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Original article

Investigation of the safety of measles–mumps–rubella vaccine in children with food allergies

Enquête sur la sécurité du vaccin contre la rougeole, les oreillons et la rubéole chez les enfants atteints d'allergies alimentaires

H. Yağmur[a,*], Ö. Kangalli Boyacioğlu[b], S. Asilsoy[a], D. Baysal Bakir[a], G. Kabadayi[a], D. Tezcan[a], Ö. Atay[a], N. Uzuner[a]

[a] *Department of Pediatric Allergy and Immunology, Dokuz Eylul University, İzmir, Turkey*
[b] *Department of Pediatric Allergy and Immunology, Kahramanmaraş Necip Fazıl City Hospital, Kahramanmaraş, Turkey*

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ABSTRACT

Study objective. – This study investigated the reaction frequency to the measles, mumps, rubella (MMR) vaccine and symptoms during this process in patients with egg allergy (EA) and/or cow's milk allergy (CMA).
Patients and methods. – Patients diagnosed with CMA and/or EA were studied and followed up at the Department of Pediatric Allergy and Immunology, Dokuz Eylul University Faculty of Medicine, between December 2021 and December 2022. These patients were vaccinated with MMR vaccine (MMR vaccine from the Serum Institute of India Pvt. Ltd.). Demographic data, clinical findings, laboratory tests, and reactions following vaccination were reviewed.
Results. – Overall, 62 patients with median age of 12 months, including 46.8% males, were investigated; 56.5%, 40.3%, and 3.2% were followed up for atopic dermatitis, urticaria, and anaphylaxis, respectively. Moreover, 44% had EA, 21% had CMA, and 35% had CMA and EA (CM&EA). Among the CMA and CM&EA groups, allergen-specific immunoglobulin E (Sp IgE) for milk and total IgE levels were significantly different ($P < 0.001$). Significant differences were observed in Sp IgE levels and skin prick test (SPT) results for milk among the EA and CM&EA groups ($P < 0.017$). Anaphylactic reactions occurred in five patients following MMR vaccination. All these patients had CMA; no mortalities were reported.
Conclusion. – Patients with food allergies should be evaluated before MMR vaccination. No reactions were observed in the group allergic to eggs. All patients who experienced reactions had CMA. This suggests that milk allergy is a significant risk factor for adverse reactions compared to EA.
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Mots clés :
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RÉSUMÉ

Objectif de l'étude. – Cette étude a examiné la fréquence des réactions au vaccin contre la rougeole, les oreillons et la rubéole (ROR) et les symptômes au cours de ce processus chez les patients souffrant d'allergie aux œufs (AE) et/ou d'allergie au lait de vache (ALV).
Patients et méthodes. – Les patients diagnostiqués avec ALV et/ou AE ont été étudiés et suivis au Département d'allergie et d'immunologie pédiatriques de la Faculté de médecine de l'Université l'Université Dokuz Eylul, entre décembre 2021 et décembre 2022. Ces patients ont été vaccinés avec le vaccin ROR (vaccin ROR du Serum Institute of India Pvt. Ltd.). Les données démographiques, les résultats cliniques, les tests de laboratoire et les réactions après la vaccination ont été examinés.

* Corresponding author.
E-mail address: halimeyagmur@hotmail.com (H. Yağmur).

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Résultats. – Soixante-deux patients d'âge médian de 12 mois, dont 46,8 % garçons, ont été étudiés ; 56,5 %, 40,3 % et 3,2 % ont été suivis pour dermatite atopique, urticaire et anaphylaxie, respectivement. Quarante-quatre pour cent souffraient d'AE, 21 % d'APLV et 35 % d'APLV et d'AE (APL&AE). Parmi les groupes APLV et APL&AE, les taux d'immunoglobuline E spécifique à l'allergène (Sp IgE) pour le lait et les taux d'IgE totales étaient significativement différents ($p < 0{,}001$). Des différences significatives ont été observées dans les taux d'IgE Sp et les résultats des tests cutanés (DTC) pour le lait parmi les groupes EA et APL&AE ($p < 0{,}017$). Des réactions anaphylactiques sont survenues chez cinq patients après la vaccination ROR. Tous ces patients souffraient d'APLV ; aucun décès n'a été signalé.

Conclusion. – Les patients souffrant d'allergies alimentaires doivent être évalués avant la vaccination ROR. Aucune réaction n'a été observée dans le groupe allergique aux œufs. Tous les patients qui ont présenté des réactions étaient atteints d'APLV. Cela suggère que l'allergie au lait est un facteur de risque significatif d'effets indésirables par rapport à l'AE.

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1. Introduction

Food allergies are an increasingly common issue worldwide, particularly in early childhood, where allergies to cow's milk and egg proteins can significantly impact infant nutrition. The approach to vaccinating infants with food allergies is crucial during this period. Despite the benefits of vaccination, some individuals still suffer from vaccine-preventable diseases due to opposition to vaccination [1,2]. Anaphylactic reactions following vaccination are considered a major contraindication to routine childhood vaccinations.

Vaccines can cause allergic reactions due to proteins and adjuvants in their formulations. Cow's milk and egg proteins, in particular, are present in several vaccines. Examples include the influenza, yellow fever, measles–mumps–rubella (MMR), and diphtheria–tetanus–pertussis (DTaP, Tdap, Td) vaccines [3]. The MMR vaccine, particularly, contains egg protein, which has long been associated with complications in children with allergies. However, previous studies have suggested that reactions to vaccines are more often caused by other substances, such as gelatin, neomycin, and latex, rather than egg protein itself. As a result, the MMR vaccine can generally be administered safely to children with egg allergies [4,5]. In Turkey, the Priorix® vaccine (GlaxoSmithKline) was previously used. Since 2021, however, the measles, mumps, rubella vaccine from the Serum Institute of India Pvt. Ltd. has been introduced. It is recommended that the MMR vaccine should not be administered to patients with a history of anaphylaxis to egg protein. Caution should also be exercised, and it may be preferable to avoid administering it to patients with milk allergy.

This study aimed to investigate the frequency of vaccine reactions and the associated symptoms in children with EA and/or CMA —the most prevalent food allergies— who were vaccinated with the MMR vaccine (Serum Institute of India Pvt. Ltd.) at our clinic.

2. Materials and methods

2.1. Population

Patients diagnosed with EA and/or CMA and followed up at the Pediatric Allergy and Immunology outpatient clinic of our hospital between December 2021 and December 2022 were investigated. These patients were vaccinated with the MMR vaccine (Measles, Mumps, Rubella - Serum Institute of India Pvt. Ltd.), which is part of our clinic's routine vaccination schedule.

Demographic data, clinical findings, diagnoses, skin prick test (SPT) results, total IgE levels, eosinophil counts, allergen-specific IgE (Sp IgE) levels, and reactions following vaccination were recorded. As part of routine practice, allergic patients were vaccinated and observed for at least 4 hours. Diagnosis was based on clinical history, examination, and laboratory tests, with food allergies confirmed based on the removal of suspected allergens (egg and/or cow's milk) from the diet. Each patient underwent a systemic examination prior to vaccination, and physical findings were evaluated both before and after vaccination.

2.2. SPT and Sp IgE measurement

SPTs for allergenic substances were performed on all patients by our dedicated personnel, using histamine as a positive control and saline as a negative control. Adverse conditions and medications that could affect the skin tests were avoided. Prick-to-prick skin tests were conducted using the food itself as the allergen. A skin induration of ≥ 3 mm compared to the negative control, along with Sp IgE levels of ≥ 0.35 kUA/L measured using CAP-FEIA (ImmunoCAP-Fluorescence Enzyme Immunoassay System)/(Thermo Fisher Scientific, Uppsala, Sweden), were considered positive.

2.3. Ethics approval

Ethical approval for the study was obtained from the Dokuz Eylul University Faculty of Medicine Local Ethics Committee (Decision No: 2024/01-08).

2.4. Statistical analysis

The Statistical Package for the Social Sciences (SPSS, IBM) Version 26 software was used for data analysis. Normality of the study data was assessed using the Kolmogorov–Smirnov test. Descriptive statistics for patient information and blood parameters are presented as counts (n), percentages (%), minimum values, maximum values, and medians with interquartile ranges (IQRs). Comparisons between patients with and without post-vaccination allergic reactions, as well as those with both EA and CMA, were conducted using the Chi-squared test and the Mann–Whitney U test. A P-value of < 0.05 was considered statistically significant. For multiple comparisons, significance values were adjusted using the Bonferroni correction, with a corrected P-value threshold of < 0.017 considered statistically significant.

3. Results

In the study, 62 patients were evaluated, with a median age of 12 months (range: 9–72 months), including 46.8% males. Of these

Table 1
Medical records of the patients.

	n	%	Median (IQR)	Min–Max
Sex and age (months)			12 (1)	9–72
Male	29	46.8	12 (0)	9–15
Female	33	53.2	13 (1)	9–72
Diagnosis				
Atopic dermatitis	35	56.5		
Urticaria	25	40.3		
Anaphylaxis	2	3.2		
Eos number (mm^3/L)			400 (500)	100–9500
Total IgE ([IU]/mL)			52.3 (101.3)	3–794
Sp IgE egg white (kU/L)			4.24 (14.29)	0–100
Sp IgE egg yolk (kU/L)			1.25 (5.20)	0–100
Sp IgE milk (kU/L)			0.21 (2.78)	0–100
SPT egg white (mm)			7.5 (7)	0–18
SPT egg yolk (mm)			4 (5)	0–14
SPT milk (mm)			1.5 (5)	0–19
Cow's milk and/or egg allergy				
Cow's milk	13	21		
Eggs	27	43.5		
Cow's milk and eggs	22	35.5		
Family history of allergy				
Yes	22	35.5		
No	40	64.5		

n: number; %: percent; IQR: Interquartile range; Min–Max: minimum–maximum; SPT: skin prick test; Eos: eosinophil; IgE: immunoglobulin; Sp IgE: specific IgE.

patients, 56.5% were diagnosed with atopic dermatitis, 40.3% with urticaria, and 3.2% with anaphylaxis. A parental history of allergy was noted in 35.5% ($n = 22$) of the cases. Among the patients, 44% ($n = 27$) had EA, 21% ($n = 13$) had CMA, and 35% ($n = 22$) had CM&EA. Data on eosinophil counts, total and Sp IgE values, SPT results, and family history of allergy are provided in Table 1.

A review of SPT results indicated that egg white was positive in 50 cases, egg yolk in 44 cases, and cow's milk in 41 cases. The eosinophil count was 400 cells/mm^3 (range: 100–9500 cells/mm^3), and eosinophils constituted 3.8% of the total white blood cells (range: 1%–38%). Total IgE levels were 52.3 IU/mL (range: 3–794 IU/mL). The IQR for Sp IgE levels was as follows: egg white 4.24 kU/L, egg yolk 1.25 kU/L, and milk 0.21 kU/L (range: 0–100 kU/L).

A comparison between the CMA, EA, and CM&EA groups revealed no significant differences in sex, age, patient diagnosis, eosinophil count, eosinophil percentage, or family history of allergy ($P = 0.099$, $P = 0.826$, $P = 0.207$, $P = 0.514$, and $P = 0.294$, respectively).

A comparison between the CMA and CM&EA groups showed significant differences in Sp IgE levels for milk and total IgE levels ($P < 0.001$ and $P < 0.002$, respectively). However, no significant difference was found in milk SPT results ($P = 0.279$). There were no significant differences between the CM&EA and EA groups in Sp IgE levels for egg white and yolk, SPT results for egg white and yolk, or total IgE levels ($P = 1.000$ for all comparisons; $P = 0.225$ and $P = 0.115$ for total IgE, with $P > 0.017$ as the threshold). Significant intergroup differences were observed in Sp IgE levels and SPT results for milk ($P < 0.001$ for both) (Table 2).

Anaphylactic reactions following MMR vaccination were observed in five patients ($n = 5/62$, i.e., 8%) in this study. Of these, three were female and two were male. In the first case, symptoms of urticaria, pruritus, respiratory distress, and nausea occurred 10 minutes after vaccination. In the second, third, and fifth cases, symptoms including restlessness, intense crying, and urticaria on the face and trunk occurred at 5, 10, and 15 minutes after vaccination, respectively. The fourth case presented with restlessness, generalized urticaria, and respiratory distress at 3 minutes after vaccination. Adrenaline was intramuscularly administered (0.01 mg/kg/dose) promptly to all patients diagnosed with anaphylaxis. Oral antihistamines and inhaled beta agonists were also provided to those with respiratory distress. No patient required additional doses of adrenaline. All affected patients had CMA and were followed up for urticaria, anaphylaxis, and atopic dermatitis. Additional patient data are provided in Table 3.

Eosinophil percentage, eosinophil count, total IgE levels, Sp IgE levels for milk, and median SPT values for milk were higher in patients who experienced allergic reactions upon vaccination compared to those who did not ($P = 0.003$, $P = 0.007$, $P = 0.010$, $P < 0.001$, and $P < 0.001$, respectively). No reactions were observed in the EA group. The presence of CMA was a significant factor in the occurrence of reactions.

4. Discussion

This study investigated reactions in patients with CMA and/or EA following administration of the MMR vaccine containing alpha-lactalbumin. A history of milk allergy, rather than EA, was identified as a significant risk factor. Clinicians should be alerted to act upon elevated Sp IgE levels, increased SPT diameter values, and the severity of symptoms at the time of diagnosis.

Vaccines are among the most effective preventive measures for protecting children and communities against infections. From birth, children receive various vaccines according to the vaccination schedules established by each country. Hypersensitivity reactions may occur due to components such as culture residues (milk, egg, *Saccharomyces cerevisiae*), adjuvants (aluminum salts, polysorbate), stabilizers (gelatin), antibiotics (neomycin, gentamicin), latex, and microbiological substances present in these vaccines [6,7].

Previous studies have investigated reactions to the MMR vaccine and suggested that allergic reactions were more likely associated with adjuvants in the vaccine rather than with egg or milk proteins. Kwittken et al. reported an anaphylactic reaction in a 7-year-old patient without food allergies, which was attributed to neomycin in the MMR vaccine [8]. In another study, a 3-year-old patient without food allergies had a positive patch test with 20% neomycin and experienced erythema and swelling in the ear after using ear drops containing neomycin. However, this study reported no reaction following MMR vaccination [4].

Although previous studies have reported neomycin-induced vaccine reactions [8], there are also reports of no reactions upon vaccination, even when tests were positive for cow's milk, egg, and neomycin [4]. A Japanese study initially observed high rates of allergic reactions to the MMR vaccine containing neomycin and

Table 2
Classification of cases by food allergies.

	Cow's milk allergy[a] (*n* = 13)	Egg allergy[b] (*n* = 27)	Cow's milk and egg allergies[c] (*n* = 22)	*P*	*P****[b,c]
Sex, *n* (%)					
Male	9 (69.2%)	13 (48.1%)	7 (31.8%)	0.099*	
Female	4 (30.8%)	14 (51.9%)	15 (68.2%)		
Age, months (IQR)	12 (2)	12 (1)	12 (1)	0.826**	
Diagnosis, *n* (%)					
Atopic dermatitis	4 (30.8%)	17 (63%)	14 (63.6%)	0.207*	
Urticaria	9 (69.2%)	9 (33.3%)	7 (31.8%)		
Anaphylaxis	-	1 (3.7%)	1 (4.5%)		
Eos number (mm^3/L)	300 (700)	400 (400)	350 (450)	0.514**	
Sp IgE egg white (kU/L)	0 (0)	6.2 (16.3)	7.3 (37.1)		1.000
Sp IgE egg yolk (kU/L)	0 (0)	2.1 (5.1)	2.4 (16.5)		1.000
Total IgE ([IU]/mL)	93.3 (406)[b,c]	27 (49.2)	65 (165)	**0.002****	0.115
Sp IgE milk (kU/L)	11.2 (68.1)[b,c]	0 (0)	1.3 (11.6)	**< 0.001****	**< 0.001**
SPT egg white (mm)	0 (0)	9 (3)	9 (7)		1.000
SPT egg yolk (mm)	0 (0)	4 (2)	5 (2)		0.225
SPT milk (mm)	6 (5)	0 (0)	5 (5)	0.279***a-c***	**< 0.001**
Family history of allergy, *n* (%)					
Yes	7 (53.8%)	8 (29.6%)	7 (31.8%)	0.294*	
No	6 (46.2%)	19 (70.4%)	15 (68.2%)		

n: number; %: percent; IQR: Interquartile range; Eos: eosinophil; Sp IgE: specific IgE; IgE: immunoglobulin; SPT: skin prick test; *: Chi-Squared test; **: Mann–Whitney U Test (IQR); ***Significance values were adjusted by Bonferroni correction for multiple tests ($P = 0.017$).

[a] Cases with cow's milk allergy

[b] Cases with egg allergy.

[c] Cases with both cow's milk and egg allergy.

Table 3
Data of cases with reactions after MMR vaccination.

n = 5	Case 1	Case 2	Case 3	Case 4	Case 5
Age (months)	42	12	13	72	12
Sex	Female	Female	Male	Female	Male
Diagnosis	Urticaria	Anaphylaxis	Atopic dermatitis	Urticaria	Urticaria
History of allergic disease in the family	No	No	No	Yes	No
Allergenic food	Cow's milk	Cow's milk and eggs	Cow's milk and eggs	Cow's milk	Cow's milk
Type of reaction associated with vaccine	Anaphylaxis	Anaphylaxis	Anaphylaxis	Anaphylaxis	Anaphylaxis
Total IgE ([IU]/mL)	378	223	42	537	650
Eosinophils (mm^3/L)	700	9500	400	1000	1200
Milk Sp IgE (IU/mL)	> 100	79	17.1	> 100	85.6
Egg white Sp IgE (IU/mL)	< 0.10	3.6	22.6	< 0.10	< 0.10
Egg yolk Sp IgE (IU/mL)	< 0.10	5.3	14.4	< 0.10	< 0.10
Milk SPT (mm)	10	19	15	15	12
Egg white SPT (mm)	Negative	17	11	Negative	Negative
Egg yolk SPT (mm)	Negative	10	10	Negative	Negative

n: number; IgE: immunoglobulin; SPT: skin prick test; Sp IgE: specific IgE.

0.2% gelatin [5]. However, following the development of a gelatin-free vaccine in consultation with the manufacturer, these reactions were nearly eliminated after 1998 [9,10].

Reactions to the MMR vaccine may occur in patients with EA; however, such instances are rare [11,12]. Most studies have supported the vaccine's safety, noting that it contains egg allergens at picogram levels [6]. In cases of CMA, reactions may be observed with diphtheria–tetanus–pertussis (DTaP, Td, Tdap) and MMR vaccines. Due to the very low content of milk protein in these vaccines, individuals with CMA generally tolerate them well [13]. However, the MMR vaccine procured by the Ministry of Health in Turkey after 2021 contains unknown amounts of alpha-lactalbumin. With the increasing prevalence of food allergies in Turkey, particularly to cow's milk, post-vaccination reactions have been increasingly reported, especially in recent cases involving CMA [14–16].

In the present study, all patients were vaccinated according to the vaccination scheme in place in Turkey starting from birth [17]. This indicates that trace amounts of aluminum, neomycin, and gelatin in the diphtheria–tetanus–pertussis vaccine were repeatedly administered to our patients without causing reactions. Regarding milk allergens, no reactions were observed with the nanogram levels of casein in the diphtheria–tetanus–pertussis vaccine. However, reactions did occur following MMR vaccination, which contains an unknown amount of alpha-lactalbumin. Therefore, the reactions observed in this study were not associated with the adjuvants in the vaccine, although we were unable to confirm this through in vitro or in vivo tests (e.g., basophil activation tests with aluminum, neomycin/gentamicin, gelatin, lymphocyte transformation tests, SPTs, or patch tests) [4,8].

Casein and whey proteins are the most common causes of allergic reactions among cow's milk proteins. Allergic reactions are generally prolonged in patients with higher casein levels [18],

whereas alpha-lactalbumin, a whey protein, is rapidly absorbed from the intestinal epithelium and can quickly trigger allergic reactions [19]. Although we did not specifically test for casein and whey proteins in our patients, their prior vaccinations support the hypothesis that the reactions were likely caused by the rapidly absorbed alpha-lactalbumin. Additionally, no reactions were observed with the Priorix® vaccine in patients previously monitored at our clinic for CMA. However, reactions increased with the administration of the Indian-origin vaccine, based on clinical follow-up observations.

Regarding another allergen, eggs, the MMR vaccine is produced using chicken embryo cultures. It has been reported that the vaccine can be safely administered to children with EA [6]. Additionally, Turkish studies have reported no serious reactions to the vaccine in cases of EA. In our study, no reactions were observed with the MMR vaccine in patients with EA alone. This suggests that a history of milk allergy, rather than EA, is a more significant concern.

In conclusion, hypersensitivity reactions can occur with any vaccination. Patients with food allergies should be thoroughly evaluated before receiving vaccines, particularly if the vaccine contains alpha-lactalbumin, as the quantity in the vaccine is unknown. Because of the busy schedules within the Turkish healthcare system, the authors conducted direct vaccinations in our clinic after informing and obtaining consent from the parents.

In high-risk cases, desensitization may be considered after testing with SPTs and the vaccine. However, it is important to note that anaphylaxis can also occur during this procedure. For patients with milk protein allergy, MMR vaccination should be administered in clinics with specialists trained to manage any potential reactions, including anaphylaxis.

4.1. Limitations of the study

The relatively small sample size limits the generalizability of the study results to the general population. However, the study still provides valuable insights into predicting reactions to vaccination. Additionally, data on the current reactions of patients with food allergies were not available.

Disclosure of interest

The authors declare that they have no competing interest.

Contribution

All authors contributed significantly to the design and development of the manuscript, analysis of the results, and preparation of the manuscript. They are responsible for approving the final version and its processing.

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