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Original article

Effectiveness and impact of rotavirus vaccines in Saudi Arabia: A single hospital-based study

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ABSTRACT

Background and study aims: Rotavirus is the most important cause of severe gastroenteritis in children. The primary public health intervention is vaccination. Rota vaccine has been included to the national vaccination schedule in Saudi Arabia since 1 January 2013. Here we aim to evaluate the effectiveness and impact of rotavirus vaccines in Saudi Arabia following the addition of rotavirus vaccine to the national vaccination schedule.

Patients and methods: Retrospective analysis of electronic data of children admitted to al Jeddani Hospital, Jeddah, Saudi Arabia, with gastroenteritis between 1 September 2011 and 31 August 2012 (1 year before the implementation of Rota vaccine; group 1) compared to those admitted between 1 September 2015 and 31 August 2016 (3 years after the implementation of the vaccine; group 2).

Results: A total of 730 patients with gastroenteritis had documented rotavirus stool analysis. Their median age was 32 (16–56) months, 54% male and 46% female. The prevalence of rotavirus-positive gastroenteritis significantly decreased from 38.5% in group 1 to 13.2% in group 2, $P = 0.0001$. The median age of rotavirus infection significantly increased to 44 (21–56) months after the implementation of rotavirus vaccine compared to 16 (12–36) months before routine vaccination, $P = 0.003$.

Conclusion: Rotavirus gastroenteritis has significantly decreased among Saudi children, especially infants below 24 months of age, after the implementation of rotavirus vaccine in the national vaccination programme.

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Introduction

Acute gastroenteritis is a leading cause of post-neonatal under-five mortality worldwide [1]. Rotavirus is the most important cause for severe gastroenteritis in this age group and accounts for 37% of child mortality from diarrhoea [2,3]. Most of these deaths occurred in developing countries [4].

Rotavirus is a genus of double-stranded RNA viruses in the family *Reoviridae*. There are eight species of this virus, referred to as A, B, C, D, E, F, G and H. *Rotavirus A*, the most common species, causes more than 90% of rotavirus infections in humans [5]. Immunity develops with each infection, so subsequent infections are less severe and adults are rarely affected [6].

Rotavirus is highly infectious. Its prevalence does not decrease with improving sanitation, and the rate of hospitalisations remains high despite the use of oral rehydrating solution. Nitazoxanide significantly reduces the duration of rotavirus-induced diarrhoea, but has no effect on the median duration of fever or vomiting or the proportion of children requiring parenteral rehydration [7]. Hence, the primary public health intervention is vaccination [8]. Two vaccines against rotavirus A infection have been approved for global use: Rotarix® and RotaTaq®. Both are safe and effective in children. They are taken orally and contain attenuated live virus [9].

Rota vaccine has been included to the national vaccination schedule in Saudi Arabia since 1 January 2013 [10]. In this study, we aim to evaluate the effectiveness and impact of rotavirus vaccines in Saudi Arabia in a single private hospital setting in the Western province of Saudi Arabia following the addition of rotavirus vaccine to the national vaccination schedule.

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Patients and methods

A retrospective analysis was performed of electronic data of patients below 16 years of age admitted to Al Jeddani Hospital 'Ibn Sina College Hospital', Jeddah, Saudi Arabia, with gastroenteritis defined by the presence of diarrhoea and/or vomiting with or without fever. Al Jeddani Hospital is a secondary private 100-bed hospital. This study was approved by the local ethics committee.

Group 1: patients admitted to the hospital between 1 September 2011 and 31 August 2012 (1 year before the introduction of Rota vaccine in routine national vaccination schedule in Saudi Arabia).

Group 2: patients admitted to the hospital between 1 September 2015 and 31 August 2016 (3 years after the introduction of Rota vaccine in routine national vaccination schedule in Saudi Arabia).

Stool analysis for rotavirus was retrospectively checked. Patients with documented stool analysis for rotavirus were included in the study. Demographic, clinical and laboratory data of these patients were analysed.

Stool analysis for rotavirus

SD BIOLINE rotavirus kits (Standardia, Seoul, South Korea) were used to detect rotavirus group A antigen in faecal specimens. The kit contained an immune assay test using two types of antibodies in solid-phase sandwich immunochromatography to detect a specific group of proteins including the major inner capsid protein present in group A rotavirus. The letter cassette has of the alphabet T as test line and C as control line. Test is positive if both lines are coloured.

Statistical analysis

Testing was performed using SPSS20. Kolmogorov-Smirnov test was used to test the distribution of data. Mann-Whitney U test and chi-square tests were used to compare nonparametric and qualitative data, respectively.

Results

Demographic data of the studied groups

A total of 730 patients with gastroenteritis had documented rotavirus stool analysis. Their median (interquartile range) age was 32 (16–56) months, and 54% were male and 46% were female. Rotavirus-positive results were obtained in 193 (26.4%) of them.

Characteristics of rotavirus gastroenteritis before and after the implementation of vaccine in the national vaccination schedule

The prevalence of rotavirus-positive gastroenteritis significantly decreased from 38.5% in group 1–13.2% in group 2, $P = 0.0001$ (Table 1). In addition, the median age of rotavirus infection significantly increased 44 (21–56) months after the implementation of rotavirus vaccine in the national vaccination schedule compared to 16 (12–36) months before routine vaccination, $P = 0.003$ (Table 1, Fig. 1). However, seasonal variation of rotavirus gastroenteritis was not affected by vaccination. It was still more prevalent in winter and autumn (Fig. 2).

Table 1

Characteristics of rotavirus-positive patients before and after vaccine implementation in the national vaccination schedule.

Rotavirus positive	Before vaccine implementation	After vaccine implementation	P
N (%)	147 (38.5)	45 (13.2)	0.0001
Age median (IQ range)	16 (12–36)	44 (21–56)	0.003
Sex male N (%)	93 (64)	21 (47)	0.29
TLC median (IQ range)	9.9 (6.4–11.9)	8 (5.4–10)	0.19
PMN% median (IQ range)	70 (51–77)	61 (50–80)	0.99
Lymphocyte% median (IQ range)	24 (18–42)	31 (15–45)	0.95
CRP median (IQ range)	1 (0.5–1.9)	1.3 (0.6–2.3)	0.31
Serum Na median (IQ range)	140 (137–142)	140 (139–143)	0.81

The prevalence of rotavirus significantly decreased after the implementation of rotavirus vaccine in the national vaccination schedule, and the median age of rotavirus infection significantly increased.

Rota virus positive gastroenteritis in different age groups

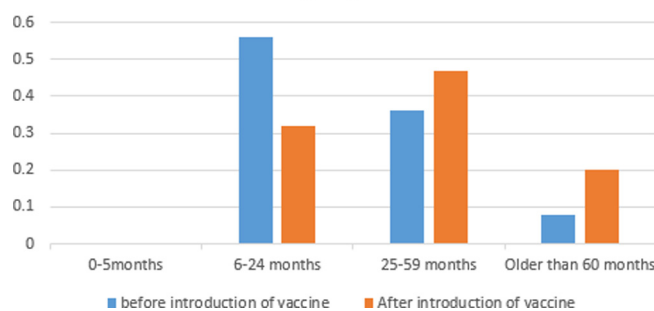


Fig. 1. Rotavirus gastroenteritis in different age groups before and after the implementation of rotavirus vaccine in the national vaccination programme.

Seasonal distribution of rota virus

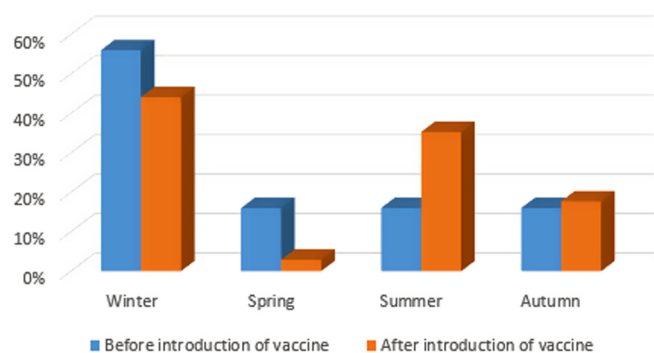


Fig. 2. Seasonal distribution of rotavirus gastroenteritis before and after the implementation of rotavirus vaccine in the national vaccination programme.

Discussion

Diarrhoeal disease is one of the common causes of morbidity and mortality in children under 5 years of age. Rotavirus is by far the most common cause of gastroenteritis in this age group [3].

Prior to the introduction of rotavirus vaccines, rotavirus contributed to 3.6 million diarrhoeal episodes in children younger than 5 years in Europe, with 231 annual deaths [11], 10,000 annual

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