Clinical Challenge

Sudden onset of neurologic symptoms in an adolescent girl

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Dizziness, photophobia, nausea, and an unsteady gait develop following a routine annual check up.

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Vasovagal responses occured spontaneously, which suggested an earlier trigger.

CASE Ms. K, aged 16 years, presented to the emergency department (ED) after being seen by her primary-care clinician 48 hours earlier for an annual physical exam and immunization update. Physical assessment was unremarkable at that time. During that exam, Ms. K received her third dose of the human papillomavirus (HPV) vaccine, Gardasil. Approximately one hour after administration, Ms. K's mother found her unconscious and drooling and called 911.

Ms. K was seen in the local ED, where this was diagnosed as a transient reaction to the immunization. Following her discharge, Ms. K developed headache, photophobia, nausea, and an unsteady gait. Since falling unconscious, the teen reported a headache on a pain scale of 7/10, photophobia, dizziness and difficulty walking. Ms. K's pediatrician referred her to a regional pediatric center for further evaluation.

1. HISTORY

Ms. K was an active teenager and honor-roll student who worked in a restaurant on weekends. She lived at home with both her parents and a younger healthy sibling. Ms. K's medical history was significant for polycystic ovaries and irritable bowel syndrome. She had been healthy prior to the physician visit two days prior. All her immunizations were up to date, and family history was negative for any medical conditions. Ms. K was not taking any medications and denied drug or alcohol use

2. EXAMINATION

Ms. K's vital signs in the ED were as follows: temperature 98.7° F, pulse 73 beats per minute (BPM), BP 110/69 mm Hg, respiration rate 20 inspirations per minute, pulse 93 BPM with oximetry 100% on room air. BP was 115/63 lying down, 117/73 while sitting, and 60/40 while standing. The teen appeared to be well-developed and well-nourished, but her behavior

was anxious and tearful. Ms. K's lungs were clear and her heart sounds were normal, but she complained of nausea. Her extremities were warm, and an unsteady gait was apparent. A detailed neurologic exam revealed that cranial nerves I-XII were intact, and the patient exhibited rapid, alternating movements that were coordinated and smooth. Ms. K's reflexes were intact, and there was evidence of a symmetrical response to pain with cutaneous hyperesthesia in soft-tissue areas. There were no meningismus signs.

3. LABORATORY DATA AND DIAGNOSIS

A CT scan of the head, brain, and sinuses was ordered to rule out increased intracranial pressure; the findings were normal. The following blood panels were performed and all were negative: a complete blood count, comprehensive metabolic profile, Epstein-Barr virus, erythrocyte sedimentation rate, and blood culture. The teen's ECG was normal. Pediatric neurology was called in on consultation and advised that Ms. K be admitted to the hospital for observation. Ms. K's diagnosis on her admission form included post-Gardasil-administration headache and syncope, vasovagal orthostatic hypotension, rule out sinusitis, rule out meningitis, and rule out transverse myelitis.

4. TREATMENT

The adolescent was hydrated intravenously with both 0.9% normal saline solution and ketorolac (Toradol). She was also given strict bed-rest orders. Her BP increased with fluid hydration. After twenty-four hours of IV hydration and ketorolac, Ms. K was discharged from the hospital. Her discharge orders included a prescription for naproxen (Naprosyn) 375 mg every eight hours and minimal activity, as tolerated. Over the course of 10 days, Ms. K's body aches, headache, and dizziness subsided, and she was weaned from naproxen, returning to school and full activity.

5. DISCUSSION

Two HPV vaccines are licensed by the FDA and recommended by the CDC. These vaccines are Cervarix and Gardasil. Both vaccines are very effective against diseases caused by HPV types 16 and 18; HPV 16 and 18 cause most cervical cancers, as well as other HPV-associated cancers. Gardasil also protects against HPV types 6 and 11, and is the only HPV vaccine that has been approved for administration in males.

In the United States, the FDA- and CDC-sponsored Vaccine Adverse Event Reporting System (VAERS) collects and summarizes reported data on adverse events during immunization. VAERS uses a clinically validated standardized terminology for aggregating data and events. Manufacturer reporting to VAERS is mandatory; however, most collected information comes from physicians, parents, or other primary reporters. Two and a half years after the recommendation for quadrivalent HPV vaccine administration, a summary of VAERS reports about Gardasil was published.[1] An adverse event following immunization is classified as one that is "life threatening, and can result in death, permanent disability, congenital anomaly, hospitalization or prolonged hospitalization; or [one that] necessitates medical or surgical intervention to preclude these outcomes."[2] At the time this article was written, VAERS reports specific to Gardasil were triple the rate of all other vaccines combined. One reason was considered to be a greater public awareness about a "new product."[1]

Syncope, dizziness, nausea, vasovagal responses, and headache were the most commonly reported side effects. A study from Australia acknowledged a higher-than-average anaphylaxis rate after the administration of the HPV vaccine as well. All reported patients in that study recovered after treatment with adrenaline.[3]

After the summary report was published, a Gardasil advisory was issued by the CDC. Clinicians were asked to observe patients for 15 minutes after administration of the vaccine. The Gardasil package insert acknowledges that syncope is sometimes associated with tonic-clonic movements, and has been reported after administration. The insert also states that this type of muscle spasm is transient and responds to the supine or Trendelenburg position. The increased reporting of syncope after administration of HPV vaccination among teenage girls is attributed in part to an adolescent fear of medical procedures, dehydration, or pain responses.

Relative to the post-syncopal reports to VAERS in children older than age 5 years, 49% of Gardasil-reactive patients were adolescent females aged 11 to 18 years. At least one of the three adolescent vaccines (HPV vaccine; meningococcal conjugate vaccine; and tetanus, diphtheria, pertussis vaccine) was implicated in 60% of reports involving a single vaccine; HPV was the most frequently reported vaccine type (in 52% of single-vaccine reports).[4]

A statement on the CDC website detailed the Gardasil-related adverse events on file.

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As of September 15, 2011, approximately 40 million doses of Gardasil were distributed in the U.S. and VAERS received a total of 20,096 reports of adverse events following Gardasil vaccination: 19,075 reports among females and 569 reports for males, of which 504 reports were received after the vaccine was licensed for males in October 2009. VAERS received 452 reports of unknown gender. Of the total number of VAERS reports following Gardasil, 92% were considered to be nonserious, and 8% were considered serious. As of September 15, 2011, there have been a total of 71 VAERS reports of death among those who have received Gardasil. There were 57 reports among females, three were among males, and 11 were reports of unknown gender.[4]

The alternative vaccine, Cervarix, which was licensed in October 2009, has a significantly lower level of adverse events, as reported to VAERS. As of September 2011, there have been only 52 reported adverse events with the majority (98%) being nonserious.

6. SUMMARY

Reports of neurologic side effects of vaccinations are frequently received with varying degrees of skepticism. The CDC and FDA continually monitor all adverse events reported in conjunction with vaccines licensed in the United States. As providers involved in the distribution of the Vaccine Information Sheet, these organizations ensure that all vaccine information is included for parents and patients. Vaccine safety is essential to preventing disease, but patient safety postimmunization is also vital. ■

Dr. Quinn is a clinical assistant professor at Rutgers College of Nursing. Her research interests include childhood-obesity interventions, primary-care pediatric issues, and vaccination safety.

References

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3. Brotherton JM, Gold MS, Kemp AS, et al. Anaphylaxis following quadrivalent human papillomavirus vaccination. *CMAJ*. 2008;179:525-533. Available at www.ncbi.nlm.nih.gov/pmc/articles/PMC2527382/.
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All electronic documents accessed on September 15, 2012

"How's my inane chitchat?"

"As far as we can tell, Mr. Schroeder, your glasses are smudged."

"No refunds."