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Original Article

Evaluation of infants administered prophylactic intravenous immunoglobulin following exposure to measles

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Abstract

Introduction: Intravenous immunoglobulin (IVIG) is an alternative for post-exposure prophylaxis if a vaccine is contraindicated and intramuscular immunoglobulin is unavailable. We retrospectively examined the effect of IVIG administration time on measles development in measles-contact infants younger than 6 months of age.

Methodology: Contact tracing of measles cases was performed by the Istanbul Public Health Directorate (IPHD) between August 24, 2012, and June 16, 2013. The mothers of 187 infants younger than 6 months were found to have negative IgG for measles. Under IPHD supervision, IVIG (0.4 g/kg) was administered to these infants within the first 6-10 days following exposure. These infants were monitored for rash and fever by IPHD for up to 28 days after IVIG prophylaxis. The study was conducted retrospectively, infants were divided into two groups, those who received IVIG at 6 days and later. These groups were compared according to the development of measles.

Results: Only 2 out of 187 infants developed measles after IVIG prophylaxis. No significant difference in measles frequency was observed between infants who received IVIG within the first 6 days after exposure and those who received IVIG after 6 days. Nine infants received IVIG in the first 3 days, and none of them developed measles. The risk of developing measles was higher in infants who had experienced contact at home ($p = 0.002$).

Conclusion: IVIG administration may provide stronger protection in the first 3 days and may be given until 10 days after exposure.

Key words: Measles; immunoglobulin; post-exposure prophylaxis; infant.

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Introduction

Measles is a highly contagious disease spread by aerosol transmission. It is characterized by a maculopapular rash with cough and fever. The disease generally has a mild course; however, serious complications may develop, with pneumonia and encephalitis being the most serious complications [1]. Such complications are more common in infants under 1 year of age and among adults over 20 years of age. In developed countries, 1-3 out of every 1,000 cases result in death [2].

Children who develop measles in the first year of life have an estimated 1 in 158 risk of subacute sclerosing panencephalitis in their later life [3]. The incidence of measles is 10-100 times higher in developing countries than in developed countries, and malnutrition contributes to this rate. The mortality rate due to measles among young infants and children with immune deficiency is high [1-4].

Measles elimination policies have been

implemented in Europe since 1998 [5]. In Turkey, a measles elimination program was initiated by the Ministry of Health in 2002 [6]. As a result of this elimination program, only 0-34 cases were detected per year between 2006 and 2010. Two doses of measles-mumps-rubella (MMR) vaccine are included in the national childhood vaccination program, as the first dose is given at 12 months and the second dose at 4-6 years of age.

However, the number of measles cases increased significantly in Europe in early 2009, and the number of cases increased primarily in Western Europe in 2011. In 2011, approximately 26,000 cases were reported in Europe, and 54% of these cases were reported in France [7]. In addition, most of the imported cases in the United States came from either the European Region or the Philippines after 2008 [8,9]. The lack of vaccination among certain groups has resulted in an increase in the number of cases in recent years. Religious or philosophical beliefs, limited access to healthcare, and anti-vaccination movements are major factors contributing to the decline in vaccination rates [8].

In Turkey, only 7 cases were identified in the year 2010, 105 cases were identified in 2011, 349 cases were identified in 2012, and 7,405 cases were identified in 2013 [10]. This increase in the number of measles cases in 2012 and 2013 may be associated primarily with cases imported from European and Balkan locations.

Measles remains contagious 4 days before and 4 days after the onset of rash. The virus is highly contagious, and 75% of susceptible individuals exposed to the virus develop the disease [11]. For post-exposure protection, measles vaccination or immunoglobulin administration is recommended. Current data demonstrate that protection can be ensured if the measles vaccine is administered within 72 hours after exposure [12]. The post-exposure protection rate of the vaccine is in the range of 68%-100% [13,14]. The onset of measles can be prevented or modified if intramuscular immunoglobulin (IMIG) is administered to susceptible individuals within 6 days of exposure to measles [12]. A Cochrane review found that up to 83% of susceptible individuals given IMIG did not develop measles compared to untreated susceptible individuals [15]. Intravenous immunoglobulin (IVIG) preparations also contain measles antibodies at concentrations similar to those in IMIG preparations; therefore, IVIG may be given rather than IMIG [12,16]. To our knowledge, several studies of post-exposure IMIG administration for measles have been published, although only a few studies of post-exposure IVIG administration for measles have been published. A Cochrane review showed that measles post-exposure prophylaxis was 83% effective with immunoglobulin, but 11 in 13 included studies were published in the past century (1920–1972), while only two studies were published in the 21st century (2001 and 2009) [15]. In a study conducted in Austria in 2021 with 63 infants who received IVIG for post-exposure prophylaxis during the measles outbreak, the effectiveness of IVIG post-exposure prophylaxis was calculated to be 99.2% (95% CI: 87.8–100%) [17]. Due to the limited number of studies on the efficacy of IVIG for post-exposure prophylaxis in the last decades when donors who have had the natural disease decreased and more vaccinated donors were available, in this study, the effect of IVIG administration time used for post-exposure prophylaxis on the development of measles was retrospectively examined in infants younger than 6 months whose mothers had negative measles IgG test during the period between August 2012 and June 2013 when the number of measles cases increased.

Methodology

The number of measles cases in Turkey has increased substantially, particularly in Istanbul. The number of measles cases in Turkey was 349 in 2012 and 7405 in 2013. Several precautions were recommended

Table 1. Measures recommended by the Ministry of Health Measles Advisory Board against increasing measles cases.

Measures recommended
1. Children in primary school 1st grade and kindergarten were quickly vaccinated
2. In case of exposure within 3 days, a single dose of monovalent measles vaccine was given to infants aged 6-9 months, and a single dose of MMR vaccine was given to infants aged 9-12 months, in addition to the MMR vaccine administered at 12 months of age. In cases where measles vaccine was not contraindicated, MMR or monovalent measles vaccine was administered to susceptible persons with close contact within 72 hours of such contact
3. Since IMIG is not available in Turkey, IVIG (0.4 g/kg) was recommended for the following groups in close contact within the first 6-10 days after this contact: - Healthy infants younger than 6 months of age whose mothers had a negative measles IgG test; - Infants under 6 months of age whose mother has measles; - Children with primary or secondary immunodeficiency due to HIV, immunosuppressive therapy or disease, regardless of their vaccination status or previous measles; and - Unvaccinated pregnant women with a negative measles IgG test

by the Advisory Board for Measles of the Ministry of Health in response to the increased number of measles cases. These precautions were coordinated and implemented by the Istanbul Public Health Directorate (IPHD) (Table 1). First, children in primary school 1st grade, and kindergarten were quickly vaccinated. In addition, in case of exposure within 3 days a single dose of a monovalent measles vaccine was given to infants 6-9 months of age, and a single-dose MMR vaccine was administered to infants 9-12 months of age as an additional dose in addition to our routine measles vaccination program. Second, in cases where the measles vaccine was not contraindicated, the MMR or the monovalent measles vaccine was administered to susceptible individuals who experienced close contact, within 72 hours of such exposure. Third, seeing that IMIG is not available in Turkey, IVIG (0.4 g/kg) was recommended to individuals in the following groups who experienced close contact, within the first 6-10 days after this contact:

i. healthy infants younger than 6 months of age whose mothers' measles IgG test result was negative;
ii. infants under the age of 6 months whose mothers had measles;
iii. children with primary or secondary immunodeficiency due to HIV, immunosuppressive therapy or disease, regardless of their vaccination status or previous measles;
iv. unvaccinated pregnant women with a negative measles IgG test result.

Close contact was defined by the Ministry of Health Measles Advisory Board as any of the situations:

i. any contact at home with a confirmed patient,
ii. sleeping in the same room with the patient,
iii. being with the patient in the same care center, or
iv. being in the waiting room with the patient (i.e., waiting in the same waiting room of a hospital).

Contact tracing of measles cases was performed by IPHD between August 24, 2012, and June 16, 2013. Mothers of infants younger than 6 months who were reported as close contacts were tested for measles IgG. The mothers of 187 infants younger than 6 months were found to have negative IgG for measles. Under the coordination of the IPHD, the existing IVIG room in the pediatric infectious diseases service of Kanuni Sultan Süleiman Training and Research Hospital was used for IVIG administration to these infants.

Under the supervision of the IPHD, IVIG (0.4 g/kg) was administered to these infants within the first 6-10 days following exposure. These infants were monitored for rash and fever by the IPHD for up to 28 days after IVIG prophylaxis.

IVIG administration was recommended by the Advisory Board for Measles of the Ministry of Health, as described above. In this study, the effectiveness of IVIG prophylaxis was investigated retrospectively according to the time of IVIG administration after exposure in children receiving IVIG. The day of postexposure immunoglobulin administration was calculated as the time between the date an exposed individual was given IVIG and the date that close contact with a confirmed patient occurred or, if contact was sustained, a rash developed in a confirmed measles patient. The study was conducted retrospectively, infants were divided into groups that underwent IVIG both in the first 6 days and afterwards. These groups were compared according to the development of measles.

Approval for the study was obtained from the Ethics Committee of Kanuni Sultan Suleiman Training and Research Hospital. This research was conducted in accordance with the Declaration of Helsinki.

Descriptive statistics were used to summarize the data. Qualitative variables were compared between the two groups with the Chi-square test with Fisher's exact test, when necessary. In all analyses, differences were considered statistically significant if $p < 0.05$.

Results

A total of 207 people who were in close contact with measles patients and thought to need prophylaxis with IVIG after exposure were identified. Nine of these individuals refused IVIG administration. Among the remaining 198 individuals who were in close contact with measles patients, 187 of them were infants younger than 6 months of age whose mothers had a negative measles IgG test result, 8 of them were children with immune deficiency (5 of them were on immunosuppressive therapy, one of them had Fanconi aplastic anemia, one of them had acute lymphoid leukemia) and 3 of them were unvaccinated pregnant women with a negative measles IgG test result. Of 187 infants, 93 (49%) were male, and 94 (51%) were female.

One hundred and thirty-six (73%) out of the 187 individuals who were in close contact with measles patients had waited in the same corridor at a healthcare institution, 29 (15%) shared the same room at a child

protection institute, 9 (5%) came in contact at home, and 13 (7%) were passengers traveling with a patient with measles in vehicles such as airplanes The age range was 1-174 days (median: 81 days). The classification of individuals who were in close contact with measles patients and who were considered to require post-exposure prophylaxis with IVIG is shown in Figure 1.

In terms of post-contact protection, the average value of the time to IVIG administration was 5.6 days (95% CI 5.4 to 5.86). IVIG was applied to 156 (83%) of these infants within the first 6 days after exposure, 30 of these infants within 7-10 days of exposure and one infant on the 16th day. Only two of the 187 infants who were in close contact with a measles patient and subsequently received IVIG developed measles. These two cases were in contact with a patient at home. These infants received IVIG on days 6 and 8 following contact. Therefore, 99% of all infants that received IVIG did not develop measles. No statistically significant difference in terms of measles development was observed between individuals given IVIG within the first 6 days after close contact with a confirmed case and individuals who were given IVIG on day 7 or later after exposure (Fisher's exact test; $p = 0.305$; Table 2). In addition, only 9 patients underwent IVIG in the first 3 days and none of these infants had measles. None of these infants had contact at home. All infants tolerated IVIG well with no reported adverse effects during their hospital stay.

Only one person who had close contact with a measles patient received IVIG on day 16, and that individual also did not develop measles. Six of 9 individuals who were in close contact with a patient at home received IVIG within the first 6 days after exposure, and 3 of such individuals received IVIG within 7-10 days after exposure. Two of 9 individuals who were in contact with a confirmed case at home developed measles after IVIG prophylaxis. One of these individuals received IVIG on post-exposure day 6, and the other individual received IVIG on day 8. When the proportions of these two groups that developed measles were compared with Fisher's exact test, no statistically significant difference was observed ($p = 0.583$; Table 3). The risk of developing measles in individuals who were in close contact at home was significantly higher than in individuals who had close contact in other ways ($p = 0.002$; Table 4).

Figure 1. Classification of individuals who were in close contact with measles patients and who were considered to require post-exposure prophylaxis with IVIG.

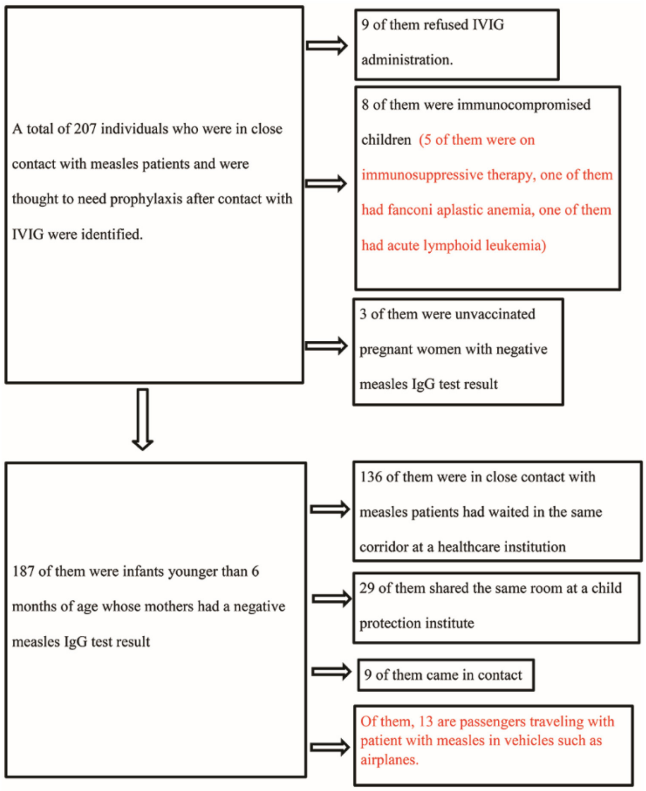

Table 2. Frequency of measles in infants given IVIG in the first 6 days after exposure and afterward.

The day of post-exposure IG administration (min-max; median day)	Measles (n, %)	
	Exposed individuals who did not develop measles	Individuals exposed to measles who had measles
≤ 6 (1-6; 5)	155 (84%)	1 (50%)
≥ 7 (7-16; 8)	30 (16%)	1 (50%)
Total (n, %)	185 (100%)	2 (100%)

Fisher's exact test; successful prevention p value = 0.305.

Table 3. The frequency of measles among those with contact at home.

The day of post-exposure IG administration (min-max; median day)	Measles (n, %)	
	Exposed individuals who did not develop measles	Individuals exposed to measles who had measles
≤ 6 (5-6;6)	5 (71%)	1 (50%)
≥ 7 (8-10;9)	2 (29%)	1 (50%)
Total (n, %)	7 (100%)	2 (100%)

Fisher's exact test; successful prevention $p = 0.583$

Table 4. The frequency of measles according to the type of contact.

	Measles (n, %)	
	Exposed individuals who did not develop measles	Individuals exposed to measles who had measles
Contact at home	7 (4%)	2 (100%)
Contact outside the home	178 (96%)	0 (0%)
Total (n, %)	185 (100%)	2 (100%)

$p = 0.002$

Discussion

Prophylaxis with immunoglobulin dates back to the efforts summarized by Janeway in 1945 [18]. IMIG has been used for post-exposure prophylaxis for measles since the 1940s to prevent and modify the course of measles. However, prophylactic administration of IMIG following measles exposure was found to be ineffective in a study conducted in 1990 [19]. By contrast, in a study conducted in Australia, between March to May 2006, the efficacy of prophylactic administration of IMIG at a dose of 0.2 mL/kg following exposure to measles was 75.8% [20]. A Cochrane review found that immunoglobulin prophylaxis was 83% effective in post-exposure measles prophylaxis, but there were only two studies published in the 21st century in this review [15]. In another study conducted in Austria in 2021 including 63 infants who received IVIG for post-exposure prophylaxis, the effectiveness of IVIG post-exposure prophylaxis was calculated to be 99.2% (95% CI: 87.8–100%) [17]. In the study conducted on infants under 6 months whose mothers were IgG negative, which is a high-risk patient group for measles development, 99% of our infants did not develop measles. There have been limited studies on the efficacy of IVIG in postexposure prophylaxis in recent years when natural disease donors started to decline in numbers and more vaccinated donors became available. We think that the study done in the last decade is important in this regard.

The adjustment of IMIG doses by body weight varies from country to country. This variation may be an indication that specific antibody concentrations and IMIG effectiveness may vary among IMIG preparations [20,21]. Immunoglobulin dose and antibody titre both affect the efficacy of immunoglobulin treatment [21]. However, the minimum effective dose of measles-specific antibodies has not been identified [15]. IMIG 0.5 mL/kg is administered as a single dose, the maximum dose is 15 mL. A single dose of IMIG, which is considered to have minimal anti-measles potency, contains 25,000 mIU/mL of measles antibody; the maximum dose, 15 mL, contains approximately 380,000 mIU of measles antibody or ~5,000 mIU/kg for a 70-kg individual. In contrast, IVIG, which is considered to have minimal anti-measles potency, contains 4,270,000 mIU of measles antibody or 61,000 mIU/kg of measles antibody for a 70-kg individual at a dose of 400 mg/kg [22]. IVIG is primarily used for the prevention of infectious diseases in patients with a primary immune deficiency. Even though IVIG can be administered at a higher dose than IMIG, longer-term monitoring is believed to be needed for its clinical use in specific situations. Tapısız *et al.* [23] reported that IVIG (0.4 g/kg), which has been stated by the AAP to be appropriate for post-exposure prophylaxis for measles, was administered to 9 patients who were hospitalized for reasons unrelated to measles, due to measles development in the mother of a patient who was not in a negative pressure room at the center. None of the patients who received IVIG developed measles [23]. In a recent study that included 63 infants, a dose of 400 mg/kg IVIG was found to be 99.3% protective [17]. In the study, it was observed that measles failed to develop in 99% of exposed individuals given prophylactic IVIG at a dose of 400 mg/kg.

In the study, IVIG was given instead of IMIG because no IMIG preparations are currently available in Turkey. This is one of the few studies to evaluate the use of IVIG in measles post-exposure prophylaxis among infants under the age of 6 months in the last decades when there were more vaccinated donors than those with natural disease. In the study, 99% of the infants did not develop measles after prophylaxis with IVIG. No statistically significant difference in the frequency with which measles developed was observed between the groups given IVIG within the first 6 days after exposure and the group given IVIG ≥ 7 days after exposure, regardless of whether individuals had close contact with a measles patient at home. Only 9 infants could be given IVIG in the first 3 days. None of these infants developed measles. This is in line with UK and Australian guidelines, which state that efficacy is greater when given as early as possible (ideally within 3 days) [24,25].

In the study, it was observed that individuals who had contact with a measles patient at home had a significantly higher risk of developing measles than individuals who had other types of close contact (p = 0.002; Table 4). This finding is consistent with the results of previous studies [20,26].

The most important limitation of this study is that the study subjects were not randomly assigned into groups that either received or did not receive prophylaxis with IVIG. This study design was unavoidable because IVIG administration was recommended by the Measles Advisory Board of the Ministry of Health to prevent further increases in the number of measles cases and the complications that may occur due to measles. Therefore, a retrospective assessment of the group that received IVIG cannot adequately determine the efficacy of IVIG prophylaxis. The second limitation of this study is that IVIG administration is more time-consuming and expensive than IMIG administration. However, this choice of

treatment was necessary because IMIG is not available in Turkey. The third limitation of this study is that we do not know what happened to 9 infants whose post-exposure prophylaxis was refused by their families.

In conclusion, measles did not develop after exposure to measles following prophylactic IVIG administration in 99% of infants younger than 6 months of age whose mothers were seronegative for measles antibodies. No statistically significant difference in frequency with which measles developed were identified between infants given IVIG within the first 6 days after exposure and infants given IVIG ≥ 7 days after exposure. Although very few infants received IVIG in the first 3 days, it was not statistically suitable for comparison because the number was very small, but measles did not develop in any of these infants. It may be more important to use prophylaxis within the first 3 days after exposure, if possible. Additionally, immunoglobulin administration may be given until 10 days after exposure. However, the risk of developing measles in home-contact infants was higher than in infants with other types of close contact. Therefore, when IMIG supply is limited, IVIG administration may be preferable for these infants. Larger, randomized studies are needed to assess the protective efficacy of post-exposure IVIG prophylaxis for measles.

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