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Session: 254. Vaccines for the Elderly and Immune Compromised
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Background. Herpes zoster (HZ) and its related complications are associated with a significant burden of illness in older adults, which negatively impacts patients' physical functioning and quality-of-life (QoL). The recombinant zoster vaccine (RZV) shows high efficacy for the prevention of HZ in older adults but is associated with local and systemic reactions. Therefore, this study assessed the impact of RZV reactogenicity upon the physical functioning and QoL of participants.

Methods. 401 adults aged ≥50 years received a dose of RZV at 0 and 2 months in this open-label, single-arm, multicenter study (NCT02979639). Changes in mean SF-36 Physical Functioning score were assessed between pre-dose-1 vaccination and post-dose-1 vaccination for 7 days (primary endpoint). Decreased scores are associated with decreased physical functioning. QoL, reactogenicity and safety were also assessed. The current analysis was performed post-dose-1 vaccination of the 2-dose RZV schedule.

Results. No clinically meaningful reductions in overall mean SF-36 Physical Functioning scores from pre- to post-RZV dose-1 were observed (mean +1.9 points) and no overall quality-adjusted-life-year loss was recorded post-dose-1. However, grade 3 reactogenicity occurred in 9.5% of participants, and was associated with a transient, clinically-important decrease in SF-36 Physical Functioning score (impacting activities such as walking, carrying groceries, climbing stairs) on Days 1–2 post-first-vaccination (Table 1). The solicited local symptoms were pain (77.5%), redness (23.0%) and swelling (13.3%); the most frequent solicited systemic reactions were fatigue (33.5%), headache (28.3%) and myalgia (26.8%).

Conclusion. Overall, the physical functioning and QoL of older adults were not significantly affected by a first RZV dose. Grade 3 reactogenicity was associated with a small transient decrease in physical functioning 1–2 days post-dose-1 that resolved by Day 3 post-vaccination.

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Table 1. Mean SF-36 Physical Functioning scores pre- and post-first vaccination by day, reactogenicity grade and symptom type (total vaccinated cohort)

Day	Grade 0 N=64	Grade 1 or 2 N=299	Grade 3 N=38	No symptoms N=64	Local symptoms N=321	Systemic symptoms N=220
Pre-vaccination						
-7	76.8	82.8	75.5	76.8	81.8	81.8
0	82.3	84.3	75.8	82.3	83.5	82.8
Post-vaccination						
1	84.8	84.1	65.2	84.8	82.0	79.7
2	84.7	85.5	68.0	84.7	83.8	82.3
3	84.9	85.7	74.8	84.9	84.5	83.7
4	84.8	85.6	75.7	84.8	84.5	83.6
5	85.0	85.7	77.2	85.0	84.8	84.0
6	85.0	85.7	74.7	85.0	84.5	83.7
7	83.1	85.4	75.5	83.1	84.7	82.9

Norms of SF-36 Physical Functioning scores in the US for ages 45–54, 55–64, 65–74 and 75–89 are 0.80, 0.78, 0.78 and 0.76, respectively (Fryback et al. Med Care. 2007;45(12):1162–70); High scores represents high level of functioning/quality-of-life; **N**, total number of vaccinated participants; **Reactogenicity grading**: 0 (none/normal); 1 (mild); 2 (moderate); 3 (severe; prevents normal activity); for swelling/redness: greatest surface diameter, 0 (<20mm); 1 (≥20-≤50mm); 2 (>50-≤100mm); 3 (>100mm); for temperature: 0 (<37.5°C); 1 (37.5-38.0°C); 2 (38.1-39.0°C); 3 (>39.0°C); Participants were characterised according to maximum reactogenicity grade reported within 7 days post-dose 1

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2490. A Phase 1, Randomized, Observer Blind, Antigen and Adjuvant Dosage Finding Study to Evaluate the Safety and Immunogenicity of an Adjuvanted, Trivalent Subunit Influenza Vaccine in Elderly Subjects ≥65 Years of Age

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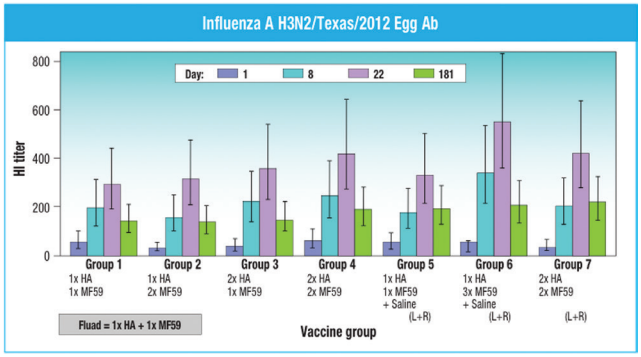
Background. Influenza virus infection in the elderly remains one of the ten leading causes of death. One successful strategy to enhance the magnitude of their influenza vaccine immune response has been the addition of the adjuvant MF59®.

Methods. 196 subjects ≥ 65 years of age were enrolled in a dose ranging study with seven treatment arms to assess the safety and immunogenicity of the current formulation of aTIV compared with aTIV-modified formulations in which the dosage of MF59 was doubled or tripled and/or the dosage of the three influenza virus strains (A/H1N1, A/H3N2, and B) was doubled. Vaccine was administered by single or bilateral deltoid inoculations. The antibody responses to all three influenza virus vaccine strains were compared 21 days after a dose or doses of aTIV or aTIV-modified formulations, as measured by hemagglutination inhibition (HI) assay and microneutralization (MN) assay.

Results. In general, HI and MN titers at Day 22 increased to a greater degree with the dosage of MF59 compared with that of HA (HI presented in Figure 1). This was evident when comparing the HI and MN titers where antigen content was a constant 45 µg, but MF59 dose ranged from 9.75, 19.5 to 29.25 mg in a single vaccine dose (Group 1, 2 and 6, respectively). Generally, the highest titers against all strains were evident with the highest MF59 dose (29.25 mg). The relationship of antigen content and immunogenicity of the vaccine was less apparent when comparing titers between groups in which HA antigen content doubled from 45 to 90 µg. Administering the dose of MF59 (19.5 mg) and TIV (90 µg) into either a single arm or dividing between two arms resulted in comparable titers. The incidence of solicited AEs tended to increase with the dose of MF59 and to a lesser degree, antigen. The majority of solicited AEs were mild to moderate in severity. The number of unsolicited AEs were similar across the different dosages used in this trial.

Conclusion. In elderly subjects ≥65 years of age, increase in MF59 dose is associated with increased immunogenicity against all 3 components of seasonal influenza vaccine.

Figure 1. Geometric mean titer (HI) against influenza A/H3N2/Texas/2012 according to dose of MF59 and HA.



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2491. Post-Exposure Prophylaxis With Ribavirin Plus Lopinavir/Ritonavir for Middle East Respiratory Syndrome in Healthcare Workers

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Background. In 2015, an outbreak of Middle East Respiratory Syndrome coronavirus (MERS-CoV) infection occurred in South Korea involving 186 patients, 39 of whom were healthcare workers (HCWs) exposed to the infection. An effective post-exposure prophylaxis (PEP) strategy may limit the spread of infection; however, there is no consensus regarding PEP for MERS-CoV infection. In this study, we assessed (1) the efficacy of oral ribavirin and lopinavir/ritonavir as PEP for HCWs exposed to patients with severe MERS-CoV pre-isolation pneumonia, and (2) safety of the PEP regimen.

Methods. We retrospectively enrolled 43 HCWs with high-risk exposure to MERS-CoV from 5 hospitals affected during this outbreak in South Korea. The rate of MERS-CoV infection was compared between 22 workers at 1 hospital who received PEP consisting of oral ribavirin and lopinavir/ritonavir after exposure to patients with severe MERS-CoV pre-isolation pneumonia and 21 workers at other hospitals who did not receive PEP.

Results. Six workers (14%) developed MERS-CoV infection; all of these subjects belonged to the non-PEP group. The attack rate was lower in the PEP group compared with the non-PEP group (0% vs. 28.6%; Odds ratio = 0.405, 95% confidence interval = 0.274–0.599; $P = 0.009$). The most commonly reported side effects of PEP therapy were nausea and diarrhea, but there were no severe adverse effects associated with PEP therapy.