P-ISSN: 2664-3685
E-ISSN: 2664-3693
IJPG 2020; 3(2): 76-79
Received: 18-05-2020
Accepted: 22-06-2020

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Prevalence and severity of rotavirus infection in children vaccinated against rotavirus in a tertiary care hospital, Chidambaram

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DOI: https://doi.org/10.33545/26643685.2020.v3.i2b.98

Abstract
Background: Diarrhoea is the most important reason for illness and death in developing nations. This cross sectional study was conducted to estimate the prevalence and severity of Rotavirus infection among vaccinated and unvaccinated children admitted with acute watery diarrhoea in a tertiary care hospital, Chidambaram.
Methods: Clinical assessment of dehydration and rapid immunochromatographic test was performed in stool specimens collected from children under 30 months of age visiting Rajah Muthiah Medical College Hospital, Chidambaram due to acute watery diarrhoea.
Results: During one year study, among 115 children admitted with acute watery diarrhoea, 31(27%) children were found to be rotavirus positive. Rotavirus positivity was significantly higher (41%) in unvaccinated than in vaccinated group ($p< 0.01$). Severity of dehydration in rotavirus positive cases were significantly more (79%) in unvaccinated group ($p< 0.01$).
Conclusion: This study suggests decline in rotavirus positivity and severity in rotavirus vaccinated children hospitalised for acute gastroenteritis.

Keywords: Childhood diarrhoea, dehydration, rapid immunochromatographic test, Rotavirus vaccine

Introduction

Acute gastroenteritis is the inflammation of gastrointestinal tract with sudden onset most commonly result of infections with bacterial, viral or parasitic pathogens [1]. Among these organisms causing diarrhoea viruses are the most common causative agent. Rotavirus is the commonest cause of gastroenteritis in children predominantly in developing countries [1]. The impact of Rotavirus infection in children in India accounts for 26% of all gastroenteritis related hospitalisation.66.7% of diarrhoeal deaths in children below five years are caused by Rotavirus.

Incidence and prevalence of Rotavirus gastroenteritis is underestimated in our country. Rotavirus had been associated with severe dehydration which eventually is the main cause of death in Rotavirus associated gastroenteritis [2]. Rotavirus infection has wide range of spectrum ranging from asymptomatic infection to life threatening diarrhoea with severe dehydration. Rotavirus infection is self limited and reinfection is common. Cross protection occurs after multiple infections.

Rotavirus have marked seasonal variation. In India, epidemic peak occurs throughout the year and more during November to February. Faeco oral route is the most common mode of transmission. There is no specific treatment and only supportive measures are available. The only possible solution to reduce rotavirus burden is effective vaccination against rotavirus.

Rotateq (RV1), Rotarix (RV5) and Rotavac (116E) are the three licensed orally administered rotavirus vaccines available in markets and in India. Intussusception was considered as a serious side effect for previous vaccines and there was no such demonstrable increased risk of intussusception associated with 116E vaccine.

India introduced Rotavac,116E, live naturally attenuated monovalent human bovine reassortant strain containing G9P [11], VP4 from bovine origin and all other segments with human rotavirus origin [3] in May 2013 in low cost with effective efficacy and good safety profile [4]. It is a liquid vaccine. Single human dose of 0.5 ml contains 10^5 FFU (focus forming units) of live rotavirus 116E.

Methods

The cross sectional observation study was conducted using clinical assessment and Rapid immunochromatographic test in a tertiary care hospital from October 2018 to October 2019. Children presenting with acute watery diarrhoea satisfying inclusion criteria were enrolled into study, after getting written informed consent from the parents /guardian. A detailed history and examination of each child was carried out according to pre designed proforma. Stool samples were collected from children on presentation to hospital before starting therapy. Stool samples were collected in sterile containers. Fresh stool samples were analyzed for rotavirus antigen by SD bioline Rotavirus Ag test kit – rapid immunochromatographic assay for qualitative determination of rotavirus antigen in stool. The total number of positives and negatives were noted at the end of each day. Finally entire data was compiled and analyzed. The sensitivity of this test is 100% and specificity is 92.4%.

Preparation of extracted sample

About 15-20 ml of stool specimen was collected in a sterile wide mouthed universal container during acute stage of gastroenteritis (< 3 days of onset of symptoms). Test device and samples were allowed to come to room temperature. Assay diluent was taken in the given disposable dropper up to the line shown on it; then transferred into the sample collection tube; this step was repeated once again. About 50 mg of stool sample was taken with sample collection swab. The swab was then inserted into the sample collection tube. Swab was swirled (up to 10 times) until the sample has been dissolved into the assay diluent and the swab squeezed against the tube wall and then discarded.

Test procedure

The test device was removed from foil pouch and placed on a flat, dry and clean surface. Dropping cap was assembled on the sample collection tube. 4-5 drops of sample was added to sample well of the test device. Purple colour appears across the result window in the centre of the test device which indicates the test is working. The result was interpreted at 10-20 minutes.

Results

The stool samples from children suffering from acute gastroenteritis were collected and tested with rapid ICT card test. At the end, entire data was compiled and analyzed. Out of115 samples which were tested, 31 were positive when ICT was performed. The percentage of positivity is 27% as shown in Figure 1. Out of 115 cases with acute gastroenteritis, 81 children (70%) were immunised with rotavirus vaccine and remaining 34 were unimmunised. Among vaccinated group, 17 cases (21%) showed rotavirus positivity whereas in unvaccinated group, 41% showed rotavirus positivity. This observed difference is statistically significant with p value 0.02 which is <0.05 as shown in Table 1. In rotavirus positive cases, among vaccinated group, 3 children (18%) presented with either some or severe dehydration and around 82% of children had no dehydration whereas among unvaccinated group, 11 children (79%) presented with some or severe dehydration as shown in Table 2 and Figure 2. This observed difference is statistically significant with p value of 0.003 which is less than 0.05.

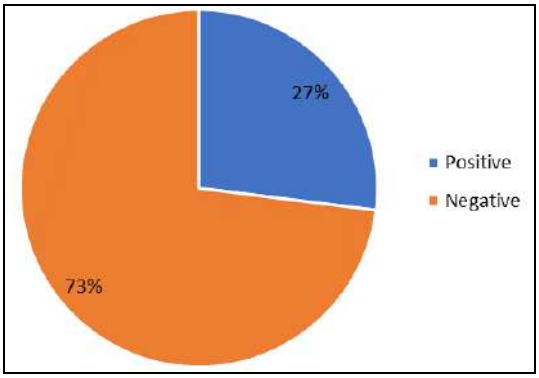

Fig 1: Prevalence of rotavirus infection

Table 1: Status of immunisation against rotavirus

Immunization status against Rotavirus	Number of AGE cases	No of RVGE cases	Percentage	No of non RVGE cases	Percentage	p value
Immunized	81	17	21%	64	79%	0.02
Non immunized	34	14	41%	20	59%	
Total	115	31		84		

Table 2: Dehydration status among vaccinated and unvaccinated in Rotavirus positive cases

Dehydration status	Total no of RVGE cases	Immunised	%	Non immunised	%	p value
No	17	14(82.4%)	82.30%	3(21.4%)	17.70%	0.003
Some	10	2(11.8%)	20%	8(57.2%)	80%	
Severe	4	1(5.9%)	25%	3(21.4%)	75%	
Total	31	17		14		

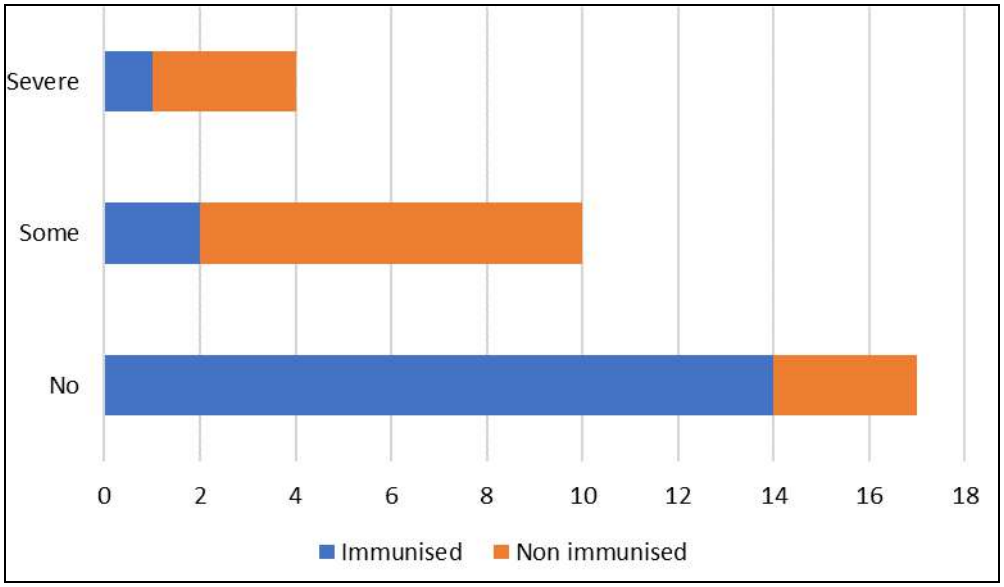

Fig 2: Dehydration status among vaccinated and unvaccinated in Rotavirus positive cases

Discussion

In this study, the prevalence of Rotavirus was 27%. The global prevalence of Rotavirus is 23-29% in hospitalised diarrhoeal cases in children. In this present study also, the prevalence of RVGE is in line with global prevalence.

This prevalence rate is similar to prevalence rate (28.57%) in a study conducted at Karnataka during 2014 by Shetty *et al*., [5] Another study conducted by Manohar *et al.* reported that Rotavirus contributes for about 25.66% of diarrhoea in children under 5 years of age [6].

In another study from western Maharashtra by Sanjay C Chavan reported 38% prevalence during 2010 [7]. High prevalence rate of 51% during 2010 was reported by Babji from Nagercoil [8].

Immunochromatography assay is the method used in this study which is an antigen antibody agglutination technique that allows the identification of group specific proteins present in group A of rotavirus. It is a rapid screening test, useful in poor resource settings. This test helps in overcoming the barriers in detection and studying the epidemiology of rotavirus infection. Sensitivity and specificity is comparable to that of enzyme immunoassay and latex agglutination [9, 10]. Comparison of ELISA with Immunochromatography test for detection of Rotavirus was conducted by a study in 2015 which concluded that ICG shows a good agreement with ELISA and showed a sensitivity of 95.24% and specificity of 97.47%.Also it has many advantages like cost-effective, easily available, convenient, easy to perform and to read results and also useful for testing single specimen at a time [11].

Out of 115 children included in this study, 81 cases were immunised and 34 cases were non immunised for Rotavirus. Among 81 immunised cases, 17(21%) cases were positive for rotavirus gastroenteritis. Out of non immunised 34 cases, 14(41%) cases were rotavirus positive. There was significant reduction in Rotavirus positivity in immunised cases indicating protective efficacy of the vaccine. Similar report was obtained in a study conducted in Ireland in 2016 [12]. A decline in rotavirus positivity in rotavirus-vaccinated children hospitalized for acute gastroenteritis was also reported by a study conducted by Jain *et al.* in Pune [13]. Above studies were similar to the present study in aspect of protective efficacy of the vaccine.

In rotavirus positive cases, among vaccinated group, 3 children (18%) presented with either some or severe dehydration and around 82% of children had no dehydration whereas among unvaccinated group, 11 children (79%) presented with some or severe dehydration. Similar disease severity scores were noted among positive and negative children in vaccinated group in a study conducted by Jain *et al.* in Pune in 2013-14. Among unvaccinated group, disease severity was reported more in rotavirus positive cases [13]. This is in accordance with our study which reported less severity of dehydration among vaccinated group of rotavirus positive cases.

Conclusion

We studied the prevalence and severity of rotavirus infection among vaccinated and unvaccinated group in children with acute watery diarrhoea. In our study, prevalence of rotavirus infection in children suffering from acute gastroenteritis is 27% indicating Rotavirus as the main causative agent of acute gastroenteritis in children below 30 months. The test used to estimate the prevalence of rotavirus gastroenteritis is immune chromatographic test which is a rapid diagnostic test.

Rotavac vaccine (116E) which was recently introduced in national immunisation schedule showed good efficacy in reducing the prevalence of rotavirus infection among vaccinated group. Our study also reports no or less severity of dehydration among vaccinated group in comparison with unvaccinated group indicating promising role of rotavirus vaccine (Rotavac).

Case control study involving large number of vaccine recipients and non recipients, monitoring rotavirus infection and genotypes in children vaccinated and non vaccinated, documenting the rotavirus vaccine history is needed to generate the data on vaccine effectiveness in different regions of country.

Limitation

Main drawback of this study is other groups of rotavirus like B and C which also contributes for human infections are not detected by ICT rapid card test. ELISA is a confirmatory test for detection of rotavirus and should be done following ICT test for confirmation of diagnosis.

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