Poster 0247

Risk of Incident Gout Following Exposure to Recombinant Zoster Vaccine in Adults Aged ≥50 Years in the United States

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Digital poster
Supplemental data
Narrated summary
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Introduction

Herpes zoster (HZ), also called shingles, typically manifests as a painful rash and can cause debilitating complications, including persistent pain or vision loss. An estimated 1 million cases occur annually in the US.[1,2]

Recombinant zoster vaccine (RZV), an adjuvanted vaccine administered as a two-dose series, was approved in October 2017 for adults aged ≥50 years for prevention of HZ.[3]

- Vaccine efficacy against HZ in Phase 3 studies was 97.2% in adults aged ≥50 years[4] and 91.3% in adults aged ≥70 years[5]

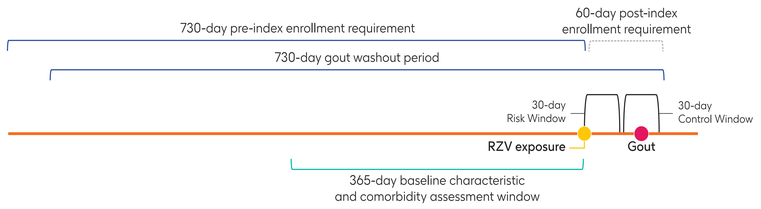
Pre-licensure clinical trials for RZV identified more frequent gout diagnoses among recipients of RZV than placebo; however, there was a lack of precision in the way risk of gout was assessed.[6,7]

This current real-world safety study assessed whether RZV is associated with an increased risk of new-onset gout among US individuals aged ≥50 years.

Methods

- **Data**: Administrative claims data from four national insurers and one regional insurer in the FDA's Sentinel System, a large, distributed data network, from January 1, 2018, to December 31, 2019
- **Inclusion criteria included**:
  1. Age ≥50 years at time of RZV dose
  2. Continuous health plan enrollment for 730 days prior through 60 days following RZV
- **Primary analysis**: Conditional Poisson regression estimating the relative risk (RR) of incident gout in the RW versus the CW after RZV dose 1 or 2. Dose 1 CW truncated at dose 2 receipt
- **Secondary analysis**: Analytically assumed a full 30-day CW following dose 1, regardless of whether dose 2 occurred in this CW. Any gout following dose 2 was attributed only to dose 2

Study design: Retrospective self-controlled risk interval (SCRI) with a 30-day risk window (RW) followed by a 30-day control window (CW)



Results

Sample characteristics

Demographics

66% male

Mean age 72.5 years (SD 8.3)

Comorbidities

40% diabetes

38% chronic kidney disease

28% ischemic heart disease

The relative risk of gout following RZV dose 1 or 2 in the primary analysis was 1.03 (0.81, 1.29)

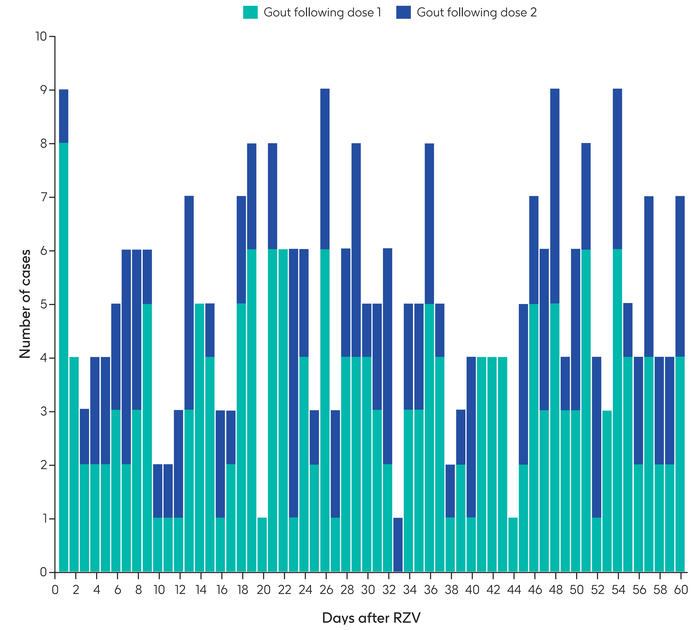
Description of analysis	Total case count, n	Cases in RW, n (%)	Cases in CW, n (%)	RR (95% CI)
Primary analysis				
Gout following RZV dose 1 or 2	302*	153 (50.7)	149 (49.3)	1.03 (0.81, 1.29)
Secondary analysis				
Gout following RZV dose 1 or 2 (30-day CW for both doses)	302	153 (50.7)	149 (49.3)	1.03 (0.81, 1.30)
Sensitivity analyses				
Gout following RZV dose 1	191	99 (51.8)	92 (48.2)	1.08 (0.80, 1.45)
Gout following RZV dose 2	111	54 (48.6)	57 (51.4)	0.95 (0.64, 1.40)
Gout following RZV dose 1 or 2, restricted to two-dose recipients with 60–183 days between doses	235	120 (51.1)	115 (48.9)	1.04 (0.80, 1.36)
Gout following RZV dose 1 or 2, adjusted for seasonality	302	153 (50.7)	149 (49.3)	1.03 (0.82, 1.30)
Gout following RZV dose 1 or 2, pre-COVID-19	293	149 (50.9)	144 (49.1)	1.03 (0.82, 1.31)

*Among 461,323 patients with ≥1 RZV dose, 302 were eligible for the SCRI analysis, with evidence of new-onset gout within 60 days

Conclusion

- This retrospective safety study found no evidence of an increased risk of gout in the 30 days following RZV vaccination relative to a 30-day control period among a large, diverse national patient population of adults aged ≥50 years

No time window in the 60 days following RZV had a statistically significant excess occurrence of gout events



Abbreviations

ACR, American College of Rheumatology; CI, confidence interval; CPT, Current Procedural Terminology; CW, control window; FDA, U.S. Food and Drug Administration; HZ, herpes zoster; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; NDC, National Drug Code; RR, relative risk; RW, risk window; RZV, recombinant zoster vaccine; SCRI, self-controlled risk interval; SD, standard deviation.

References

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Disclosures

SAK, ALS, SA, AP, CEH, DL, RP, QM, MS, and AJA report no conflicts of interest; EM has consulted for Pfizer; CNMW and DAD are employees of, and shareholders in, CHP and NJZ are employees of Optum and may own stock in UnitedHealth Group; KD has undertaken independent contract work for AbbVie/Abbott, AstraZeneca, GSK, and Pfizer; OMS, DO, HS, and VF are employees of, and shareholders in, GSK; SG is an employee of, and shareholder in, GSK and is a shareholder in Supernus Pharmaceuticals; HY is an employee of GSK. The study was funded by GSK.

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