**IMPACT OF REACTOGENICITY ON QUALITY OF LIFE AND PHYSICAL FUNCTIONING IN ADULTS ≥50 YEARS RECEIVING BOTH DOSES OF THE ADJUVANT RECOMBINANT ZOSTER VACCINE**

**Background and aims**

- Shingrix (RZV, GlaxoSmithKline, MD, USA) is a novel recombinant zoster vaccine administered to prevent herpes zoster (shingles) in adults aged ≥50 years from multiple locations across the United States.
- The study aimed to evaluate reactogenicity and safety outcomes, SF-36 quality of life assessments, and SF-36 physical functioning in adults aged ≥50 years receiving both doses of Shingrix.
- The study included 400 participants from the Shingrix Adjuvant Zoster Trial, who were ≥50 years old at randomization and had received both doses of Shingrix.

**Methods**

- **Study Design:** Double-blind, placebo-controlled, parallel-arm, 7-day follow-up study.
- **Participants:** Adults aged ≥50 years randomized to receive either Shingrix or placebo.
- **Randomization:** 1:1 allocation to Shingrix or placebo.
- **Outcome Measures:** Reactogenicity, SF-36 quality of life assessments, SF-36 physical functioning.

**Results**

- **Reactogenicity and Safety Outcomes:**
  - Grade 3 (most severe) local and systemic reactions were reported by 7.2% (local) and 11.1% (systemic) of participants.
  - The reactogenicity profile was similar after either dose; both the safety and reactogenicity outcomes were consistent across age groups.

- **SF-36 Quality of Life Assessments:**
  - The decrease in mean SF-36 PF scores observed for participants who reported grade 3 reactogenicity was significant (p < 0.05).
  - The overall QoL assessment (SF-36) and PF of adults aged ≥70 years were not significantly affected by reactogenicity up to 7 days post-RZV dose 2.

- **Conclusions:**
  - Overall, the QoL and PF of adults aged ≥70 years were not affected post-RZV dose 2, but a transient impact was observed, in particular in participants with grade 3 reactogenicity.
  - SF-36 results were consistent across age groups.

**Phase III, single-arm, open-label, multicenter study (NCT03776839)**

- **Study Participants and Demographics:**
  - Participants were adults aged ≥50 years from multiple locations across the United States.
  - The study included 400 participants from the Shingrix Adjuvant Zoster Trial.
  - Participants were ≥50 years old at randomization and had received both doses of Shingrix.

**Quality of life assessments**

- **SF-36:**
  - Standardized measures of health-related quality of life (HRQoL), including physical functioning (SF-36 PF) and general health (SF-36 GH).

**Gol results**

- **SF-36 Physical Functioning:**
  - Mean SF-36 PF score was only affected for 1-2 days post-RZV dose 2.

**What is new?**

- The reactogenicity profile is similar after either RZV dose; both the safety and reactogenicity outcomes were consistent across age groups.

**Plain Language Summary**

- About 30% of the global population will experience herpes zoster in their lifetime, and the risk of herpes zoster increases with age. Shingrix is associated with a significant reduction in the risk of herpes zoster, including pain and a decrease in quality of life.
- Reactogenicity profile is similar after either RZV dose; both the safety and reactogenicity outcomes were consistent across age groups.

**What is the impact?**

- The impact of reactogenicity reactions following Shingrix vaccination on the quality of life was evaluated in adults aged ≥50 years from multiple locations across the United States.

- Overall, no reduction in physical functioning or quality of life was observed after vaccination. However, the quality of life of patients reporting high intensity reactogenicity was decreased for up to 7 days after the vaccine dose 2.

**What are the key messages?**

- There was no significant impact on quality of life that was far less than expected in up to 7 days after vaccination.

- We associated a significant adverse event with this vaccine.

**Citations**


**Trademark statement**

- Shingrix is a registered trademark of GlaxoSmithKline Biologicals S.A., Belgium.

**Funding statement**

- This research was funded by GlaxoSmithKline Biologicals S.A., Belgium.

**Author contributions**

- Michael Chen, MD
- Caroline Hervé, PhD
- Anne Schuind, MD
- Michael Copland, MD
- Michael La, MD
- Patricia Yu, MD
- Caroline Hervé, PhD
- Anne Schuind, MD
- Michael Copland, MD
- Michael La, MD
- Patricia Yu, MD

**Conflicts of interest**

- The authors have no conflicts of interest to declare.

**Acknowledgments**

- We would like to thank the participants who volunteered in this study.

**Current affiliation**

- Michael Chen, MD: CureVac AG, Tübingen, Germany
- Caroline Hervé, PhD: The Corvallis Clinic, Corvallis, OR, USA; School of Public Health, University of California, Berkeley, CA, USA.
- Anne Schuind, MD: CureVac AG, Tübingen, Germany
- Michael Copland, MD: Shingrix Advisory Board
- Michael La, MD: Shingrix Advisory Board
- Patricia Yu, MD: Shingrix Advisory Board