to study the clinical profile and demographic data of rotavirus-associated diarrhea, among children visiting a tertiary care center and to provide background knowledge on the disease before the introduction of the vaccine in that area.

MATERIALS AND METHODS

The current observational study was performed at a tertiary care hospital in Northern India. After getting the Ethical Committee approval and informed consent from the parents, all the children <5 years of age with acute diarrhea were included in the study. A total of 7500 patients with acute diarrhea attended the

pediatrics department through outpatient department as well as through emergency during the study period of 1 year, out of which 5300 patients were in the age group of under 5 years (5300/7500, i.e., 71%). Out of these 5300 patients, 4100 satisfied the inclusion criteria. Due to limitations in the availability of the Latex agglutination test (LAT) kit, only 210 patients who satisfied the inclusion criteria, could be recruited in the study on the basis of systematic random sampling.

Acute diarrhea was defined as the passage of three or more watery or loose stools per day for at least 3 days. Children with dysentery, congenital malformations (cleft lip, cleft palate, etc.) or documented significant background diseases such as immunodeficiency syndrome or taking immunosuppressant drugs and those who had received rotavirus vaccine were excluded from the study. The patients were subjected to detailed history including demographic details and clinical examination including nutritional assessment. Nutrition was assessed by weight for age, height for age, and wasting (weight for height irrespective of age) [13].

Follow-up of the indoor patients was made until their discharge and follow-up of outdoor patients was made telephonically. A single fresh stool sample was obtained in a sterile container at the time of the first contact and subsequently stored frozen at −20°C until transferred (every fortnightly) to the Microbiology Laboratory at Sher-e-Kashmir University of Agricultural Sciences and Technology. The samples were transported in a cold chain box to maintain the requisite ambient temperature. The samples were analyzed using LAT which was performed using HiRotavirus Latex Test kit (HiMedia, Mumbai) as per the manufacturer's instructions. This is a rapid card test in which latex particles are coated with antibodies specific for rotavirus antigens present in a fecal supernatant. This test is read with the naked eye for 5 min. LAT is a simple, sensitive, and rapid test, and it is the laboratory test of choice in screening stool specimens of rotavirus suspected diarrhea patients. The sensitivity, specificity, and accuracy of LA are 69%, 100%, and 93%, respectively [14].

Numerical variables were reported in terms of mean and SD. Categorical variables were reported in terms of numbers and percentages. Association of each of the categorical variable with response variable was assessed by Chi-square test, and the strength of their association was computed by unadjusted odds ratio. All the data were analyzed using computer software Microsoft Excel and SPSS ver. 12.0 for Windows.

RESULTS

Out of 210 patients who were subjected to LAT, 108 (51.4%) were tested positive for rotavirus gastroenteritis (RVGE) and 102 (48.6%) were tested negative for RVGE. Out of 210 patients, 170 (80.9%) were hospitalized and 40 (19.1%) were managed on an outdoor basis. Among the admitted patients, 54.1% (92) had RVGE as against 40% (16) of those managed on an outdoor basis. The mean age of the studied patients was 20.73±14.15 months. The frequency of RVGE was highest in the age group of 2–3 years, constituting 86.4% (32/37) of the total patients in this age group (Chi-square value=3.40, p=0.06), (Table 1).

Overall, a male predominance was observed in both the RVGE and Non RVGE (NRVGE) group. The male to female ratio in RVGE group was 1.34. Although male children seem to suffer more from diarrhea, the difference was statistically insignificant. Rotavirus-associated diarrhea was detected in 48.9% of the patients belonging to rural areas and 53.1% of the patients belonging to urban areas. The incidence of RVGE was maximum during winters, i.e., December (100%) followed by January (92.8%) and February (93.7%) (Table 2).

In the current study, 52.5% of the patients with piped water supply had RVGE while the figure for well water and natural sources were 47.8% and 33.3%, respectively. Out of 210 admitted patients, 85.7% (180) patients with gastroenteritis had access to the sanitary lavatory as compared to 14.3% (30) patients with no access to sanitary lavatory. 50% (15) of the patients who did not have any access to sanitary lavatory had RVGE. The differences were statistically insignificant.

None of the exclusive breastfed patients had RVGE. Total 75% of the patients with RVGE were top fed and 25% were on mixed feeding. Total 59% of the patients with inadequate complementary feeding had RVGE. In this study, 34.8% of the patients with normal nutritional status had RVGE, whereas 79.5%

Table 1: Age-wise distribution of the patients (n=210)

Age (in years)	RVGE	NRVGE	Total
	No. (%)	No. (%)	
0–1	36 (43.9)	46 (56.1)	82
1–2	28 (45.2)	34 (54.8)	62
2–3	32 (86.4)	5 (13.6)	37
3–4	7 (10.9)	16 (89.1)	23
4–5	5 (83.3)	1 (16.7)	6
Total	108 (51.4)	102 (48.6)	210

Chi-square value, 3.50; p=0.06 (Non-significant), NRVGE: Non RVGE, RVGE: Rotavirus gastroenteritis

Table 2: Distribution of patients according to the month of admission

Month	RVGE	NRVGE	Total
	No. (%)	No.(%)	No. (%)
January	26 (92.8)	2 (7.2)	28 (13.3)
February	15 (93.7)	1 (6.3	16 (7.6)
March	4 (40.0)	6 (60.0)	10 (4.7)
April	2 (20)	8 (80)	10 (4.7)
May	2 (33.3)	4 (66.7)	6 (2.8)
June	2 (5.2)	36 (94.8)	38 (18.1)
July	2 (6.3)	30 (93.7)	32 (15.2)
August	16 (76.1)	5 (23.9)	21 (10.0)
September	12 (75.0)	4 (25.0)	16 (7.6)
October	2 (28.6)	5 (71.4)	7 (3.3)
November	1 (20.0)	4 (80.0)	5 (2.3)
December	24 (100.0)	0 (0)	24 (11.4)
Total	108 (51.4)	102 (48.6)	210 (100.0)

NRVGE: Non RVGE, RVGE: Rotavirus gastroenteritis

of the patients who were malnourished had RVGE (Chi-square value for linear trend=26.28, p<0.0001). There was a statistically significant difference between the severity of dehydration between RVGE and NRVGE group. Among the patients with RVGE, 10.2% had no dehydration, 54.6% had some dehydration, and 35.2% had severe dehydration. The average duration of gastroenteritis in patients with RVGE was 4.30±0.91 days. Table 3 represents the clinical symptoms related to diarrhea.

DISCUSSION

The present study was conducted to assess the burden of RVGE in children under 5 years of age in the Northern region of India. In our study, the hospital-based frequency of RVGE in children under 5 years of age was observed as 51.4% (108/210). Singh *et al*. [15] conducted a study in Amritsar on 50 consecutive children, aged 6 months–3 years with diarrhea over a period of 1 year and reported a prevalence rate of 44%. Shariff *et al*. [16] reported a prevalence rate of 38.7% in under five children in Eastern Nepal. Mathew *et al*. [17] in Ernakulam district, Kerala also detected rotavirus in 36% of diarrhea-related hospital admissions among children <5 years of age. Sarangi *et al*. [18] in her study in a tertiary care hospital of Eastern India reported a prevalence rate of 48% in under 5-year children.

The quantum of hospitalized patients in the present study was high as compared to outdoor patients, which could be explained on the basis of the fact that this study was conducted in an apex referral tertiary care hospital catering to nine districts and its neighboring states. However, the observed prevalence of RVGE in indoor (54.1%) and outdoor (40%) patients has been similar to that reported by Ahmed *et al*. [19].

As observed in the other parts of the world, the burden of rotavirus disease is predominantly borne by children <2 years of age [20]. In our study, maximum cases (88.9%) of RVGE occurred in the age group of 0–3 years similar to those reported by Ahmed *et al.* [21] and Kazemi *et al*. [22], respectively, who observed that 80.6% and 84.2% of the patients with RVGE were under 2 years of age. This can be explained by the protective effect of maternal antibodies in neonates <6 months old, and the development of natural immunity after repeated infections in children over 2 years of age.

The male preponderance in acute diarrhea as well as RVGE in our study is similar to that reported by Ahmed *et al.* [19]. The explanation for this male predominance remains unclear, and this difference bears no statistical significance. Socioeconomic status and demographic profile apparently did not influence the prevalence of RVGE and NRVGE in the present study, which is similar to that reported by Kurugöl *et al.* [23] from Turkey.

Table 3: Diarrhea related to clinical symptoms

Clinical characteristics	RVGE	NRVGE
	No. (%)	No. (%)
Fever	82 (75.9)	90 (88.2)
Less than 10 loose stools	66 (61.2)	60 (58.8)
10 or more loose stools	42 (38.8)	42 (41.2)
Vomiting	64 (59.3)	80 (78.4)

NRVGE: Non RVGE, RVGE: Rotavirus gastroenteritis

Rotavirus infection occurs all year round but is at peak during the winter months. Most studies have observed an increase in rotavirus-associated diarrhea during the winter months, i.e., October to February, throughout the country ranging from 59% to 72%, with a median of 64% [15]. The Northern regions of India being more temperate may exhibit stronger seasonal variation [3]. The occurrence of RVGE apparently did not vary with the source of water supply or with access to the sanitary lavatory at their homes, similar to the observation made by Kurugöl *et al.* [23] in Turkey.

None of the exclusively breastfed babies had RVGE which supports the consensus that breastfeeding is protective as compared to top feeding. Kurugöl *et al*. [23] also observed that the majority of the patients (84%) with RVGE were bottle fed. In the age group of 6 months–2 years, the proportion of patients with adequate complementary feeding was much less as compared to those with inadequate complementary feeding in both RVGE and NRVGE groups thus emphasizing the importance of adequate weaning for prevention of diarrhea as a whole.

The frequency of RVGE in malnourished patients was 2.5 times (62/78; 75.5%) the frequency of RVGE in patients with normal nutritional status (46/132; 34.8%). Thus, it could be interpreted that malnourished children were more prone to suffer from RVGE as compared to patients with normal nutritional status. In contrast, Bern *et al.* [24] observed no significant difference in the prevalence of rotavirus diarrhea and severity of dehydration in children with or without malnutrition in Bangladesh.

The majority (97/108; 90%) of the patients with RVGE developed dehydration. Dehydration was observed in 87.8%, 76%, and 43.7% of the patients with RVGE by Modarres *et al*. [25], Shariff *et al*. [16], and Ahmed *et al*. [19], respectively. Severe dehydration was twice (35.2%) more common in RVGE as compared to NRVGE (17.6%). Kurugöl *et al*. [23] reported that severe dehydration was present in approximately two-third (69.1%) of patients with RVGE and one-third (39.2%) of the patients with NRVGE. Since the nature of the study group has not been defined, the results observed in this study cannot be compared with the present study.

A purge rate of <10 motions/day was observed in approximately two-thirds of the patients with gastroenteritis. Fever was observed in three-fourths (82/108; 75.9%) of the patients with RVGE in the present study. This was at variance with the observations of Modarres *et al.* [25], Shariff *et al.* [16], and Ahmed *et al*. [19], who observed fever in 89.4%, 26%, and 58.4% of RVGE patients, respectively. The average duration of illness in RVGE was 4.30±0.91 days which was almost similar to NRVGE (4.20±0.81 days) in the present study. However, this was in variance with the observation made by Kurugöl *et al*. [23], who reported the average duration of illness in RVGE as 5.5±5.1 days and in NRVGE as 3.3±3.1 days.

The limitation of the current study was that it was an observational study conducted in a single center with a small

sample size (due to limited availability of test kit). The data from this study will be useful for the policymakers in taking an informed decision about the introduction of rotavirus vaccine in North India. This study is expected to encourage exclusive breastfeeding until 6 months of age besides initiation of timely and adequate complementary feeding.

CONCLUSION

The results of our study highlight that rotavirus-associated diarrhea is an important and emerging health problem, particularly among children <5 years of age. Despite the high prevalence, RVGE can successfully and confidently be managed at home and diarrheal treatment units in the hospitals thereby reducing the number of referrals of gastroenteritis cases from peripheries to tertiary care hospitals which always remain over occupied.

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