

## Our results for five years of rotavirus vaccination

### Beş yıllık rotavirüs aşı sonuçlarımız

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#### Abstract

We aimed to evaluate the results of 5 years of rotavirus vaccination experience and compare the effects of monovalent and pentavalent vaccines. This retrospective study included 2345 children vaccinated in a trial that was held between January 2007 and January 2012. Information was obtained on whether the patient was administered the monovalent or pentavalent vaccine, whether he/she had rotavirus gastroenteritis after the vaccination, and whether he/she was treated as an outpatient or an inpatient. This information was obtained from the computer records and, in cases where information was lacking, the families were called to obtain missing details. In all patients with complaints of diarrhea, rotavirus antigen analysis was done with a rapid immunochromatographic stool test. The age range of the children was 3–60 months. Of the patients included in the study, 1270 (54%) were female and 1075 (46%) male. The monovalent vaccine was administered to 1700 (72.5%) children, while the pentavalent vaccine was administered to 645 (27.5%) children. After administration of the vaccine, no major complications were reported. Symptomatic rotavirus gastroenteritis was detected in 4 % of vaccinated children. No patients died due to rotavirus infection. There was no statistically significant difference between the vaccines in terms of the incidence of rotavirus gastroenteritis and the number of children who were hospitalized or received outpatient treatment ( $P > 0.05$ ). Symptomatic rotavirus gastroenteritis was detected in only 4 % of the vaccinated children in our study. Moreover, there is no significant difference in the protection offered by the monovalent and pentavalent vaccines.

**Keywords:** Monovalent vaccine; pentavalent vaccine; rotavirus; rotavirus vaccine.

#### Özet

Beş yıldır uyguladığımız rotavirüs aşısı sonuçlarını değerlendirmeyi ve pentavalan ile ve monovalan aşının etkinliğini karşılaştırmayı amaçladık. Ocak 2007– Ocak 2012 arasında rotavirus aşısı yapılan 2345 çocuk çalışmaya alındı. Hasta verileri bilgisayar kayıtlarından elde edildi. Bilgilerine ulaşamayan çocukların aileleri telefonla arandı. Çalışmada rotavirüs gastroenteriti olup olmadığı, olduyorsa tedavinin şekli (ayaktan veya yatarak) ve hangi aşının uygulandığı (monovalan veya pentavalan) sorgulandı. Tanı için gaitada rotavirüs antijeni (rapid immunochromatographic test) bakıldı. İki aşı; rotavirüs gastroenteritine yakalanma ve ağır gastroenterit (hastanede tedavi) geçirme durumuna göre karşılaştırıldı. Veriler SPSS 15,0 istatistik program kullanılarak değerlendirildi.  $P < 0.05$  değer istatistiksel olarak anlamlı kabul edildi. Çocukların yaşları 3–60 ay arası idi. 1270'ı kız (% 54) ve 1075'i erkek (% 46) idi. 1700 (% 72,5) çocuğa monovalan, 645 (% 27,5) çocuğa pentavalan aşı yapılmıştı. Aşı yapılan çocukları % 4'ünde semptomatik rotavirus enfeksiyonu olmuştu. İki aşı; semptomatik gastroenteritine yakalanma ve ağır gastroenterit (hastanede tedavi) geçirme durumuna göre karşılaştırıldığında anlamlı bir fark bulunmadı ( $p > 0.05$ ). Rotavirüs aşısı rotavirus enfeksiyonlarını tamamiyle korumamakla birlikte, rotavirus enfeksiyonlarını büyük ölçüde azalttığı gözlemlendi. Ayrıca rotavirüs enfeksiyonunu önleme bakımından iki aşı arasında fark bulunmadı. Biz bu çalışmada, rotavirus aşısının bir an önce ulusal aşı takviminde yer almasını vurgulamak istedik.

**Anahtar kelimeler:** Monovalan aşı; pentavalan aşı; rotavirüs; rotavirüs aşısı.

#### Introduction

Rotavirus is one the main causes of severe gastroenteritis that leads to hospitalization and infant deaths, particularly among children under 5 years old. It accounts for more than 2 million hospitalizations and approximately 550,000–600,000 deaths per year worldwide (1-3). Also, it is responsible for 40% of all acute gastroenteritis cases among children under 5 years old. Nearly all children have rotavirus infection at least once till they reach the age of 5 years. Vaccination is the most important method of protection from rotavirus infections that lead to morbidity and mortality and, additionally, to a considerable economic burden. The vaccine is not included in the standard vaccination schedule for infants; however, the Ministry of Health allows the administration of the vaccine. A search of Turkish Medline and citation index performed with a search engine did not produce any publication from Turkey about the rotavirus vaccine experience. In this study, we aimed to share the 5 year results for rotavirus vaccine administration, which is a part of our hospital's

routine vaccination schedule.

#### Patients and methods

This retrospective study included 2345 children who were administered rotavirus vaccine at the Pediatrics Clinics of Fatih University Sema Hospital between January 2007 and January 2012. Patient data were obtained from computer records and in case of lack of information, their families were called and records were completed. We obtained information on whether the patient was administered monovalent or pentavalent vaccine, had rotavirus gastroenteritis or not after the vaccination, and whether he/she was treated as an outpatient or inpatient. The results of the rapid immunochromatographic test for the presence of rotavirus antigens in the stool were obtained. All of this information was obtained from the computer records. The two vaccines were compared with regard to whether the vaccinated children were infected with rotavirus later and whether they were hospitalized or treated in an outpatient setting. Data were assessed using the statistical software SPSS 15.0.  $P$  value  $< 0.05$  was considered to indicate statistical significance.

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### Results

The age range of the children was 3–60 months. Of the patients, 1270 (54%) were female and 1075 (46%) were male. Monovalent vaccine was administered to 1700 (72.5%) children, while pentavalent vaccine was administered to 645 (27.5%) children. After vaccine, major complication was not seen. Symptomatic rotavirus gastroenteritis was detected in 4 % in vaccinated children. No patients were dead of rotavirus infection. Of the children who were administered the monovalent vaccine, 73 (4.2%) had rotavirus gastroenteritis, of whom 17 (1%) were treated in the hospital and 56 (3.2%) were treated in outpatient settings. Of the children who were administered the pentavalent vaccine, 21 (3.2%) had rotavirus gastroenteritis, 4 (0.6%) of whom were treated in the hospital and 17 (2.6%) of whom were treated in outpatient settings. There was no statistically significant difference between the two vaccines with regard to the incidence of rotavirus infection and treatment setting (inpatient vs. outpatient) ( $P > 0.05$ ).

### Discussion

Acute gastroenteritis is the most important cause of morbidity and mortality in children, after lower respiratory system infections. Rotaviruses are the leading cause of severe gastroenteritis that causes infant deaths and particularly hospitalization of and diarrhea in infants and children under 5 years old (4). It is reported that children under 5 years old have a mean of 3.2 episodes of diarrhea per year worldwide. It is suggested that 5 of every 1000 children under 5 years die because of diarrhea. Gastroenteritis caused by rotaviruses has the same incidence in developed and developing countries, regardless of the hygiene conditions. It is responsible for approximately 40% of acute gastroenteritis cases seen in children under 5 years old (1,5-7). Almost all children, till they reach the age of 5, have at least one rotavirus infection. In the different cross-sectional studies conducted in Turkey, the incidence of rotavirus infection is reported to be 25–39% (8,9). In our study, symptomatic rotavirus gastroenteritis was detected in 4 % in vaccinated children at five years periods. The clinical spectrum of rotavirus infections ranges from asymptomatic infection to diarrhea and death. No our patients were dead of rotavirus infection. Vaccination is the most effective method for protection from rotavirus infections. Today, two new rotavirus vaccines (monovalent human rotavirus vaccine and pentavalent human bovine vaccine) are widely used around the world. Monovalent human virus vaccine is administered orally from the 6th week in 2 doses, with an interval of at least 4 weeks between the doses (10). Pentavalent human bovine vaccine is administered orally. The vaccination scheme recommended for this vaccine is 3 doses administered at 2, 4, and 6 months (11). In our clinic, the cost and protection offered by these two vaccines is discussed with the family, and the choice is made by the family. But our vaccination rate is still approximately 54%. The most important reason for the low rate of vaccination is the financial burden on the family. Large-scale trials conducted worldwide show that vaccination decreases the incidence of severe

rotavirus gastroenteritis by 85–96%, hospitalization rates by 85–96%, emergency admission by 94%, and consultation with a doctor by 84–86% (12-16). Based on the above data, by vaccinating 2345 babies, we were able to protect a considerably high number of children aged below 6 years from rotavirus gastroenteritis. With the decrease in hospitalization and emergency admission by 85–96%, the country has been freed of considerable expense. Additionally, recent trials have shown that rotavirus vaccines protect not only the vaccinated babies, but also non-vaccinated babies and older children, which means that it possible to achieve “herd immunity” with this vaccine (4). All of these data support the World Health Organization recommendation that rotavirus vaccine be included in the vaccination schedules of all countries.

In conclusion, Rotavirus vaccination does not entirely prevent rotavirus infections. Symptomatic rotavirus gastroenteritis was detected in only 4 % of the vaccinated children in our study. Moreover, there is no significant difference in the protection offered by the monovalent and pentavalent vaccines.

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