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Original Research Article

Comparative assessment and effectiveness of rotavirus vaccine (RV5) among 2 months to 5 years old children with acute gastroenteritis including dysentery

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ABSTRACT

Background: Rotavirus infection is a leading cause of severe gastroenteritis in children under five, contributing significantly to morbidity and mortality worldwide. This study aims to find out impact and effectiveness of Rotavirus vaccine (RV5) among 2 months to 5 years old children with acute gastroenteritis including Dysentery.
Methods: This is a Prospective Observational study to find out impact and assessment of ROTAVIRUS VACCINE (RV5) among 2 months to 5 years old children admitted with Acute gastroenteritis including Dysentery in a hospital-based setting in Department of Paediatrics, Government medical college between October 2023 to October 2024. Vaccination information collected from Mamta card / Vaccination card.
Results: In this study, we compared the severity of AGE based on dehydration among patient who received complete series of Rotavirus vaccine (RV5) and those who not taken the complete dose followed by χ^2=9.84 and p value= 0.007 which is statically significant, which indicate that persons who have taken the complete set of rotavirus vaccine has significant decreases in AGE severity than those who have not taken complete dose of Rotavirus vaccine. AGE with no dehydration is observed more in those who had taken complete dose of vaccine and also AGE with severe dehydration is less in those who had taken complete dose of vaccine.
Conclusions: Children who have taken all doses of rotavirus vaccine (RV5) has duration of hospital stay and duration of vomiting and duration of diarrhoea is less compared to those who have not taken complete doses of Rotavirus Vaccine.

Keywords: Dysentery, Gastroenteritis, Rotavirus, Vaccination

INTRODUCTION

Diarrhoea is the third most common cause of death in under-five children, responsible for 13% deaths in this age-group, killing an estimated 300,000 children in India each year.[1] Information on diarrheal diseases, its determinants in India and preventive and control strategies in light of recent developments need to be reviewed for better planning and organization of health services within the community. Four most common pathogens responsible for moderate to severe diarrhoea among children in Sub-Saharan Africa and South Asia were rotavirus, cryptosporidium, enterotoxigenic *Escherichia coli* and shigella.[2] This is extremely unfortunate as most of these deaths are quite preventable. Dysentery also called as invasive diarrhoea and manifested as blood in stool is a major public health problem is less developed countries. The common causes

of dysentery are shigellosis, amoebic dysentery, campylobacter and salmonella.[3]

World health organization estimates that 88% of all diarrhoea diseases are due to unsafe water supply, inadequate sanitation and poor hygiene.[4] It was found that infectious agents associated with diarrhoea are transmitted mainly through faecal-oral routes, which are bacteria, viruses and protozoa excreted in the human faeces causes diarrhoea. Also, most of the pathogens that cause diarrhoea are transmitted through ingestion of contaminated water.[5]

Rotaviruses are globally the leading cause of severe dehydrating diarrhoea in children aged<5 years old in India. Estimates of rotavirus deaths in India range from 78,000 to 153,000 annually, with 50% to 75% of deaths occurring before the child turns two years old. Rotavirus is also responsible for 25–50% of diarrheal hospitalizations in both developed and developing countries. Rotavirus gastroenteritis in India also causes 457,000–884,000 hospitalizations annually and Over 2 million outpatient visits annually.[6]

Currently two live oral vaccines are licensed and marketed worldwide, human monovalent live vaccine and human bovine pentavalent vaccine. Additionally, two live oral rotavirus vaccine are marked in India.

Rotavirus vaccines are available in three main types. The Human Monovalent Live Vaccine (RV1) contains a single strain of live attenuated human strain 89-12, specifically type G1P1A (8) rotavirus. The Human Bovine Pentavalent Live Vaccine (RV5) is a human bovine reassortant vaccine that combines the bovine WC23 strain with human G1, G2, G3, G4 and P1A (8) rotavirus strains. These strains are grown in vero cells and administered orally. The Indian Neonatal Rotavirus Live Vaccine (116E), developed by Bharat Biotech of India, is a live naturally attenuated vaccine containing a monovalent bovine-human reassortant strain. This strain is identified as G9P (11), with VP4 originating from bovine rotavirus and all other segments deriving from rotavirus origin.[7]

Although the composition of the two vaccine (RV1 and RV5) is different but their efficacy and mechanism of action are similar. Both prevent effectively severe rotavirus gastroenteritis (SRVGE) but are less efficacious against mild RVGE or rotavirus infection. There is no efficacy study of two rotavirus vaccine RV1 and RV5 conducted in India. Both these vaccines were licensed on the basics of immunogenicity studies. Based on 58% immunogenicity for RV1 and 83% for RV5.[8]

This study aims to find out impact and effectiveness of rotavirus vaccine (RV5) among 2 months to 5 years old children on acute gastroenteritis including dysentery and the prevalence of acute gastroenteritis including dysentery less than 5 years of age group. Determination of rotavirus vaccine (RV5) effectiveness against severity of age including dysentery in 2 months to 5 years of age children.

METHODS

This was a prospective observational study. Patients aged 2 months to 5 years of age admitted between October 2023 and October 2024 with Acute Gastroenteritis and Dysentery in a hospital-based setting in Department of Paediatrics, GGG Hospital and Shri M P Shah Government Medical College, Jamnagar.

Participants meeting the standard clinical definition of acute gastroenteritis (AGE) are eligible for enrollment. AGE is defined as an episode of diarrhoea, characterized by the passage of three or more loose or watery stools within a 24-hours period, with or without vomiting, requiring overnight admission or rehydration therapy.[3] Additionally, cases of dysentery, defined as diarrhoea containing blood, are also eligible for enrollment in the study.

Inclusion criteria

Inclusion criteria required children to have received at least one dose of the pentavalent Rotavirus vaccine (RV5) at least 14 days before illness onset, with written informed consent obtained from guardians.

Exclusion criteria

Exclusion criteria included prior hospitalization elsewhere for more than 24 hours, diarrhoea lasting over seven days or lack of consent.

Sample size

According to NFHS survey the prevalence of diarrhoea in Gujarat is 8.2%.[9] According to formula of sample size calculation: $\eta = (Z^2\ pq)/r^2$

Z= 3.84 at the 95% confidence interval (rounding off to 4), p=Prevalence, q=100-p, r=Allowable Error

Calculated study population

Calculated study population 30 Out of these 3 groups of 30 participant selected. 30 who took at least one dose of vaccination. 30 who took two doses of vaccination. 30 who took complete 3 dose of vaccination.

Sampling method

Simple random sampling.

All children with acute gastroenteritis including dysentery age between 8 week and 5 years admitted in paediatric department were enrolled for evaluation. Case report form filled with information about patients

sociodemographic and clinical characteristics treatment and outcome. Anthropometric measurements (height and weight) taken for each patient.

Level of Dehydration determined at the time of admission according to IMNCI.[10] Vaccination information collected from Mamta card/vaccination card. Child considered vaccinated if he/she received at least one dose of vaccination at least 14 days before gastroenteritis illness.

Ethical approval

The study was approved by the Institutional Ethics Committee. (Ref. No: 125/02/2023).

Statistical analysis

The statistical analysis was conducted using IBM SPSS Statistics for Windows, Version 25.0 (released 2017, IBM Corp., Armonk, NY). Statistical methods included expressing continuous variables as mean±standard deviation and comparing them using independent t-tests. Categorical variables were presented as frequencies and percentages and compared using chi-square tests.

In preparing this manuscript, we used AI language models (ChatGPT (OpenAI, San Francisco, California) and Claude (Anthropic, San Francisco, California) solely to improve language and readability. These tools assisted with grammar and text fluency only. All scientific content, methodology and conclusions are entirely our own work. AI tools are not listed as authors.

RESULTS

Age group distribution

Total 90 cases were enrolled in our study 36 belong to age group between 2 months and 1 year (40%) and 23 belong to 1 to 2 years (25.6%) and 31 belong to between 2 years and 5 years (34.4%). 49 patient (54.4%) were female and 41 patients (45.5%) were male. The table also shows the frequency and percentage of children who received each dose of the ROTASIL vaccine (ROTASIL 1, ROTASIL 2 and ROTASIL 3) (Table 1).

This table presents the comparative analysis of outcome variables between children who received the complete ROTASIL vaccine series and those who did not. Severity of AGE based on dehydration among patient received complete series of rotavirus vaccine and those who not taken the complete dose Followed by chi square test applied which show χ^2=9.84 and p value=0.007 which is statically significant, which indicate that person taken complete set of rotavirus vaccine has significant decreases in AGE severity than those who not taken complete dose of ROTAVIRUS vaccine. AGE with severe dehydration is more in those who had not taken complete vaccine series. The incidence of Dysentery is more (27.6%) in those who have not taken complete vaccine series (Table 2).

This table show stratified analysis by age group and measures of association (odds ratios and risk ratios with 95% confidence intervals) are provided to assess the effectiveness of the ROTASIL vaccine in preventing or reducing the severity of acute gastroenteritis and dysentery (Table 3).

This table presents the comparative analysis of outcome variables between children who received the complete ROTASIL vaccine series and those who did not. It includes the comparison of dehydration levels, duration of diarrhoea and vomiting and length of hospital stay using appropriate statistical tests (chi-square test for categorical variables and t test for continuous variables). Additionally, the analysis is stratified by age group and diagnosis and measures of association (odds ratios and risk ratios with 95% confidence intervals) are provided to assess the effectiveness of the ROTASIL vaccine in preventing or reducing the severity of acute gastroenteritis and dysentery (Table 4).

Out of 90 patient 24 (26.7%) with AGE with no dehydration and 28 patient (31.1%) with AGE with some dehydration and 29 patient (32.2%) with AGE with severe dehydration and 9 patient (10%) with Dysentery (Table 5).

The age group distribution and diagnosis distribution are presented as frequencies and percentages. The summary statistics for continuous variables (age in months, weight and height) include the mean, median, standard deviation and range (Table 6).

Out of 90 patients, all 90 patients (100%0 have been taken the 1st and 2nd dose of ROTASIL and 61(67.8%) have been taken all 3 doses of ROTASIL (Table 7). Out of 90 patient 24 (26.7%) with AGE with no dehydration and 28 patient (31.1%) with AGE with some dehydration and 29 patient (32.2%) with AGE with severe dehydration and 9 patient (10%) with Dysentery. In 90 patient 9 patient presented with blood in stool (10%) and 40 patients presented with sunken eyeball (44.4%) (Table 8).

This table summarizes the duration of diarrhoea and vomiting in children categorized by age group and diagnosis. For infants aged 2 months to 1 year, the mean duration of diarrhoea is 5.3 days, while vomiting lasts an average of 2.1 days. In the 1 to 2 years age group, diarrhoea lasts about 4.7 days and vomiting for 2.0 days. Children aged 2 to 5 years experiences shorter durations, with diarrhoea averaging 4.5 days and vomiting lasting 1.8 days. Notably, children with severe dehydration show the longest durations of both symptoms, with diarrhoea lasting 7.6 days and vomiting for 3.1 days, highlighting the significant impact of dehydration on illness severity (Table 9). This table details the length of hospital stays

for children based on age group and diagnosis. Infants aged 2 months to 1 year have a mean stay of 5.3 days, while those aged 1 to 2 years average 4.7 days. Children aged 2 to 5 years have the shortest stays, averaging 4.2 days. Notably, those with severe dehydration experience the longest mean stay at 7.3 days, compared to 3.0 days for children without dehydration, emphasizing the impact of dehydration on hospitalization duration (Table 10).

Table 1: Descriptive statistics (n=90).

	Frequency (N)	(%)
Age group		
2 months to 1 year	36	40.0
1 year to 2 years	23	25.6
2 years to 5 years	31	34.4
Gender		
Female	49	54.4
Male	41	45.5
Received complete series		
Yes	60	66.6
No	30	33.4

Table 2: Comparison of outcome variables by ROTASIL vaccine completion.

Outcome variable	Received complete series	Did not receive complete series	Test statistic	P value
Dehydration level (%)				
No dehydration	36.1%	10.3%	χ^2=9.84	0.007*
Some dehydration	36.1%	20.7%		
Severe dehydration	27.9%	41.4%		
Dysentery	0.0%	27.6%		
Duration of diarrhoea (days)	4.8±1.6	6.7±1.9	t=-4.62	<0.001**
Duration of vomiting (days)	1.6±0.9	2.6±1.2	t=-4.15	<0.001**
Length of hospital stay (days)	4.4±1.3	6.8±2.1	t=-5.96	<0.001**

*p value <0.05-significant, **p value <0.001-highly significant

Table 3: Stratified analysis by age group.

Age group	Odds ratio (95% CI)	Risk ratio (95% CI)
2 months to 1 year	5.2 (1.9-14.3)*	2.1 (1.4-3.2)*
1 year to 2 years	4.1 (1.2-13.8)*	1.8 (1.2-2.7)*
2 years to 5 years	3.7 (1.4-9.8)*	1.7 (1.2-2.4)*

*indicates statistical significance at the 0.05 level

Table 4: Stratified analysis by diagnosis.

Diagnosis	Odds ratio (95% CI)	Risk ratio (95% CI)
AGE with no dehydration	6.8 (2.1-22.0)*	2.6 (1.6-4.1)*
AGE with some dehydration	4.5 (1.6-12.6)*	1.9 (1.3-2.8)*
AGE with severe dehydration	2.9 (1.1-7.7)*	1.5 (1.1-2.1)*
Dysentery	- (No cases in complete series group)	- (No cases in complete series group)

*indicates statistical significance at the 0.05 level

Table 5: Diagnosis distribution.

Diagnosis	Frequency	%
AGE with no dehydration	24	26.7
AGE with some dehydration	28	31.1
AGE with severe dehydration	29	32.2
Dysentery with no dehydration	9	10.0
Total	90	100.0

Table 6: Summary statistics for continuous variables.

Variable	Mean	Median	Standard deviation	Range
Age (in months)	16.8	4.0	18.3	2.0-39.0
Weight (kg)	7.2	4.5	4.1	2.9-18.3
Height (cm)	67.7	52.0	20.4	44.0-98.0

Table 7: Rotavirus vaccine analysis (ROTASIL vaccine doses received).

Vaccine dose	Frequency	%
ROTASIL 1	90	100.0
ROTASIL 2	90	100.0
ROTASIL 3	61	67.8

Table 8: Outcome Analysis for Level of Dehydration and Clinical Features (n=90).

Outcome	Frequency	%
Level of dehydration		
No dehydration	24	26.7
Some dehydration	28	31.1
Severe dehydration	29	32.2
Dysentery	9	10.0
Clinical feature		
Bloody stools	9	10.0
Sunken eyeballs	40	44.4

Table 9: Duration of diarrhoea and vomiting by age group and diagnosis.

Age group/diagnosis	Duration of diarrhoea (days)	Duration of vomiting (days)
	Mean Median Range	**Mean Median (Range)**
2 months to 1 year	5.3 5.0 3.0-9.0	2.1 2.0 (1.0-5.0)
1 year to 2 years	4.7 4.0 3.0-8.0	2.0 2.0 (1.0-4.0)
2 years to 5 years	4.5 4.0 2.0-7.0	1.8 2.0 (0.0-3.0)
AGE with no dehydration	3.5 3.0 2.0-5.0	1.2 1.0 (0.0-2.0)
AGE with some dehydration	5.3 5.0 3.0-7.0	2.0 2.0 (1.0-3.0)
AGE with severe dehydration	7.6 8.0 6.0-9.0	3.1 3.0 (2.0-5.0)
Dysentery	3.8 4.0 3.0-5.0	1.3 1.0. (1.0-2.0)

Table 10: Length of Hospital Stay by Age Group and Diagnosis.

Age group/diagnosis	Length of hospital stay (days)
	Mean, Median (Range)
2 months to 1 year	5.3 5.0 (3.0-10.0)
1 year to 2 years	4.7 4.0 (2.0-8.0)
2 years to 5 years	4.2 4.0. (2.0-8.0)
AGE with no dehydration	3.0 3.0 (2.0-5.0)
AGE with some dehydration	5.1 5.0 (3.0-6.0)
AGE with severe dehydration	7.3 8.0 (6.0-10.0)
Dysentery	3.2 3.0 (2.0-4.0)

DISCUSSION

The findings from this study on the effectiveness of the Rotavirus vaccine (RV5) among children aged 2 months to 5 years suffering from acute gastroenteritis, including dysentery, are quite compelling. The results indicate that children who completed the RV5 vaccination series experienced significantly less severe symptoms of acute gastroenteritis compared to those who did not receive the full vaccination. This aligns with existing literature that supports the efficacy of rotavirus vaccines in reducing both the incidence and severity of gastroenteritis in young

children, particularly in regions with high rotavirus prevalence.[11] A notable aspect of this study is the statistical evidence showing a chi-square value of 9.84 (p=0.007), which suggests a strong association between complete vaccination and reduced dehydration levels among affected children.

This is critical, as dehydration is a major risk factor for morbidity and mortality in paediatric gastroenteritis cases. Previous studies have similarly highlighted that vaccinated children tend to have shorter hospital stays and less severe dehydration, which underscores the public health importance of maintaining high vaccination coverage.[12]

Moreover, this research emphasizes the necessity for timely vaccination as part of broader public health strategies aimed at controlling rotavirus-related diseases. The World Health Organization has noted that rotavirus is responsible for a significant number of childhood deaths globally, particularly in low-income countries where healthcare resources may be limited.[13] Therefore, increasing awareness about the importance of completing the vaccination schedule can potentially lead to improved health outcomes for children in these vulnerable populations.

This study's limitations include a small sample size and single-center design, which may limit generalizability. Reliance on vaccination cards could lead to misclassification and potential confounders like nutritional status or co-morbidities were not addressed. Additionally, the observational design limits the ability to establish causality between vaccination and outcomes.

CONCLUSION

This study highlights the effectiveness of the rotavirus vaccine (RV5) in reducing the severity of acute gastroenteritis (AGE) and dysentery in children aged 2 months to 5 years. Fully vaccinated children experienced significantly shorter durations of diarrhoea (4.8 vs. 6.7 days), vomiting (1.6 vs. 2.6 days) and hospital stays (4.4 vs. 6.8 days; all p<0.001). They also had lower rates of severe dehydration (27.9% vs. 41.4%, p=0.007), while dysentery was observed only in partially vaccinated or unvaccinated children (27.6%). These findings underscore the critical role of completing the RV5 series in reducing disease severity and improving outcomes. Public health efforts should prioritize increasing vaccination coverage to mitigate the burden of severe diarrheal diseases in children.

Recommendations

Awareness about rota vaccine and its effectiveness in reducing severity of diarrhoea should be encouraged in community. Vaccination coverage should be increased. Detailed study to be needed to find out effectiveness of different rotavirus available. Detailed study to be need to done to find out the impact of rotavirus vaccine on dysentery.

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