2743. Safety of Recombinant Influenza Vaccine Compared with Inactivated Influenza Vaccine in Adults
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Background: In 2013, a recombinant trivalent influenza vaccine (RIV, Flublok®) was licensed for use against influenza virus subtypes A and B contained in the vaccine for persons 18–49 years of age and approved for all adults 218 years of age in 2014. The study aim was to evaluate the safety of RIV compared with trivalent standard-dose, inactivated influenza vaccine (IIV3) in Kaiser Permanente Northern California (KPNC).

Methods: This was an observational, retrospective cohort study including all persons ≥218 years vaccinated in KPNC facilities with RIV or IIV3 during the 2015–2016 influenza season as part of routine clinical care. We compared the rates of pre-specified diagnoses of interest (Guillain–Barre Syndrome, pericarditis, pleural effusion, narcolepsy/catatexy, asthma, acute hypersensitivity reactions and fever) using International Classification of Diseases codes during post-vaccination risk intervals 0–2, 0–13, 0–41, and 0–180 days, as well as all-cause hospitalization rates 0–180 days following vaccination. Comparing cohorts, we estimated odds ratios (ORs) and 95% confidence intervals (CIs) using logistic regression analyses adjusted for age, sex, race/ethnicity, month of vaccination, and concomitant receipt of other vaccinations.

Results: During the study period, 21,976 persons received RIV and 283,683 received IIV3. Comparing RIV with IIV3, there were no statistically significantly elevated outcomes. RIV vaccination was associated with significantly decreased fever in the 0–41 day risk interval (OR 0.38, 95% CI 0.14–0.86) and all-cause hospitalization (OR 0.86, 95% CI 0.61–0.73) in the 0–180 day risk interval. Further analyses found that the lower rates of hospitalization in RIV recipients was mostly, though not fully related to pregnancy-related hospital events in the IIV3 cohort and to the presence of additional unmeasured confounding. There were no serious adverse events or deaths related to RIV or IIV3.

Conclusion: This study did not identify any safety concerns regarding the use of RIV in adults. Understanding the observed reduction in all-cause hospitalization will need additional studies.

Disclosures. All authors: No reported disclosures.

2744. A Phase I Randomized, Observer-Blind, Controlled, Dose Escalation Trial of the Safety and Tolerability of a Single Intramuscular Dose of a PAL Adjuvant (Laboratory Code, FB-631) Co-administered with Seasonal TIV (2013–2014) to Healthy Adults 18–50 Years of Age
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Background: Inactivated influenza vaccines (IV) efficacy is variable and sometimes poor. In this phase 1 trial the safety and immunogenicity of a novel nanoparticle adjuvant (Papaya Mosaic Virus (PapMV or PAL) at different dose levels combined with inactivated trivalent IV (TIV; FLUVIRAL® 2013–2014, Sanofi Pasteur) was licensed for use against influenza virus subtypes A and B contained in the vaccine for persons 18–49 years of age and approved for all adults ≥218 years of age in 2014. The study aim was to evaluate the safety of RIV compared with trivalent standard-dose, inactivated influenza vaccine (IIV3) in Kaiser Permanente Northern California (KPNC).

Methods: This was an observational, retrospective cohort study including all persons ≥218 years vaccinated in KPNC facilities with RIV or IIV3 during the 2015–2016 influenza season as part of routine clinical care. We compared the rates of pre-specified diagnoses of interest (Guillain–Barre Syndrome, pericarditis, pleural effusion, narcolepsy/catatexy, asthma, acute hypersensitivity reactions and fever) using International Classification of Diseases codes during post-vaccination risk intervals 0–2, 0–13, 0–41, and 0–180 days, as well as all-cause hospitalization rates 0–180 days following vaccination. Comparing cohorts, we estimated odds ratios (ORs) and 95% confidence intervals (CIs) using logistic regression analyses adjusted for age, sex, race/ethnicity, month of vaccination, and concomitant receipt of other vaccinations.

Results: During the study period, 21,976 persons received RIV and 283,683 received IIV3. Comparing RIV with IIV3, there were no statistically significantly elevated outcomes. RIV vaccination was associated with significantly decreased fever in the 0–41 day risk interval (OR 0.38, 95% CI 0.14–0.86) and all-cause hospitalization (OR 0.86, 95% CI 0.61–0.73) in the 0–180 day risk interval. Further analyses found that the lower rates of hospitalization in RIV recipients was mostly, though not fully related to pregnancy-related hospital events in the IIV3 cohort and to the presence of additional unmeasured confounding. There were no serious adverse events or deaths related to RIV or IIV3. Comparing cohorts, we estimated odds ratios (ORs) and 95% confidence intervals (CIs) using logistic regression analyses adjusted for age, sex, race/ethnicity, month of vaccination, and concomitant receipt of other vaccinations.

Conclusion: This study did not identify any safety concerns regarding the use of RIV in adults. Understanding the observed reduction in all-cause hospitalization will need additional studies.

Disclosures. All authors: No reported disclosures.