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Comparison of Simultaneous and Separate Administration of MenACWY-TT (Nimenrix®) and 4CMenB (Bexsero®) Vaccines in Childhood in Terms of Fever and Other Side Effects

Çocukluk Çağında MenACWY-TT (Nimenrix®) ve 4CMenB (Bexsero®) Aşılarının Birlikte ve Ayrı Zamanlarda Uygulamanın Ateş ve Diğer Yan Etkiler Açısından Kıyaslanması

Fatih Fakirullahoğlu[1](İD), Derya Susam[2](İD), Hatice Gülhan Sözen[1](İD)

[1] *Clinic of Pediatrics, Bahçeşehir University Faculty of Medicine, Medical Park Göztepe Hospital, İstanbul, Türkiye*
[2] *Bahçeşehir University Faculty of Medicine, İstanbul, Türkiye*

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Abstract

Objective: *Neisseria meningitidis* is a gram-negative diplococcus that causes meningitis and invasive meningococcal disease. Vaccination offers protection against this pathogen, and different effective vaccines are available for different serogroups. Among these are MenACWY-TT (Nimenrix®), targeting serogroups A, C, W, and Y, and 4CMenB (Bexsero®), targeting serogroup B. Since meningococcal vaccines are not included in the national immunization schedule, they are administered upon physician recommendation and parental request. The most common side effects are fever and irritability. This study aimed to compare the incidence of fever and other adverse effects between the simultaneous and separate administration of Nimenrix and Bexsero vaccines.

Material and Methods: Between February 2017 and September 2024, we evaluated the side effects of Nimenrix and Bexsero vaccines administered simultaneously at different anatomical sites and at different times in our outpatient clinic.

Results: Our findings showed that the simultaneous administration of Nimenrix and Bexsero did not increase the incidence of fever (26.6%). Bexsero administered alone resulted in a higher rate of fever (43.7%). In contrast, the group that received only Nimenrix had a significantly lower incidence of fever (8.4%).

Öz

Giriş: *Neisseria meningitidis* gram-negatif bir diplokok olup menenjit ve invaziv meningokok hastalığına neden olmaktadır. Bu etkenden aşılanmayla korunmak mümkün olup farklı serogruplara karşı farklı etkin aşılar bulunmaktadır. A, C, W ve Y suşlarına yönelik MenACWY-TT (Nimenrix®) ve B suşuna yönelik 4CMenB (Bexsero®) bu aşılar arasındadır. Ulusal aşı takviminde yer almaması nedeniyle hekimlerin önerisi ve ailelerin istekleri ile yapılabilen meningokok aşılarının en sık görülen yan etkileri ateş ve huzursuzluktur. Bu çalışmada, Nimenrix ve Bexseronun birlikte ve ayrı zamanlarda uygulamanın ateş ve diğer yan etkiler açısından kıyaslanması amaçlandı.

Gereç ve Yöntemler: 2017 Şubat-2024 Eylül tarihleri arasında polikliniğimizde, aynı anda farklı bölgelerden birlikte uyguladığımız ve teker teker farklı zamanlarda uyguladığımız Nimenrix ve Bexsero aşılarının yan etkileri karşılaştırılmıştır.

Bulgular: Çalışmamızda, Nimenrix ve Bexsero aşılarının aynı anda uygulanmasının ateş (%26.6) oranlarını artırmadığı, hatta Bexsero aşısının tek başına yapılmasının daha fazla oranda ateşe (%43.7) neden olduğu saptanmıştır. Tek başına Nimenrix yapılan grupta ise bu oran %8.4 olarak tespit edilmiştir.

Correspondence Address/Yazışma Adresi

Fatih Fakirullahoğlu

Clinic of Pediatrics, Bahçeşehir University
Faculty of Medicine, Medical Park Göztepe Hospital
İstanbul, Türkiye

E-mail: dr.fatihfakirullah@gmail.com

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Conclusion: Considering adverse effects and national vaccination practices, we suggest that both vaccines can be safely administered simultaneously at 3, 5, and 13 months.

Keywords: Meningococcus, meningococcal vaccines, nimenrix, bexsero, adverse effects

Sonuç: Sonuç olarak yan etki ve ulusal aşı takvimi değerlendirildiğinde her iki aşının 3.- 5. ve 13. aylarda aynı anda uygulanmasının uygun olacağını düşünmekteyiz.

Anahtar Kelimeler: Meningokok, meningokok aşıları, nimenrix, bexsero, yan etki

Introduction

Neisseria meningitidis is a gram-negative diplococcus that causes meningitis and invasive meningococcal disease (IMD). Global data from 2010–2018 show that serogroup B (MenB) has become the leading cause of IMD, while serogroup C (MenC) remains endemic. Rising trends have also been reported for serogroups W (MenW) and Y (MenY) (1).

In a multicenter study from Türkiye (2017-2018), *N. meningitidis* was the most frequent pathogen in bacterial meningitis. Serogroups B (54.7%) and W (7.5%) were most common, with 34.8% of the cases in children under one year (2). These findings emphasize the importance of early vaccination. In a prior study (2013-2014), serogroup W accounted for 42.4% and B for 32.9% (3). This variability over time underscores the need for early protection against both serogroups (4).

Vaccines offer effective protection against IMD. Available types include conjugate tetravalent, recombinant monovalent, and newer conjugate pentavalent vaccines (5). Nimenrix is a conjugate tetravalent vaccine (MenACWY-TT), approved from six weeks of age, with two doses two months apart and a booster at 12 months (6).

4CMenB vaccine Bexsero targets serogroup B through reverse vaccinology. It is approved for use from two months of age, with two primary doses given two months apart and a booster dose recommended between 12 and 15 months of age (7).

The pentavalent conjugate vaccine Penbraya (MenACWY-TT/MenB-FHbp) targets individuals aged ≥10 years, especially where both MenACWY and MenB coverage is needed (8). Thus, protection against serogroups A, C, W, Y, and B in early childhood requires two separate vaccines.

This study compares side effects, particularly fever and irritability, of MenACWY-TT (Nimenrix) and MenB-4C (Bexsero), which are not yet included in the national immunization program of Türkiye and are administered upon physician recommendation or parental request. It also aims to inform future decisions on their inclusion and optimal scheduling.

Materials and Methods

This retrospective observational cohort study was conducted after obtaining approval from the Bahçeşehir University Clinical Research Ethics Committee (Approval number: 2024-03/02), dated October 16, 2024. The ethics approval covered the retrospective evaluation of data from patients vaccinated between February 2017 and September 2024 in our outpatient clinic.

The study population consisted of three groups: 119 children who received the MenACWY-TT (Nimenrix) vaccine alone, 119 who received the MenB-4C (Bexsero) vaccine alone, and 158 who received both vaccines during the same visit. In the simultaneous administration group, the two vaccines were injected into different anatomical sites, typically the right and left thighs.

All vaccinations in this study were performed following informed consent from the caregivers, after detailed explanation of the available options. The choice to receive either one or both vaccines during the same visit was entirely based on parental preference. Vaccines were administered only to children who were clinically healthy on the day of vaccination, with no signs of fever or active infection. No prophylactic antipyretics were given prior to vaccination. Our outpatient clinic maintains active communication with families during the post-vaccination period. Parents were encouraged to report any post-vaccination symptoms, particularly fever or irritability, by phone on the same day. In addition, these symptoms were re-evaluated at the subsequent routine clinic visit, allowing verification and correction of any incomplete or unclear information. In cases where no symptoms were observed, this was also explicitly documented during follow-up. We believe that this close and structured communication with caregivers contributed significantly to the reliability of the symptom data collected. Fever was defined as a body temperature exceeding 37.3 °C, measured using digital temporal artery thermometers approved by the clinic. The degree of fever was categorized as mild (37.3 °C-38.0 °C) and moderate (38.1 °C-39.0 °C), based on the highest recorded temperature within the first 48 hours after vaccination. Duration of fever was calculated as the time from the first detection of fever until the temperature returned to below 37.3 °C and was grouped as up to 24 hours or up to 48 hours. In cases where body temperature exceeded 38.5 °C and persisted despite initial observation, caregivers were advised to administer paracetamol according to age-appropriate dosing guidelines. Restlessness was defined as excessive crying, irritability, sleep disturbances, or general agitation as subjectively observed by the caregivers. Its duration was estimated by the parents and recorded in hours, then categorized into three intervals: up to 24 hours, up to 48 hours, and up to 72 hours. All definitions and recording instructions were explained to families

during the vaccination visit, and the importance of accurate follow-up was emphasized. These instructions and definitions are part of the standard vaccination follow-up protocol routinely applied in our outpatient clinic.

Data Collection and Exclusion Criteria

Data were collected retrospectively from electronic and written medical records maintained in our outpatient vaccination clinic. Information regarding vaccine type, administration date, patient age, sex, and post-vaccination symptoms (fever, restlessness, and other complaints) was extracted from standardized follow-up forms completed by caregivers and verified during follow-up visits or phone calls. Children with incomplete vaccination records, missing follow-up data, or uncertain symptom reporting were excluded from the analysis. Additionally, patients who received antipyretics prophylactically, or who had any signs of acute illness (e.g., fever, upper respiratory tract infection, or gastrointestinal symptoms) at the time of vaccination, were not included in the study.

Statistics

Statistical analyses were performed using SPSS version 25 (IBM Corp., Armonk, NY, USA). Descriptive statistics were used to summarize demographic characteristics and the distribution of post-vaccination symptoms across the study groups. Categorical variables, including the presence and severity of fever, as well as the duration of fever and restlessness, were compared using Pearson's chi-square (χ^2) test or Fisher's exact test, where appropriate. A p-value of <0.05 was considered statistically significant.

Results

The incidence of fever was 8.4% (n= 10) in the Nimenrix group, 43.7% (n= 52) in the Bexsero group, and 26.6% (n= 42) in the simultaneous administration group. A significantly higher rate of fever was observed in the Bexsero-only group (p< 0.001) (Table1).

The incidence of irritability was 10.1% (n= 12) in the Nimenrix group, 42.0% (n= 50) in the Bexsero group, and 19.0% (n= 30) in the simultaneous administration group. Again, irritability was significantly higher in the Bexsero-only group (p< 0.001) (Table 1).

Among the individuals who received the Bexsero vaccine, the incidence of fever and irritability decreased with increasing age at vaccination. Notably, no fever cases were reported after 13 months of age, and irritability rates dropped to as low as 9.1% (n= 1). These findings indicate that fever and irritability significantly vary depending on the age at which the vaccine is administered (Table 2).

Discussion

Globally, countries have adopted different vaccination recommendations based on the predominant meningococcal serogroups and risk groups within their borders (9). The U.S. Centers for Disease Control and Prevention (CDC) identify complement deficiency, use of complement inhibitors, anatomical or functional asplenia, and HIV infection as risk factors for meningococcal disease (10). In its 2020 report, the CDC recommended the MenACWY vaccine for adolescents aged 11-12 years and children over two months at increased risk for meningococcal disease (10). In its updated report from

Table 1. Effects of simultaneous and separate administration of Nimenrix and Bexsero

		Nimenrix (n= 119)	Bexsero (n= 119)	Nimenrix+Bexsero (n= 158)
Fever	Present Absent	**8.40%** 91.6%	**43.70%** 56.3%	**26.60%** 73.4%
Degree of fever (°C)	37.3°-38°	50.0%	23.1%	40.5%
	38°-39°	50.0%	76.9%	59.5%
Duration of fever	Up to 24 hours	100.0%	84.6%	90.5%
	Up to 48 hours	0.0%	15.4%	9.5%
Restlesness	Present	10.1%	42.0%	19.0%
Duration of restlesness	Up to 24 hours	100.0%	78.0%	90.0%
	Up to 48 hours	0.0%	18.0%	6.7%
	Up to 72 hours	0.0%	4.0%	3.3%

Table 2. Fever rate of Nimenrix and Bexsero regarding age of vaccination

		Nimenrix	Bexsero	Nimenrix+Bexsero
Fever-time of vaccination	3 month-5-month old	9.8%	51.8%	29.8%
	6 month-12-month old	8.7%	36.0%	20.0%
	≥13-month old	0.0%	0.0%	13.6%

November 2024, the MenB vaccine is routinely recommended for individuals aged 16-23 years and children over 10 years of age with an increased risk of meningococcal disease (11).

According to the European Centre for Disease Prevention and Control, Italy recommends MenB at 3, 5, 15, and 24 months and MenACWY at 12 months and between 12 and 18 years. In Germany, MenB is recommended at two and four months, with MenB and MenC administered concurrently at 12 months. In France, MenB is given at three months, and both MenB and MenC are administered simultaneously at five and 12 months (12). MenB is routinely administered in the United Kingdom at two and four months, followed by Hib/MenC and MenB at 12 months, and MenACWY at 14 years (13).

The intensive immunization schedule during the first six months of life in the pediatric population has raised the potential for meningococcal vaccines to be co-administered with other routine childhood vaccines. A study conducted in Italy found that simultaneous administration of the 4CMenB vaccine with the pneumococcal conjugate vaccine, the hexavalent combination vaccine (DTaP-Hib-IPV-HepB; diphtheria, tetanus, acellular pertussis, Haemophilus influenzae type b, inactivated poliovirus, and hepatitis B), and oral rotavirus vaccine did not compromise vaccine safety (14).

Another study demonstrated that co-administration of MenACWY vaccines with DTaP, HPV (human papillomavirus), hepatitis A, hepatitis B, influenza, MMR (measles, mumps, and rubella), and varicella vaccines, and MenB vaccines with DTaP, HPV (human papillomavirus), influenza, hepatitis B, and pneumococcal conjugate vaccines, did not affect the immune response and had an acceptable overall safety profile (15).

A retrospective cohort study in Spain evaluated 1.255 pediatric cases under five years of age hospitalized for IMD. Of these, 96.25% (n= 1209) were healthy children with no comorbidities, while underlying pathologies were identified in 46 cases (3.65%). Among these comorbidities, 34 cases (2.71%) had congenital malformations, 7 (0.56%) cases had malignant neoplasms, and 7 (0.56%) cases had chronic pulmonary diseases. Notably, genetic or acquired immunodeficiencies, as defined by the CDC, were detected in only 2 (0.15%) cases (16).

A population-based study conducted in Denmark from 1977 to 2015 identified chronic comorbidities in 6.9% (n= 353) of 5.121 pediatric patients diagnosed with IMD. However, many of these cases did not meet the CDC's criteria for high-risk classification (17).

In light of these findings, it can be concluded that most pediatric cases of IMD were previously healthy and had no known comorbidities or defined risk factors. Therefore, meningococcal vaccination appears to be indicated for the entire pediatric population. Additionally, since primary immunodeficiencies such as complement deficiencies are often not diagnosed until the second or third decade of life, prophylactic vaccination becomes even more clinically important in children who have not yet been classified into a risk group (18).

Meningococcal vaccines' most common side effects include redness and swelling at the injection site, muscle pain, fever, fatigue, and irritability (5,19,20). In a multicenter study conducted in Europe, the five-component meningococcal vaccine MenABCWY (Penbraya) was compared with the simultaneous administration of Bexsero and Nimenrix in terms of immunogenicity, safety, tolerability, and adverse events, particularly fever. The Penbraya group exhibited higher rates of fever, decreased appetite, irritability, and injection site tenderness than the Nimenrix+Bexsero group. The study was terminated in Phase 2b due to potential safety concerns, as two-month-old infants in the Penbraya group required lumbar puncture due to fever and irritability, and pleocytosis was detected in the cerebrospinal fluid. In this study, fever >38°C occurred in 56% of participants after the first dose at 2 months, 22.3% after the second dose, and 19.3% after the booster dose at 12 months in the Nimenrix + Bexsero group. The decline in fever incidence with age aligns with the findings of our study (Table 2). Furthermore, both groups demonstrated strong immune responses to MenB and MenACWY serogroup antigens (21).

In our study, simultaneous administration of Nimenrix and Bexsero on the same day did not statistically increase the rates of fever and irritability. It resulted in a lower fever incidence than Bexsero administered alone. These findings suggest that co-administration of meningococcal vaccines in the pediatric population may offer a more favorable safety profile than separate administration.

The hypothesis that simultaneous exposure to multiple antigens may modulate immune activation in a more regulated manner, thereby reducing the release of pyrogenic cytokines responsible for fever, remains a topic of ongoing research (22). However, further investigation is required to elucidate this mechanism fully.

This study has several limitations. First, its retrospective observational design may be subject to inherent biases, including recall bias and reporting variability by caregivers. Although data collection was standardized through caregiver instructions and systematic follow-up, the accuracy of symptom reporting—particularly for subjective findings such as restlessness—could still be influenced by parental perception. Second, although children with overt signs of illness were excluded, underlying or undiagnosed medical or genetic conditions may have influenced post-vaccination reactions in ways that could not be accounted for. Third, the study focused on short-term post-vaccination outcomes; therefore, potential late-onset adverse events or complications beyond the observation window could not be evaluated. Despite these limita-

tions, the large sample size, structured follow-up process, and consistent clinical practice protocols strengthen the reliability of the findings.

Conclusion

In conclusion, considering the high risk of IMD under the age of one, the fact that the majority of cases occur in children without any risk factors, and the prevalent serogroups in our country, both vaccines should be administered at an early age. The observation that co-administration of Nimenrix and Bexsero results in fewer adverse effects, such as fever, suggests that simultaneous vaccination may reduce outpatient clinic visits. Due to the current national immunization program, we propose that both vaccines can be co-administered at 3, 5, and 13 months of age.

Ethics Committe Approval: This study was approved by the Bahçeşehir University Ethics Committee for Non-Interventional Research (Decision no: 2024-03/02, Date: 16.10.2024).

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