

Impact of Introduction of Rotavirus Vaccination in Universal Immunization Programme on morbidity and mortality pattern of under five children due to Diarrheal Diseases in North 24 Parganas District of West Bengal

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Received: 15-07-2021 / Revised: 11-08-2021 / Accepted: 19-10-2021

Abstract

Background: Rotavirus infection is the leading cause of moderate to severe acute diarrhea in infants worldwide. Morbidity and mortality from this disease can be reduced by age-specific vaccination and other preventive measures like hand washing. **Objectives:** This study was undertaken to assess the changes in prevalence of episodes of diarrhea at public health facilities at different intervals before and after of Rota virus vaccine introduction in UIP and also to determine the changes in presentation of diarrheal disease. This study also tried to determine the interval of time after which the impact of Rota virus vaccine becomes evident as a public health intervention. **Methods:** Community based Cross sectional study conducted in 4 rural blocks of North 24 Parganas district. December 2018 to June 2020 was considered as study period. Children with diarrheal disease and on ORS therapy were included as complete enumeration methods. Record review and interview were taken as Study technique. Pre-vaccination is considered diarrheal episodes before month of September 2019 and post vaccination is considered as episodes after month of September 2019. **Results:** Episodes of hospitalisation were reduced 33%, 8%, 23 % and 19% following 1 month, 3 month, 6 month and 9 month post vaccination. Diarrhea with no and some dehydration episodes reduction was 5% and 8% 9 month post vaccination. **Conclusion:** Rota Virus vaccination may be treated as one of the most important intervention to reduce morbidity of under 5 children

Key words: Rota Virus, Vaccine, Diarrhea, Morbidity

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Introduction

Rotavirus infection is the leading cause of severe acute diarrhea in infants worldwide. The vast majority of cases occur before the age of 5 years. Each year, rotavirus causes approximately 111 million episodes of gastroenteritis requiring only home care, 25 million clinic visits, 2 million hospitalizations, and 352,000–592,000 deaths (median, 440,000 deaths) in children <5 years of age. By age 5, nearly every child will have an episode of rotavirus gastroenteritis, 1 in 5 will visit a clinic, 1 in 60 will be hospitalized, and approximately 1 in 293 will die. Children in the poorest countries account for 82% of rotavirus deaths[1]. From the patho-physiological view, Rota Virus causes an intestinal epithelium dysfunction in the small intestine. Rota Virus damaged enterocytes are more capable for bacterial invasion causing secondary bacterial infections[2,3]. Apart from causing significant morbidity, Rotavirus is responsible for a large share in under 5 mortality. It is also observed that Rotavirus was the leading cause of diarrhea deaths (199 000, 95% UI 165 000-241 000), followed by Shigella spp (164 300, 85 000-278 700) and Salmonella spp (90 300, 95% UI 34 100-183 100). Among children under 5 years old, the three aetiologies responsible for the most deaths were rotavirus, Cryptosporidium spp, and Shigella spp[4]. Rotavirus is a leading cause of moderate to severe acute diarrhea in India; it accounts for

24% of cases of diarrhea among children less than 23 months of age and 13% of cases of diarrhea among children aged 24–59 months of age[5]. In 2013, an estimated 47,100 rotavirus deaths occurred in India, 22% of all rotavirus deaths that occurred globally[6].

Global Action Plan for Pneumonia and Diarrhea (GAPPD) was formulated with the goal of ending preventable death from Pneumonia and diarrhea by 2025. One of its important objectives is to reduce mortality from diarrhea in children less than 5 years of age to < 1 per 1000 live birth. The incidence of rotavirus disease was observed to be similar in both industrialized and developing countries, suggesting that adequate control may not be achieved by improvements in water supply, hygiene, and sanitation. Consequently, the development, trial, and widespread use of rotavirus vaccines were recommended to prevent severe and fatal rotavirus disease[1].

Routine Immunization(RI) targets to vaccinate 27 million new born each year with all primary doses and 100 million children of 1-5 year age with booster doses of UIP vaccines. In addition, 30 million pregnant mothers are targeted for TT vaccination each year. To vaccinate this cohort of 157 million beneficiaries, 10 million immunization sessions are conducted, majority of these are at village level. As per Coverage Evaluation Survey (2009), 89.8% of vaccination in India is provided through Public sector (53% from outreach session held at Anganwadi centre (25.6%), sub centre (18.9%) etc.) while private sector contributed to only 8.7%[7]. A significant and sustained reduction in the proportion of hospital admissions for acute gastroenteritis due to rotavirus was seen among children younger than 5 years following rotavirus vaccine introduction[8]. The National Technical Advisory Group on Immunization (NTAGI), Ministry of Health and Family Welfare (MoHFW), Government of India (GoI) has recommended the

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introduction of Rotavirus vaccine in the country in a phased manner in the Universal Immunization Programme (UIP). Rotasiil® (RV5), a live attenuated, oral, freeze-dried vaccine containing five viruses (Human and Bovine reassortant strains) of serotype G1, G2, G3, G4 and G9. It is manufactured by Serum Institute of India Pvt. Ltd. The vaccine is to be reconstituted before use with a diluent (Citrate bicarbonate buffer). It is given as a 3-dose regimen at 6 weeks, 10 weeks, and 14 weeks of age[9].

This study was undertaken to assess the changes in prevalence of Diarrheal Disease Episodes at Public Health Facilities at different intervals before and after of Rota virus vaccine introduction in UIP and also to determine the changes in presentation of Diarrheal Disease Episodes at Public Health Facilities pre-introduction and post-introduction of Rota virus vaccine introduction in UIP. This study also tried to determine the interval of time after which the impact of Rota virus vaccine becomes evident as a public health intervention.

Materials and Methods

This is a community based Cross sectional study conducted in study setting is 4 rural blocks of North 24 Parganas district ie Amdanga , Madhyamgram ,Biswanathpur and Chhotojagulia .One third blocks of total 12 blocks were chosen by Simple Random Sampling in North 24 Parganas health district. Rotavirus vaccination program was implemented from the Month of September 2019 at North 24 Parganas. December 2018 to June 2020 was considered as study period. All the children below 5 year of age who attended the subcentres in the reference period have been included in the study if they meet all of the following criteria.

Inclusion Criteria

1. Presented to one of the subcentres in mentioned blocks for treatment of Diarrheal Episodes
2. Should be <5 year of age
3. The child should be either treated with oral rehydration therapy or referred to hospital.

Exclusion criteria

Patients will be excluded from enrolment if any of the following apply:

1. More than 5 year of age

2. Unable to obtain informed consent from the parent/caregiver or guardian.

Data were collected in predesigned and pretested schedule and several parameters like age, gender, severity of diarrhea, hospitalization due to diarrhea were included. Death due to diarrheal diseases is collected from IDSP report and IPD register of the respective block hospitals. To ascertain the death and hospitalization, the houses of the children were visited and family members were interviewed. The collected data were checked for completeness and consistency and entered in the computer on Excel sheets.

Study tools include IDSP report of the blocks, Sub centre clinic register, referral register, hospital IPD register etc. Record review and interview were taken as Study technique. Pre-vaccination is considered diarrheal episodes before month of September 2019 and post vaccination is considered as episodes after month of September 2019. Definitions as formulated in Diarrheal disease control Fortnight[10] under National Health Mission was considered for diarrhea with no and some dehydration. As per the modified case definitions of P form under IDSP (2019) ,Passage of 3 or more loose watery stools in the past 24 hours. (with or without vomiting) was considered as diarrheal episode. Total cases meant all cases with no, some and severe dehydration.

Ethical approval was obtained from Ethical Committee of Medical College ,Kolkata before data collection. Application was made to CMOH, North 24 Parganas before commencement of the study.

Results

Impact of study was measured by comparing different morbidity indicators due to diarrhea in under 5 children at fixed time interval following vaccination with the same time gap before introduction of vaccination.

Hospitalizations was reduced 33% just after 1 month of vaccination (table 1), though episodes remained almost same. Episodes of diarrhea was reduced 4.19% after 3 month post vaccination and episodes of hospitalization 8.33% reduced(table 2).

Diarrheal episodes reduction was 5.89 % and 4.74% respectively after 6 and 9 month post vaccination. Reduction of hospitalization was 23 % and 19% respectively 6 and 9 month post vaccination and reduction of some dehydration episodes were 19% and 8 % respectively(table 3 and table 4). Significant mortality reduction was not found(Figure 1).

Table 1. Table showing impact of vaccination at 1 month (August 2019/October 2019)

Details of diarrheal episodes	Pre-Vaccination					Post Vaccination					Changes
	Amdanga Block	Madhaym gram Block	Chhotoja gulia	Biswanat hpur	Tot al	Amdanga Block	Madhaym gram Block	Chhotoja gulia	Biswanat hpur	Tot al	
Total No of Diarrheal Episodes	66	83	14	148	311	62	76	37	139	314	+0.96 %
Dirrhoea with no dehydration	59	77	12	108	256	46	64	27	117	254	- 0.78%
Dirrhoea with some dehydration	7	6	2	40	55	16	12	10	22	60	+9%
No. of Hospitalization due to Diarrhea	3	4	2	12	21	2	4	2	6	14	- 33.33 %

Table 2. Table showing impact of vaccination at 3 months (June 2019/December 2019)

Details of diarrheal episodes	Pre-Vaccination					Post-Vaccination					Changes
	Amdannga Block	Madhaym gram Block	Chhotoja gulia	Biswanat hpur	Total	Amdannga Block	Madhaym gram Block	Chhotoja gulia	Biswanat hpur	Total	
Total No of Diarrheal Episodes	90	111	36	97	334	92	113	26	89	320	-4.19%
Dirrhoea with no dehydration	80	91	35	62	268	76	90	20	69	255	-4.85%
Dirrhoea with some dehydration	4	16	10	35	65	16	22	6	20	64	-1.53%
No. of Hospitalization due to Diarrhea	3	11	8	26	48	15	15	3	11	44	-8.33%

Table 3. Table showing impact of vaccination at 6 months (March 2019/March 2020)

Details of diarrheal episodes	Pre-Vaccination					Post-vaccination					Change
	Amdannga Block	Madhaym gram Block	Chhotoja gulia	Biswanat hpur	Total	Amdannga Block	Madhaym gram Block	Chhotoja gulia	Biswanat hpur	Total	
Total No of Diarrheal Episodes	87	98	65	106	356	80	97	66	92	335	-5.89%
Dirrhoea with no dehydration	67	74	50	76	267	56	82	48	73	259	-3%
Dirrhoea with some dehydration	20	24	15	30	89	24	14	15	19	72	-19%
No. of Hospitalization due to Diarrhea	12	16	8	21	57	13	9	9	13	44	-23%

Table 4. Table showing impact of vaccination at 9 months (December 2018/June 2020)

Details of diarrheal episodes	Pre-Vaccination					Post-Vaccination					Changes
	Amdannga Block	Madhaym gram Block	Chhotoja gulia	Biswanat hpur	Total	Amdannga Block	Madhaym gram Block	Chhotoja gulia	Biswanat hpur	Total	
Total No of Diarrheal Episodes	66	69	112	132	379	62	89	98	112	361	-4.74%
Dirrhoea with no dehydration	50	48	89	99	286	48	59	78	87	272	-5%
Dirrhoea with some dehydration	16	21	23	33	93	22	17	22	25	86	-8%
No. of Hospitalization due to Diarrhea	10	12	12	18	52	6	12	14	10	42	-19%

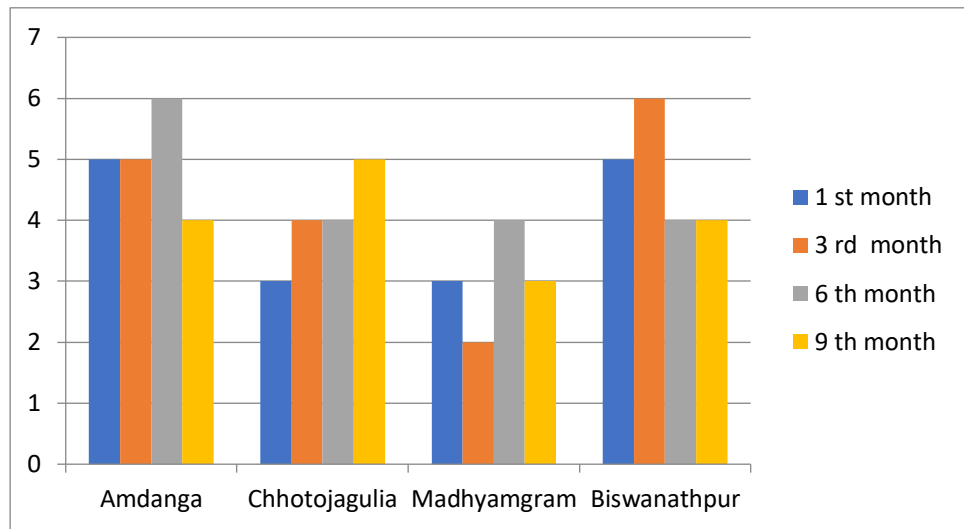


Fig 1: Mortality due to diarrhea in different months of vaccine introduction

Discussion

Month at definite interval after introduction of vaccination is compared with month prior to same length before introduction of vaccination. As a whole in terms of total no of episodes, Biswanathpur block reported more number of cases than other blocks because of this block is located away from the district headquarters. No of private facility is also less compared to other blocks. More number of people is dependent on government health services. Other blocks are located in urban vicinity and have access to private health care. Data was collected from care givers of the patients related to government health facility.

In the first month following introduction of Rota virus vaccine, there is no significant change in prevalence of total no of diarrheal episodes. Severity of diarrheal episodes also did not show any difference. Probably this is due to very small cohort who received vaccination at the first month. The other reason may be there is poor sero conversion of the beneficiaries after first dose of Rota virus vaccination. In the 3rd month following introduction of vaccination, there is no significant difference in total no diarrheal episodes. But if diarrheal episodes with no and some dehydration are considered, there is slight reduction in number of episodes. But the reduction is too small to have a public health impact. It may be increasing size of the cohort receiving the Rota virus vaccine. As numbers of infants who have received multiple doses of vaccine are also getting increased, there may be sero conversion of more no of infants to be protected against diarrhea. In the sixth month following vaccination there is reduction in all forms of diarrhea, severe form of diarrhea is more reduced than milder form. As cases with severe diarrhea and hospitalization are reduced more, there is less expenditure on the part of state on health issues. This month (6th month) is probably threshold of impact of Rota virus vaccination in the community. Introduction of Rota Virus vaccine may be regarded as an effective public health intervention which renders an early impact. The burden of the state on health is reduced. In ninth month following introduction of Rota virus vaccine it is observed that total cases due to diarrhea are decreasing irrespective of status of dehydration. Total hospitalizations due to diarrhea are also decreased by 19%. Similar to this study, other study also highlighted the need to incorporate rotavirus vaccines into immunization programmes in countries that have not yet introduced them and underline the importance of high-quality surveillance [8]. The impact on vaccination is more on the cases with some dehydration. It is also observed that significant and sustained reduction in the proportion of hospital admissions for acute gastroenteritis due to rotavirus was seen among children younger than 5 years following rotavirus Vaccine introduction [8]. In case of

mortality due to diarrheal diseases there is no significant impact of vaccination of Rota virus on mortality. Probably it is due to small size of the cohort receiving Rota virus vaccine. It is also observed that the reporting of death in IDSP portal is also very low. Globally, it is estimated that the number of rotavirus deaths in children <5 years of age declined from 528 000 (range, 465 000-591 000) in 2000 to 215 000 (range, 197 000-233 000) in 2013. So the impact of Rota Virus Vaccination is yet to come.

Conclusion

After 6 months of introduction of Rota virus vaccine, the number of cases due to diarrhea begun to decrease. This may be treated as threshold in which community protection is noticed. Rota virus Vaccine protects severe form diarrhea. Rota Virus vaccination may be treated as one of the most important intervention to reduce morbidity of under 5 children. RVV has no impact on death due to diarrhea in first 9 months of introduction.

Limitations

There are several limitations of the study. All the children of the block area are not always included in the reports provided by the health care workers. Many of the guardians prefer private health clinics than the government health services. As months of equal interval of months are compared, there is chance of variation of number of episodes due to seasonal variation of the disease. As total no of diarrheal episodes were considered causes of diarrhea other than Rota virus was not taken into account.

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Conflict of Interest: Nil Source of support: Nil