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Fatal varicella due to the vaccine-strain varicella-zoster virus

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Abbreviations: VZV, varicella-zoster virus; VAERS, Vaccine Adverse Event Reporting System; RSV, respiratory syncytial virus; IV, intravenous; ALL, acute lymphoblastic leukemia; PCR, polymerase chain reaction; TREC, T-cell receptor excision circles; ORF, open reading frame

We describe a death in a 15-mo-old girl who developed a varicella-like rash 20 d after varicella vaccination that lasted for 2 mo despite acyclovir treatment. The rash was confirmed to be due to vaccine-strain varicella-zoster virus (VZV). This is the first case of fatal varicella due to vaccine-strain VZV reported from the United States. The patient developed severe respiratory complications that worsened with each new crop of varicella lesions; vaccine-strain VZV was detected in the bronchial lavage specimen. Sepsis and multi-organ failure led to death. The patient did not have a previously diagnosed primary immune deficiency, but her failure to thrive and repeated hospitalizations early in life (starting at 5 mo) for presumed infections and respiratory compromise treated with corticosteroids were suggestive of a primary or acquired immune deficiency. Providers should monitor for adverse reactions after varicella vaccination. If severe adverse events develop, acyclovir should be administered as soon as possible. The possibility of acyclovir resistance and use of foscarnet should be considered if lesions do not improve after 10 d of treatment (or if they become atypical [e.g., verrucous]). Experience with use of varicella vaccine indicates that the vaccine has an excellent safety profile and that serious adverse events are very rare and mostly described in immunocompromised patients. The benefit of vaccination in preventing severe disease and mortality outweigh the low risk of severe events occurring after vaccination.

Introduction

Single-antigen varicella vaccine (Varivax®, Merck and Co.) was introduced in the United States in 1995. It contains live attenuated varicella-zoster virus (VZV). The routine childhood varicella vaccination program in the United States has led to substantial declines in varicella-related morbidity and mortality.[1,2] Experience during the first decade of the program with nearly 50 million doses of varicella vaccine distributed indicates that the vaccine has an excellent safety profile.[3] Serious adverse events reported to the Vaccine Adverse Event Reporting System (VAERS) were rare: 1276 reports or 2.6 events/100 000 doses distributed; vaccine-strain VZV was confirmed in few cases that included pneumonia, hepatitis, herpes zoster with meningitis, and severe rash.[3–16] To date, there has been one published report of fatal varicella due to vaccine-strain VZV in a child from Germany who received varicella vaccine (Varilrix®, GlaxoSmithKline) while in remission from acute lymphoblastic leukemia (ALL).[14] We describe a case of fatal varicella due to vaccine-strain VZV after vaccination with Varivax®.

Patient Presentation

The patient, a 15-mo-old Hispanic white girl, received her first dose of varicella vaccine (Varivax®), along with measles, mumps, rubella, *Haemophilus influenzae* type b, and pneumococcal vaccines at age 1-y. She was born healthy, weighing 6.9 pounds; mother had no pregnancy complications. Her family history was negative for history of inherited immune deficiencies or severe recurrent infections, and she had a healthy older sister; her parents were second-cousins. She was healthy and developing normally until 5 mo, when she had a hospitalization for respiratory syncytial virus (RSV) bronchiolitis with hypoxia. Subsequently, she was diagnosed with global developmental delay, failure to thrive (weighed 14 pounds at age 15 mo), type II fiber atrophy, profound hypotonia, and gastroesophageal reflux. She had a gastrostomy tube placed at age 9 mo due to poor feeding. Before her first birthday, she had several other episodes of bronchiolitis, pneumonia due to RSV, and aspiration pneumonia that resulted in 4 more hospitalizations; several of her hospitalizations required steroid therapy and two required mechanical ventilation

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(**Table S1**). Quantitative serum immunoglobulin levels measured at 10 mo were normal, except for elevated IgE levels (424, normal range: 0.8–7.3 IU/ml[17]). An HIV test was reported as negative although documentation not found in available records. At the time of vaccination, her only medication was lansoprazole and she was showing improvement neurologically (able to sit without support with no head lag, able to lift her arms showing four-fifths strength in her arms, had regained reflexes, and was alert and responsive).

One week after vaccination, the patient was hospitalized for severe respiratory distress and was treated with albuterol, budesonide, and amoxicillin clavulanate. On hospital day 10 (16 d post-vaccination), she was started on IV methylprednisolone, 3.5 mg every 12 hours for 3 d (equivalent to 8.8 mg/day of prednisone) followed by prednisolone via g-tube 3.5 mg every 12 hours for 2 d (equivalent to 7.0 mg/day of prednisone). Her respiratory distress resolved and she was discharged on hospital day 14.

On the day of hospital discharge, her mother noticed a rash on one of her hands that disseminated into a generalized vesicular rash by the next day, at which point she was seen by her primary care physician and started on oral acyclovir (200 mg/5 ml suspension). A skin lesion specimen collected the next day (20 d post-vaccination) was positive for vaccine-strain VZV by polymerase chain reaction (PCR). Four days after rash onset, the patient developed another episode of respiratory distress and was hospitalized. On admission, she had diffuse vesicular and crusted lesions and was febrile to 104°F. Chest X-ray showed increased opacity in the left lung. She was switched to IV acyclovir (130 mg IV every 6 hours) and started on broad-spectrum antibiotics. Starting on hospital day 4, she received IV methylprednisolone (12 mg 1 dose for 1 d then 6 mg once a day for 2 d), followed by 2 doses of prednisolone for one day. On hospital day 11, the patient had an episode of acute respiratory failure and was intubated. She required high-frequency oscillatory ventilation until her death 7 weeks later. IV acyclovir was discontinued on hospital day 12, restarted on hospital day 21 (130 mg IV every 6 hours), and continued until her death. On hospital day 24, she was started on low-dose prolonged steroid therapy protocol for acute respiratory distress syndrome (IV methylprednisolone for 32 d, starting with 13 mg for 1 dose and tapered to 0.4 mg twice a day). Despite ongoing acyclovir treatment, she continued to develop recurrent crops of vesicular skin lesions every 7–8 d throughout her hospitalization. Her respiratory status deteriorated with each new crop of lesions. Chest X-ray showed bilateral interstitial infiltrates consistent with viral pneumonia that became increasingly confluent, with worsening interstitial edema and opacification. On the day of her death, she had 50–100 skin lesions.

A bronchial lavage specimen collected on hospital day 19 was positive for vaccine-strain VZV DNA. An additional bronchial lavage specimen collected on hospital day 34 was also VZV-positive but not genotyped. A bronchial alveolar lavage specimen collected on hospitalization day 19 and blood collected on hospitalization days 23–26 and 51–53 were positive for *Pseudomonas aeruginosa* by culture; blood cultures on other dates were negative. Several urine specimens collected between hospitalization days 20–44 were positive for *Candida albicans* by culture.

Blood collected on hospitalization day 11 showed normal complement levels and normal humoral response to tetanus toxoid. A T-cell deficiency was considered as the patient's T-cell counts on hospital days 11 and 17 were low: absolute T-cell counts: 223 and 864 respectively (normal: 1600–6700); CD8 counts: 46 and 180 (normal: 400–2100); and CD4 counts: 169 and 656 (normal: 1000–4600). However, her lymphoid subsets were all within normal range (e.g., CD8 and CD4 T-cell percentages were 14% and 51%, respectively). Her white blood cell counts were within normal range; neutrophil levels were high at times. Her newborn blood spot testing performed post-mortem was negative for severe combined immunodeficiency/severe T-cell lymphopenia (measured by T-cell receptor excision circles [TREC] analysis); this result would not exclude severe primary immune deficiencies with detectable T cells but impaired T-cell function (e.g., MHC class II deficiency[18]). In addition, nutritional status can impact T-cell function.[19] One indication of such a problem was low albumin (2.2–2.9 g/dL on multiple samples; normal 3.4–3.8 g/dL), with the nadir recorded on hospital day 26.

Vaccine-strain VZV in skin and bronchial lavage specimens was identified at the Centers for Disease Control and Prevention (CDC) by real-time PCR targeting 4 vaccine-associated single nucleotide polymorphisms at open reading frame (ORF) 38, ORF 54, and ORF 62.[20]

Discussion

We describe a case of severe varicella due to vaccine-strain VZV with rash that lasted 2 mo despite acyclovir treatment. The patient developed acute respiratory distress syndrome, sepsis, and multi-organ failure, resulting in death. This patient did not have a known immunocompromising condition. However, she may not have had a fully functional immune system as evidenced by her prior hospitalizations and therapy, and course of current illness with persistent VZV infection; a full investigation of her immune competency was not conducted.

Most serious laboratory-confirmed varicella vaccine adverse events have been described among immunocompromised patients; for some, the immunocompromising condition was not identified until after they experienced a severe adverse event post-vaccination.[4,6,7,11,13,15] The medical histories of some of these patients included failure to thrive, recurrent infections or oral candidiasis.[6] To date, one other varicella death due to vaccine-strain VZV was reported.[14] This death occurred in a 4-y-old girl from Germany who received varicella vaccine (Varilrix®) 5 mo after complete remission from ALL;[14] at the time of vaccination, the patient was on chemotherapy that was interrupted for one week before and after vaccination. The patient developed seizures, respiratory insufficiency, petechiae, hematomas, and vesicular lesions on her oral and vaginal mucosa 32 d after varicella vaccination. She subsequently died of acute respiratory distress syndrome and multi-organ failure. Vaccine-strain VZV was isolated from peripheral blood.

It is unknown why the patient described in this report had severe varicella from vaccine-strain VZV. One possible explanation is that she might have had primary immune deficiency with T-cell dysfunction, although some evidence would not support this: she was born healthy and did not have some of the common infections found in persons with primary immune deficiency (i.e., thrush and candida dermatitis), many of her infections were acquired during hospitalization and responded to therapy, her neurological problems were associated with hypoxia and showed progress towards improvement, and her lymphocyte percentages were normal. The patient had a low absolute T-cell count but T-cell function was not measured; the low T-cell levels detected during the last hospitalization should be interpreted with caution in the absence of pre-hospitalization data since they may have been influenced by steroid treatment or viral suppression. Cases of severe varicella due to vaccine-strain VZV in persons with T-cell dysfunction have been described.[4,7] Varicella vaccine is contraindicated for persons with T-cell immunodeficiencies excluding HIV-infected persons with CD4 percentages ≥15%.[5] This case-patient's symptoms may have also been exacerbated by treatment with steroids 1 week after vaccination. According to current guidelines, the steroid dosage used to treat this patient would not be classified as high-dose (≥2mg/kg for ≥14 d or ≥20 mg/day) or considered to be sufficiently immunosuppressive to raise concern about the safety of vaccination with live-virus vaccines.[21,22] However, this dose may have been able to cause immune suppression if an underlying immune deficiency was also present or in the context of her underlying conditions (failure to thrive, possible protein malnutrition). Moreover, her steroid doses were high on occasion, supporting the possibility of immunosuppression due to steroids.[23] Steroid therapy in the week before or following varicella vaccination has been associated with post-vaccination rash in a retrospective analysis of children with ALL.[24] Experts recommend that steroid therapy be discontinued for ≥1 mo before vaccination[21,22] and some experts also suggest withholding steroid therapy for 2–3 weeks after vaccination if this can be done safely.[5] Rashes confirmed to be caused by the vaccine-strain VZV have been reported at a median of 21 d after varicella vaccination (range: 5–42 d).[25]

Acyclovir-resistance could be another contributor to her course of illness. Acyclovir-resistant wild-type VZV has been reported among immunocompromised persons, primarily HIV-infected.[26–29] Vaccine-strain VZV has been shown to have similar susceptibility to antivirals as wild-type virus.[30] Acyclovir-resistant vaccine-strain VZV has been reported in 2 cases among children who were both diagnosed with neuroblastoma and received chemotherapy within 1 week after varicella vaccination.[8,12] Both patients had lesions that became verrucous despite prolonged acyclovir treatment (approximately 7 mo and 5 weeks, respectively). Their lesions resolved after foscarnet and stem cell transplant therapy.[8,12]

The benefits of varicella vaccination outweigh the very low risk of serious adverse events occurring. For persons with remarkable medical histories, investigation prior to vaccination should be considered to determine whether these patients are immunocompetent. Providers should carefully monitor for any signs of adverse reactions after vaccination. If persons with underlying medical conditions develop a rash after vaccination, they should be immediately treated with acyclovir. Experts suggest considering acyclovir resistance and use of foscarnet if there is no response (i.e., lesions do not improve) within 10 d to 3 weeks of treatment with acyclovir or the lesions appear verrucous.[31,32] Since testing for acyclovir resistance is not commonly available, providers may need to rely on clinical judgment to suspect acyclovir resistance.[33]

In the pre-vaccine era, varicella resulted in >10 000 hospitalizations and 100–150 deaths annually in the US. Varicella deaths are now extremely rare and hospitalizations have declined >90% among children.[2] Despite its excellent safety profile, in rare cases, vaccine-strain VZV can result in severe varicella-related complications and even death. Thus far, most have been reported among immunocompromised children or among those who appear to have existing, but poorly understood, immunologic abnormalities.[3–5,11,13–15] Reporting to VAERS and laboratory testing is critical for monitoring vaccine safety and improving our understanding of risk factors for these events. Identification and genotyping of vaccine-strain VZV is performed at the CDC and Columbia University (program supported by the vaccine manufacturer).[9,21] Information on VZV laboratory testing at CDC is available at: http://www.cdc.gov/chickenpox/lab-testing/index.html.

Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

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Disclaimer

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention, US Department of Health and Human Services.

Contributor's Statement Page

Jessica Leung: Ms Leung conceptualized and designed the case-report; acquired, reviewed, and interpreted the data; drafted and revised the manuscript; and approved the final manuscript as submitted. Subhadra Siegel: Dr Siegel acquired, reviewed, and interpreted the data; revised the manuscript; and approved the final manuscript as submitted. James F Jones: Dr Jones reviewed and interpreted the data; revised the manuscript; and approved the final manuscript as submitted. Cynthia Schulte: Ms Schulte acquired, reviewed, and interpreted the data; revised the manuscript; and approved the final manuscript as submitted. Debra Blog: Dr Blog acquired, reviewed, and interpreted the data; revised the manuscript; and approved the final manuscript as submitted. Scott Schmid: Dr Schmid supervised PCR-based varicella strain discrimination diagnostics; reviewed and interpreted the data; revised the manuscript; and approved the final manuscript as submitted. Stephanie Bialek: Dr Bialek conceptualized and designed the case-report; reviewed and interpreted the

data; drafted and revised the manuscript; and approved the final manuscript as submitted. Mona Marin: Dr Marin conceptualized and designed the case-report; reviewed and interpreted the data; drafted and revised the manuscript; and approved the final manuscript as submitted.

Supplemental Materials

Supplemental materials may be found here:
www.landesbioscience.com/journals/vaccines/article/26200

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