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Adverse Events Following Rotavirus Vaccination in Infants: A Single-Center Study in Turkiye

İnfantlarda Rotavirüs Aşılaması Sonrası Advers Olaylar: Türkiye'de Tek Merkezli Çalışma

Nursel Atay Ünal(1), Tuğba BEDİR DEMİRDAĞ(1), Betül ERDOĞDU(2), Betül ÖNAL(2), Meltem POLAT(1), Bahar ÇUHACI ÇAKIR(3), Hasan TEZER(1), Aysu DUYAN ÇAMURDAN(3), Anıl TAPISIZ(1)

ABSTRACT

OBJECTIVE: This study aims to assess the adverse events following rotavirus vaccination, which is a major cause of preventable hospitalizations in early childhood.

MATERIAL AND METHODS: At Gazi University Faculty of Medicine Hospital, rotavirus vaccination is recommended for all immunocompetent children in the social pediatrics clinic. This study included healthy infants who received a rotavirus vaccine between June 1, 2020, and December 31, 2022. Unfortunately rotavirus vaccines are still not included in the national immunization program in Türkiye. The decision on vaccination and vaccine type was made together with families, based on information regarding doses, cost, and efficacy. Patients were monitored daily for one week after each dose of vaccination and contacted six months after the completion of the vaccination series.

RESULTS: During the study period, 107 healthy infants (mean age: 4.1 months) received the rotavirus vaccine. Of these, 11 received RotaTeq® and 96 received Rotarix®. Adverse events occurred in 4 infants (3.7%). Among those vaccinated with Rotarix®, one experienced transient vomiting and diarrhea, another had intermittent bloody stools for one week, and a third had a single episode of bloody stool. One infant vaccinated with RotaTeq® experienced 2 episodes of non-bloody, watery diarrhea. All symptoms occurred after the first dose, resolving without additional treatment or hospitalization. No adverse events previously reported in the literature, such as fever, intussusception, irritability, seizures, apnea, bloating, bronchospasm, nasopharyngitis, bronchiolitis, Kawasaki disease, allergic reactions, or immune thrombocytopenic purpura, were observed following vaccination.

CONCLUSION: Vaccination has the potential to reduce hospitalization rates, prevent complications associated with rotavirus infection, enhance protection against rotavirus disease. Rotavirus vaccine should be recommended for all infants without contraindications, and parents should be thoroughly informed of its benefits and safety. The findings of this study, based on a limited infant population, provide supportive evidence for the short-term safety of rotavirus vaccines. However, larger, multicenter studies are needed to confirm these results and to further define the safety profile of these vaccines.

Keywords: Rotavirus vaccine; adverse events; Post-Vaccination Monitoring

ÖZET

AMAÇ: Bu çalışmada erken çocukluk döneminde önlenebilir hastane yatışlarının önemli bir nedeni olan rotavirüs aşılaması sonrası oluşan advers olayların değerlendirilmesi amaçlanmıştır.

GEREÇ VE YÖNTEMLER: Gazi Üniversitesi Tıp Fakültesi Hastanesi'nde, sosyal pediatri kliniğinde tüm immünokompetan çocuklara rotavirüs aşısı önerilmektedir. Bu çalışmaya 1 Haziran 2020 ile 31 Aralık 2022 tarihleri arasında rotavirüs aşısı olan sağlıklı bebekler dahil edildi. Ne yazık ki rotavirüs aşıları Türkiye'de hala ulusal bağışıklama programına dahil değildir. Aşılama ve aşı türü kararı doz, maliyet ve etkinlik hakkındaki bilgilere dayanarak ailelerle birlikte verildi. Hastalar her aşı dozundan sonra 1 hafta boyunca günlük izlendi ve aşılama serisinin tamamlanmasından altı ay sonra iletişime geçildi.

BULGULAR: Çalışma süresince 107 sağlıklı bebeğe (ortalama yaş: 4,1 ay) rotavirüs aşısı uygulanmıştır. Bunlardan 11'ine RotaTeq® ve 96'sına Rotarix® uygulandı. Dört bebekte (%3,7) olumsuz olaylar meydana geldi. Rotarix® ile aşılanan bebeklerden birinde geçici kusma ve ishal, bir diğerinde bir hafta boyunca kanlı dışkılama ve üçüncüsünde tek bir kanlı dışkılama görüldü. RotaTeq® ile aşılanan bir bebekte 2 kez kanlı olmayan, sulu ishal görüldü. Tüm semptomlar ilk dozdan sonra ortaya çıktı ve ek tedavi veya hastaneye yatış olmadan düzeldi. Aşılamadan sonra ateş, intususepsiyon, iritabilite, nöbetler, apne, şişkinlik, bronkospazm, nazofarenjit, bronşiolit, Kawasaki hastalığı, alerjik reaksiyonlar, veya immün trombositopenik purpura gibi literatürde daha önce bildirilen hiçbir olumsuz reaksiyon görülmedi.

SONUÇ: Aşılamanın hastaneye yatış oranlarını azaltma, rotavirüs enfeksiyonuyla ilişkili komplikasyonları önleme, rotavirüs hastalığına karşı korumayı artırma potansiyeli vardır. Rotavirüs aşısı kontrendikasyonları olmayan tüm bebeklere önerilmeli ve ebeveynler faydaları ve güvenliği konusunda kapsamlı bir şekilde bilgilendirilmelidir. Bu çalışmada sınırlı sayıda infanttan oluşan bir popülasyonda elde edilen bulgular, rotavirüs aşılarının kısa vadeli güvenliği açısından destekleyici niteliktedir. Ancak bu sonuçların doğrulanması ve aşıların güvenlik profilinin daha kapsamlı biçimde ortaya konabilmesi için, daha geniş örneklemli ve çok merkezli çalışmalara ihtiyaç vardır.

Anahtar sözcükler: Rotavirüs aşısı; advers olay; aşılama sonrası izlem

(1) Department of Pediatric Infectious Diseases, Faculty of Medicine, Gazi University, Ankara, Türkiye.
(2) Department of Pediatrics, Faculty of Medicine, Gazi University, Ankara, Türkiye.
(3) Department of Social Pediatrics, Faculty of Medicine, Gazi University, Ankara, Türkiye.

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Sorumlu Yazar / Corresponding Author:
Nursel ATAY ÜNAL
Address: Department of Pediatric Infectious Disease, Gazi University Faculty of Medicine, Gazi Üniversitesi Tıp Fakültesi Hastanesi E Blok -1.Kat Çocuk Enfeksiyon Hastalıkları Bilim Dalı, 06560 Yenimahalle, Ankara, Turkiye
Tel: +90 506 545 9321
E-mail: nur.sel@hotmail.com

Yazar bilgileri:
Nursel ATAY ÜNAL: 0000-0002-0118-1961, e-mail:nur.sel@hotmail.com
Tuğba BEDİR DEMİRDAĞ1: 0000-0002-6341-1849, e-mail:tugbabedir@gmail.com
Betül ERDOĞDU2: 0009-0007-5437-6504, e-mail: betulerdogdu@gazi.edu.tr
Betül ÖNAL2:0009-0008-3162-4808, e-mail: betulonal@gazi.edu.tr
Meltem POLAT1: 0000-0002-4608-1286, e-mail: meltemtemizhan@gmail.com
Bahar ÇUHACI ÇAKIR3: 0000-0003-1299-8464, e-mail: baharcc44@yahoo.com
Hasan TEZER1: 0000-0001-6871-4112, e-mail: hasantezer@yahoo.com
Aysu DUYAN ÇAMURDAN3: 0000-0001-8384-7423, e-mail: aysucamurdan@yahoo.com
Anıl TAPISIZ1: 0000-0002-6897-8297, e-mail: anilaktas@gazi.edu.tr

INTRODUCTION

Rotaviruses are the most common causes of severe diarrhea in infants and young children (1). Worldwide, approximately 1.7 billion cases of childhood acute gastroenteritis occur each year. In countries where vaccination is not widely implemented, rotavirus is responsible for 35-60% of acute severe diarrhea cases in children under 5 years of age. In developing countries, the case fatality rate of rotavirus infection in children seeking medical care is approximately 2.5%. This rate can be higher in areas with limited access to healthcare services. In 2013, rotavirus was estimated to have caused 215,000 deaths globally (2). Between 2013 and 2017, rotavirus continued to cause an estimated 122,000-215,000 child deaths annually (3-7).

Despite the availability of effective vaccines, rotavirus continues to cause considerable morbidity and mortality, particularly in developing countries. In Türkiye, recent studies report rotavirus positivity rates in children with acute gastroenteritis ranging from 9.8% to 40%, with hospitalization frequently required due to dehydration and related complications. Moreover, nosocomial rotavirus infections have been shown to prolong hospital stays and significantly increase direct medical costs, highlighting the preventable economic burden associated with the disease (8-10).

Rotavirus vaccines are currently not included in Türkiye's national immunization program and must be purchased out-of-pocket by families, leading to unequal access. A recent study among healthcare workers' families found that the rotavirus vaccination rate was only 55.6%, with cost being the most frequently cited barrier (10). This exclusion not only contributes to the ongoing disease burden but also exacerbates disparities in vaccine coverage, particularly among socioeconomically disadvantaged groups. Therefore, generating robust national data on vaccine safety is essential for guiding health policy and supporting the potential integration of rotavirus vaccines into the public immunization schedule. Rotavirus is highly contagious. Its typical clinical features include acute, watery, non-bloody diarrhea, often accompanied by vomiting and fever. In temperate climates, rotavirus infections peak during the cooler, dry seasons. In tropical environments, seasonality is less pronounced. Rotavirus diarrhea can be severe and may lead to severe dehydration which may require hospitalization (4).

Vaccines are available for the prevention of rotavirus, and vaccination is one of the most important measures to reduce severe rotavirus-associated diarrhea, related hospitalizations and mortality (1). By the end of 2023, rotavirus vaccines were introduced in 123 countries, with an estimated global coverage of 55%. Despite over 120 countries implementing national rotavirus vaccination programs, the vaccine is still not part of the routine immunization schedule in our country and is recommended to families as a non-routine vaccine.

Studies involving more than 60,000 infants published to date have shown that these vaccines are both safe and effective, providing protection against severe disease or the need for hospitalization with an efficacy rate of 85%-95% (5). In countries with low socioeconomic status and high mortality rates, moderate efficacy has been reported, with protection against severe rotavirus diarrhea ranging from 50% to over 90% (1). Two live oral rotavirus vaccines are marketed internationally: the monovalent (RV1) Rotarix® and the pentavalent (RV5) RotaTeq® (1,11). RV1 is administered in two doses, and RV5 in three doses, with both vaccines given at min 4-week intervals starting from 6 weeks of age (1). Although global data support their efficacy and safety, concerns regarding vaccine-associated adverse events—such as intussusception, Kawasaki disease, and immune thrombocytopenic purpura (ITP)—persist and have been documented in the literatüre (12,13). While large-scale randomized controlled trials and post-marketing surveillance generally show no significant increase in these adverse outcomes (14,15), their potential occurrence continues to affect public and parental perceptions (10,13). Therefore, monitoring real-world vaccine safety, particularly in countries like Türkiye where vaccines are administered electively and out-of-pocket, is essential for building trust and informing national policy (10). This study aims to evaluate the adverse events following vaccination against rotavirus infection, which is a leading cause of preventable hospitalizations during early childhood.

MATERIAL AND METHOD

Rotavirus vaccination is recommended for all immunocompetent children who are being followed up in the social pediatrics clinic, as part of non-routine vaccinations in Gazi University Faculty of Medicine Hospital, This study included healthy infants who received any of the rotavirus vaccines between June 1, 2020, and December 31, 2022, at our center. The study was conducted in accordance to the ethical principles laid down in the Declaration of Helsinki and its later amendments. Furthermore, approval for the study was obtained from the Gazi University Faculty of Medicine Ethics Committee. The decision to vaccinate and the choice of vaccine type were made together with the families, after sharing information regarding the number of doses, cost, and efficacy. An adverse event was defined as the onset of any new symptom within seven days following vaccine administration that could potentially be attributed to the vaccine. These included vomiting, diarrhea (any deviation from the child's usual pattern), bloody stool, fever, irritability, seizures, apnea, bloating, bronchospasm, nasopharyngitis, rash, cough, hypotonia, decreased appetite, signs suggestive of Kawasaki disease (such as conjunctivitis, lymphadenopathy, mucositis, rash, extremity changes), allergic reactions, and hematochezia. Adverse events were subclassified into gastrointestinal (vomiting, diarrhea, bloody stool), systemic (fever, irritability, seizures), respiratory (bronchospasm, nasopharyngitis), allergic, and other categories. Fever was defined as an axillary body temperature of ≥38.0°C, while diarrhea was defined as the passage of three or more watery or loose stools in a 24-hour period. Bloody stool referred to the visible presence of blood in the stool, and vomiting was defined as one or more episodes of forceful expulsion of gastric contents. Only symptoms that were not present prior to vaccination and that occurred within the defined observation window were considered vaccine-related adverse events. To evaluate the severity of acute gastroenteritis episodes, the Vesikari Clinical Severity Scoring System was utilized. This system assigns points based on the clinical features of gastroenteritis, including the duration of diarrhea (1–3 days = 1 point; 4–5 days = 2 points; ≥6 days = 3 points) and maximum number of diarrhea episodes in 24 hours (1–3 = 1 point; 4–5 = 2 points; ≥6 = 3 points). Similarly, vomiting duration (1 day = 1 point; 2 days = 2 points; ≥3 days = 3 points) and maximum number of vomiting episodes in 24 hours (1–2 = 1 point; 3–4 = 2 points; ≥5 = 3 points) are scored. Fever is rated as <37.1°C = 0 points; 37.1–38.4°C = 1 point; 38.5–38.9°C = 2 points; ≥39.0°C = 3 points. Dehydration severity is scored as none = 0 points; some = 2 points; severe = 3 points. Finally, treatment is scored based on the level of medical intervention needed: no treatment = 0 points; outpatient care = 1 point; hospitalization = 2 points. The total score ranges from 0 to 20. A score of 0–6 indicates mild disease, 7–10 is considered moderate, and a score of ≥11 represents severe gastroenteritis. After vaccination, patients were monitored daily for one week and contacted six months after the completion of the vaccination series. For each patient, the score was recorded in an Excel file. Data were presented as percentages, and the frequency of vaccine-associated adverse events was determined. In patients with vaccine associated adverse events, the duration of symptoms was also noted. Infants with underlying gastrointestinal diseases, known food allergies, respiratory symptoms close to the time of vaccination, recent gastroenteritis symptoms, or other conditions that could cause conflict in the interpretation of vaccine-related adverse events were excluded from the study.

Statistical Analysis

Statistical analysis was performed using SPSS 23.0 software. Descriptive statistics were calculated, presenting means (±SD) for normally distributed numerical data and medians (IQR) for non-normally distributed data, while categorical variables were summarized using absolute frequencies and percentages.

RESULTS

A total of 107 healthy infants received the rotavirus vaccine during the study period. Two infants were excluded from the analysis: one was diagnosed with cow's milk protein allergy during follow-up, and the other developed acute pyelonephritis shortly after vaccination, which could interfere with the assessment of vaccine-related adverse events. The mean age of the infants was 4.1 months (min=2 months, max=7 months, IQR:3-5). The study group consisted of 64 female and 43 male infants. Eleven infants were vaccinated with RotaTeq® and 96 infants with Rotarix®. The demographic characteristics of the vaccinated infants are presented in Table 1.

Table 1. Demographic Characteristics of Vaccinated Infants			
Variable	**Rotarix® (RV1) n = 96**	**RotaTeq® (RV5) n = 11**	**Total n = 107**
Age (months)	Mean ± SD: 4.17 ± 1.15	Mean ± SD: 4.27 ± 1.78	Mean ± SD: 4.18 ± 1.21
Sex, n (%)			
Female	58 (60.4%)	6 (54.5%)	64 (59.8%)
Male	38 (39.6%)	5 (45.5%)	43 (40.2%)
Number of Doses Administered			
First dose	96 (100%)	11 (100%)	107 (100%)
Second dose	96 (100%)	11 (100%)	107 (100%)
Third dose (only RV5)	—	11 (100%)	11 (10.3%)

Four infants (3.7%) experienced adverse events related to vaccination. Adverse events were observed in three patients following the administration of the Rotarix® vaccine. One patient experienced transient vomiting (3 episodes) and diarrhea (2 episodes of non-bloody, non-mucoid, watery stools). Another patient exhibited intermittent bloody stools lasting for one week. In the third patient, a single episode of bloody stool was noted after vaccine administration. One infant who received RotaTeq® experienced diarrhea (2 episodes of non-bloody, non-mucoid, watery stools). In all cases, symptoms were occurred after the first dose. No additional treatment or hospitalization was required for either infant. Follow-up doses were recommended and administered to these infants. None of the infants experienced fever, intussusception, irritability, seizures, apnea, bloating, bronchospasm, nasopharyngitis, bronchiolitis, Kawasaki disease, allergic reactions, or immune thrombocytopenic purpura after vaccination. The frequency, type, and duration of adverse events observed following the administration of Rotarix® and RotaTeq® vaccines are detailed in Table 2.

Table 2. Frequency, Type, and Duration of Adverse Events by Vaccine Type					
Adverse Event Category	**Specific Event**	**Rotarix® (RV1) n = 96**	**RotaTeq® (RV5) n = 11**	**Total n = 107**	**Duration of Symptoms**
–	**Any adverse event**	3 (3.1%)	1 (9.1%)	4 (3.7%)	1 day – 7 days (range)
Gastrointestinal	Vomiting	1 (1.0%)	0 (0.0%)	1 (0.9%)	1 day
	Diarrhea	1 (1.0%)	1 (9.1%)	2 (1.9%)	1 day
	Bloody stool	2 (2.1%)	0 (0.0%)	2 (1.9%)	1-7 days†
	Intussusception	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Systemic	Fever	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
	Irritability	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
	Seizures	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Respiratory	Bronchospasm	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
	Nasopharyngitis	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Allergic	Allergic reaction	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Other	Kawasaki Disease	0 (0.0%)	0 (0.0%)	0 (0.0%)	—

† One patient exhibited intermittent bloody stools lasting for one week, while another had a single episode of bloody stool following vaccine administration.

DISCUSSION

Our study found a low rate (3.7%) of vaccine-associated adverse events following rotavirus vaccination, and no serious complications such as intussusception, Kawasaki disease, or immune thrombocytopenic purpura were observed. This rate is markedly lower than those reported in large-scale clinical trials, where mild adverse events such as vomiting and diarrhea were observed in up to 19% of cases (14). Compared to a recent VAERS-based safety review reporting vomiting in 9.8%, diarrhea in 10.1%, and intussusception in up to 1.9% of vaccinated infants (13), our findings indicate a more favorable safety profile, though this could partially be attributed to the limited sample size. It remains uncertain whether the low incidence of adverse events in our study reflects true vaccine safety or is influenced by underreporting or limited statistical power. Nonetheless, the absence of serious adverse events supports the established safety profile of rotavirus vaccines in similar cohorts. In pre-licensure studies, mortality rates (<0.1%) and the incidence of serious adverse events (approximately 2.5%) were reported to be similar between the vaccine and placebo groups (14,16). No fatalities or serious adverse events were observed in our study.

It is well established that currently available rotavirus vaccines have similar efficacy and safety profiles (1). In one infant vaccinated with Rotarix®, short-term vomiting and an increase in the frequency of watery stools were observed; bloody stools were observed in two patients. An increase in the frequency of watery stools was also observed in one infant vaccinated with RotaTeq®. The duration of symptoms in three infants were of less than 24 hours' duration. In one patient, the symptoms persisted for one week. Adverse events in all infants occurred after the first dose of the vaccine. According to the literature, high rates of adverse events, including fever (approximately 42%), vomiting (approximately 13%), and diarrhea (approximately 19%), have been reported in both the vaccine and placebo groups, all of which were mild (16). Compared with the literature, lower adverse events were observed in our study. None of the patients experienced irritability, bloating, intussusception, bronchospasm, nasopharyngitis, seizures, Kawasaki disease, allergic reactions, or immune thrombocytopenic purpura following vaccination.

A Cochrane review of the four rotavirus vaccines that have received prequalification from the World Health Organization demonstrated that no increased risk of intussusception was observed after any dose in randomized controlled trials of each vaccine, which is consistent with the data from our study (14). However, post-marketing evaluations of rotavirus vaccines have found that the risk of intussusception varies depending on the vaccine and the region where the study was conducted. In many high- and middle-income countries, the incidence of intussusception has been documented as low, with 1-6 cases of intussusception per 100,000 vaccinated infants for both Rotarix® and RotaTeq® (17). A safety study of Rotarix® in 63,225 infants vaccinated at 2 and 4 months of age showed no increased risk of intussusception (15). At this point, it is important to emphasize that the benefits of rotavirus vaccination outweigh the small risk of intussusception.

Although cases of Kawasaki disease have been reported in clinical trials and post-marketing surveillance of rotavirus vaccines, no evidence of an association was found in the surveillance of over 2 million doses of rotavirus vaccine administered to infants born between 2006 and 2017 (12). In our study, no cases of Kawasaki disease were recorded during the follow-up period.

A Vaccine Adverse Event Reporting System (VAERS) -based study on rotavirus vaccines reported 9.8% of events linked to Rotarix®, 86.2% to RotaTeq®, and 4.0% to unknown brands (13). The analysis included 17,750 safety reports and 50,650 vaccine-event pairs. Of these, 9,784 (55.1%) adverse events were reported in children under six months of age, with most cases involving gastrointestinal disorders. The most frequently reported and statistically significant adverse events following immunization were non-serious events. These included fever (1,935 events, Reporting Odds Ratio (ROR) 1.17 [95% CI 1.12–1.22]), vomiting (1,746 events, ROR 3.19 [95% CI 3.04–3.34]), diarrhea (1,672 events, ROR 5.75 [95% CI 5.48–6.04]), crying (1,273 events, ROR 7.80 [95% CI 7.38–8.25]), and irritability (1,254 events, ROR 7.68 [95% CI 7.26–8.12]). A total of 962 cases of intussusception were reported, with a significantly elevated ROR of 27.23 [95% CI 25.51–29.07]. Furthermore, Kawasaki disease was reported in 54 cases, with an ROR of 14.61 [95% CI 10.96–19.49]. This study provides valuable insights into the safety profile of rotavirus vaccines, emphasizing the importance of continued monitoring and evaluation of vaccine-associated adverse events.

The known benefits of oral vaccination outweigh the risks of known adverse events. In 2013, rotavirus-related deaths accounted for approximately 3.4% of all child deaths, with a cause-specific mortality rate of 33 per 100,000 children under the age of 5 (7). The global impact of the rotavirus vaccine is clearly demonstrated by the analysis of data from 69 countries participating in the Global Rotavirus Surveillance Network, which showed a 40% reduction in rotavirus prevalence after the introduction of the vaccine, as well as reductions in rotavirus-related hospitalizations, overall acute gastroenteritis hospitalizations, and gastroenteritis-related deaths in various countries (18). Between 2013 and 2017, an estimated 122,000-215,000 child deaths occurred annually due to rotavirus, representing a 59%-77% decrease since the year 2000 (3,7,19,20).

From a national perspective, Türkiye continues to bear a substantial rotavirus burden. For instance, Barutçu et al. reported a 40% positivity rate for rotavirus in children with acute gastroenteritis in Şanlıurfa and highlighted that hospitalization rates were significantly higher among rotavirus-positive children (8). A study comparing community-acquired and nosocomial rotavirus infections showed that nosocomial cases prolonged hospital stays by an average of six days and significantly increased healthcare costs, with direct hospitalization expenses rising from approximately $120 to $175 USD. Despite this burden, rotavirus vaccines are still not included in Türkiye's national immunization program and must be purchased out-of-pocket (9). Moreover, a recent national study focusing on healthcare workers' families revealed that although awareness levels were high, the rotavirus vaccination rate was only 55.6%, with cost being the primary barrier (10). These studies collectively support the urgent need for including rotavirus vaccines in Türkiye's national immunization program. Our data further strengthen this case by demonstrating real-world safety in a clinical setting and underscoring the opportunity to prevent both medical and economic consequences through broader vaccine coverage. This study has several strengths. It provides real-world safety data on rotavirus vaccination in a clinical setting and contributes to national literature in a context where rotavirus vaccines are not yet part of the routine immunization program. The structured follow-up protocol, including both short-term and longer-term monitoring, allowed for detailed assessment of adverse events. Additionally, the exclusion of infants with underlying conditions minimized confounding factors. However, the study has limitations, including its single-center design, relatively small sample size, and reliance on parental reporting, which may lead to underreporting or recall bias. Another limitation is the potential underreporting of mild or transient adverse events. Since data collection relied partially on parental reporting, some mild symptoms may have gone unnoticed or unreported, leading to possible underestimation of the true incidence of adverse events. Future studies incorporating objective clinical follow-up or electronic monitoring tools may improve the accuracy of event detection. Moreover, the imbalance between the number of participants receiving RV1 and RV5 vaccines limits the ability to compare the safety profiles of the two vaccine types comprehensively. Multicenter studies with larger and more balanced cohorts are needed to further validate these findings. In conclusion, the findings of this study, based on a limited infant population, provide supportive evidence for the short-term safety of rotavirus vaccines. The administration of rotavirus vaccines has the potential to reduce hospitalization rates, prevent complications associated with rotavirus infection, improve protection against rotavirus disease in children. The rotavirus vaccine should be recommended for all infants without contraindications, and parents should be adequately informed about its benefits and safety. However, larger, multicenter studies are needed to confirm these results and to further define the safety profile of these vaccines.

Conflict of Interest: The authors have no conflicts of interest to declare.

Researchers' Contribution Rate Statement: Concept/Design: NAÜ, TBD, BE, BÖ, BÇÇ, ADÇ, HT, MP, AT; Analysis/Interpretation: NAÜ, TBD, BE, BÖ, BÇÇ, ADÇ, HT, MP, AT; Data Collection: BE, BÖ, NAÜ, TBD; Writer: NAÜ, TBD, AT; Critical Review: NAÜ, AT; Approver: AT. All authors reviewed the results and approved the final version of the article.

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