34. Oops, I Didn’t Follow My Post Vaccination Instructions

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Session: P-2. Adult Vaccines

Background: Smallpox vaccine is derived from vaccinia virus, a large, double-stranded DNA virus. With the worldwide eradication of smallpox, routine vaccination with vaccinia virus is no longer performed. However, at-risk laboratory and health care personnel continue to be vaccinated against smallpox, and large numbers of military personnel in the United States resumed smallpox vaccination after the anthrax bioterrorism in 2001. Two available smallpox vaccines are part of the strategic stockpile in the United States; one is a replication-deficient modified vaccinia Ankara vaccine (MVA), and the other is a replication-competent smallpox vaccine (ACAM2000). Among others, one of the potential complications of smallpox vaccine is an accidental autoinoculation or accidental inoculation of close contacts.

Methods: A 27-year-old female presented to the employee health clinic at Vidant Medical Center with a 7-day lesion on her right upper extremity. She denied any fever, chills, pets at home, insect bites or trauma to the area. She was using inhaled nebulizers for her asthma and lived in Greenville, NC, with her boyfriend. The lesion was non-itchy, approximately 5 mm blister like rash that ulcerated with a grayish, white center after bandage changes, and avoiding skin-to-skin contact.

Initial Lesion

Disclosures: Joseph Eiden, MD, PhD, FluGen (Consultant) Ruth Ellis, MD, FluGen (Consultant) Roger Atchison, ScM, FluGen (Consultant) Renee Herber, BS, FluGen (Employee) Pamuk Bilisel, PhD, FluGen (Employee)

Lesion after Unroofing

5. Pneumococcal Vaccination in High-Risk Adults: An Initial Analysis

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Session: P-2. Adult Vaccines

Background: Despite CDC’s recommendation, vaccination rates for adults at high-risk of invasive pneumococcal disease are below HealthyPeople 2020 goals. Comparatively little is known about influencers on vaccine-seeking behavior in this population, particularly related to social determinants of health. To address this gap, this study assessed the potential influence of select social determinants on uptake of and time to pneumococcal vaccination among a high-risk, insured US population.

Methods: Using the MarketScan commercial claims databases between 2013–2016, adults patients (aged 18–64 years) were followed from their first diagnosis for a condition deeming them high-risk for invasive pneumococcal disease through one year following the diagnosis and observed for pneumococcal vaccination in outpatient clinics and pharmacies. Publicly-available data on select social determinants of health were incorporated into analyses, guided by the WHO vaccine hesitancy matrix. Logistic regression determined predictors of vaccination and a generalized linear model compared days to being vaccinated while controlling for baseline demographic and clinical characteristics.

Results: A total of 173,712 patients were analyzed of which 25.3% were vaccinated against invasive pneumococcal disease within the first year of being deemed high risk, nearly all of which (98.5%) were received in outpatient clinics. The odds of vaccination were particularly high in areas of higher health literacy (OR: 1.02; 95% CI: 1.019–1.025), and more liberal-voting communities (OR: 1.23, 95% CI: 1.23–1.88). Conversely, the odds of vaccination were particularly low in areas of higher poverty (OR: 0.14; 95% CI: 0.068–0.304) and with more limited

Figure 1: Initial Lesion on the Right Upper Extremity

Figure 2: Lesion after Unroofing for Specimen Collection

35. Pneumococcal Vaccination in High-Risk Adults: An Initial Analysis Incorporating Social Determinants of Health

Justin Gatwood, PhD, MPH; Chi-Yang Chiu, PhD; Sohul A. Shuvo, MS; Sujith Ramachandran, PhD; Kenneth Hohmeier, PharmD; Tracy Hagemann, PharmD; University of Tennessee College of Pharmacy, Nashville, Tennessee; University of Tennessee College of Medicine, Memphis, Tennessee; University of Tennessee College of Graduate Health Sciences, Memphis, Tennessee; University of Mississippi School of Pharmacy, University, Mississippi

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36. Safety and Reactogenicity of the Adjuvanted Recombinant Zoster Vaccine in Immunocompromised Populations: an Overview of 6 Trials

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Session: P-2. Adult Vaccines

Background: Herpes zoster (HZ) is common after allogeneic hematopoietic stem cell transplantation (HCT) and associated with high morbidity. While antiviral prophylaxis reduces incidence, increased risk remains after discontinuation and vaccination strategies are needed. A non-live adjuvanted recombinant zoster vaccine (RZV) has been developed but not yet studied in this population.

Methods: In this single center prospective observational cohort study, allogeneic HCT patients who had HCT ≥18 years old and 9–24 months from HCT were eligible to receive two doses of RZV separated by ≥8 weeks as part of revised institutional vaccination guidelines. The primary endpoint was safety and reactogenicity in the total vaccinated cohort (TVC). The secondary endpoints were incidence and severity of chronic graft versus host disease (cGVHD) in the TVC compared to historical controls and incidence rates of HZ in the TVC and modified total vaccinated cohort (mTVC).

Results: Of the 158 participants (mean age 55 years; 91 [58%] male) in the TVC, 150 (95%) received second vaccine. 91.2% had solicited reactions with 83.7% injection site reactions (18.7% grade 3) and 82.8% general reactions (26.5% grade 3). In the subgroup receiving first vaccine at 9–12 months after HCT, cumulative incidence of cGVHD was similar to historical controls at predefined time points between 9–15 months (unadjusted incidence rate ratio [IRR] 1.1 [95% CI 0.84–1.44]; adjusted IRR 1.05 [95% CI 0.86–1.28]). There were 4 (2.5%) HZ cases during the study period with IR 28.34/1000 person-years over median follow up 281 days (IQR 190, 354) in the mTVC. All cases occurred after antiviral prophylaxis discontinuation and one case resulted in death.

Conclusion: Two doses of RZV after allogeneic HCT was safe and acceptable despite high rates of reactogenicity. There was no evidence of an increase in cGVHD, relapse, or death compared to historical controls and overall low rates of breakthrough HZ similar to those reported after autologous HCT. Immunogenicity studies and placebo-controlled trials are needed to determine vaccine response and efficacy so that timing of RZV and its potential impact on discontinuation of antiviral prophylaxis can be determined.

Disclosures: Nicolas C. Issa, MD, AlCuris (Scientific Research Study Investigator); Astellas (Scientific Research Study Investigator); GSK (Scientific Research Study Investigator); Merck (Scientific Research Study Investigator)

37. Safety Profile of the Adjuvanted Recombinant Zoster Vaccine (RZV) in Immunocompromised Populations: an Overview of 6 Trials

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Session: P-2. Adult Vaccines

Background: Immunocompromised (IC) populations are at increased risk of herpes zoster (HZ) and its related complications. RZV demonstrated >68% efficacy against HZ in autologous hematopoietic stem cell transplantation (HSCT) recipients ≥18 years of age (YOA). Here we present the safety data across 6 clinical trials in IC populations: autologous HSCT recipients, HIV-infected adults, renal transplant recipients, patients with solid tumor and patients with hematological malignancies.

Methods: All 6 studies (Table 1) enrolled IC adults ≥18 YOA in RZV and Placebo groups. Safety was evaluated in the total vaccinated cohort (TVC). Solicited adverse events (AEs) were collected for 7 days and unsolicited AEs for 30 days after each dose. Serious AEs (SAEs), and potential immune-mediated diseases (pMDs) were collected from dose 1 until 1 year post-dose or study end (for causally related [assessed by investigator] and fatal SAEs). Data are presented by age group: 18–49 YOA and ≥50 YOA. Reactogenicity data are pooled across the 6 studies and other safety data are presented by study.

Table 1. Clinical trials with immunocompromised populations included in our analysis

Results: 1587 (RZV) and 1529 (Placebo) adults were included in the pooled TVC. Solicited AEs were more frequently reported in the RZV than Placebo group. Pain, fatigue, headache, myalgia, shivering and fever were reported more frequently in the RZV 18–49 YOA than in the RZV ≥50 YOA (Figure 1). Solicited AEs were mostly mild/moderate and lasted ≤3 days and grade 3 solicited AEs lasted ≤2 days (median duration). Across studies, the percentage of adults reporting ≥1 unsolicited AEs was similar between RZV (18–49 YOA: 37.4–80.6%; ≥50 YOA: 36.9–87.2%) and Placebo (18–49 YOA: 31.4–90.0%; ≥50 YOA: 30.1–89.4%) (Figure 2). Overall, the percentage of adults with ≥1 SAE (Figure 3), causally related SAEs, fatal SAEs and pMDs was similar between RZV and Placebo and between age groups. Overall, no safety concern was identified.

Figure 1. Percentage of participants with solicited local and systemic AEs, reported 6 pooled studies (7 days post-vaccination, overall/participant, pooled total vaccinated cohort)

Figure 2. Percentage of participants with solicited systemic AEs reported 6 pooled studies (7 days post-vaccination, overall/participant, pooled total vaccinated cohort)

Figure 3. Percentage of participants with solicited local AEs reported 6 pooled studies (7 days post-vaccination, overall/participant, pooled total vaccinated cohort)