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Session: 254. Vaccines for the Elderly and Immune Compromised
Saturday, October 6, 2018: 12:30 PM

Background. Vaccine immune response is impaired in cancer patients. Follicular helper T lymphocytes (cTfh) are essential for high affinity and long lasting humoral response. The objective of this study was to evaluate the role of cTfh in the immune response induced by influenza vaccine in children with acute lymphoblastic leukemia (ALL).

Methods. Children with ALL in maintenance therapy and a control group of healthy children were included. Blood samples were taken on the day of vaccination (D0), and on day 28 (D28). The humoral response was evaluated by haemagglutination inhibition test and frequency of cTfh was studied by flow cytometry.

Results. Twenty-four children with ALL and 8 healthy children were included: 67 and 38% were women, median age of 5 years old in both groups. A 33% (8/24) of patients and 63% (5/8) of controls were seroprotected at D28. Seroprotected children at D28 were significantly older than non-protected ones (10 and 3.6 years respectively, P = 0,004). During follow-up, three children with ALL had influenza infection. An increase of percentage of cTfh cells from D0 to D28 was observed in both groups, but it was significant only in ALL patients (average for ALL, D0-D28: 18–23%, P = 0.003 and average for controls, D0-D28: 22–26%). No differences were found between seroprotected and non-seroprotected children in cTfh cell at D0 or D28. The increase of percentage of cTfh cells from D0 to D28 was observed in both groups, it was significant only in non-seroprotected subjects (average for seroprotected, D0-D28: 21–24% and average for non-seroprotected, D0-D28: 18–24%, P = 0.004).

Conclusion. Children with ALL achieved a lower seroprotection than healthy children. After vaccination, both groups had an increase of cTfh cells. We did not found an association between the percentage of cTfh cells and seroprotection at D28. The association between the lack of humoral response and cTfh dysfunction should be evaluated in further studies (We report public funding from Fondecyt grant Nº 11150970).

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2486. The Effectiveness of High-Dose Hepatitis B Vaccination in Patients Receiving Immunomodulatory Therapy

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Session: 254. Vaccines for the Elderly and Immune Compromised
Saturday, October 6, 2018: 12:30 PM

Background. The course of hepatitis B virus (HBV) infection is more severe in patients using immunomodulatory drugs (ID) than in the normal population. This study evaluates the results of double-dose administration of HBV vaccine of 40 µg at months 0, 1, 2, and 6.

Methods. Anti-HBs negative patients presenting to our polyclinic between January 1 and July 1, 2017 and using ID were administered a double dose of HBV vaccine at months 0, 1, 2, and 6. Patients' primary diseases and comorbid factors were recorded. Anti-HBs titers above 10 mIU/mL 1 month after completion of vaccination schedules were regarded as response to vaccine.

Results. Eighty patients presented during the study. Seventeen patients failing to attend follow-ups were excluded. Twenty-eight (44.4%) of the 63 patients enrolled were men and 35(55.6%) were women. Patients' ages ranged between 18 and 66, with a mean age of 44.2 (±12.2) and a median value of 46. Comorbid factors were essential hypertension in 5 patients, diabetes mellitus in 4, and hypothyroid in 3. Vaccination was started within 2 weeks before commencement of ID or simultaneously with a biological agent in 29(46%) patients, and anti-HBs titers above 10 mIU/mL were achieved in 24 (82.8%). Thirty-four (54%) patients were started on vaccination while using medication [mean 21.1(±27.7) months], and anti-HBs titers above 10 mIU/mL were achieved in 29. Response was achieved in 53(84.1%) of all the patients in the study, while no response was obtained in 10 (15.9%). No gender difference was observed between the responding and non-responding patients. Response to vaccine was independent of sex, comorbid diseases, immunosuppressive agents, and time of commencement of vaccination (Table 1).

Table 1: Analysis of patients' vaccination responses

Vaccination response	Anti-HBs negative (n=10. 15.9%)	Anti-HBs positive (n=53. 84.1%)	
Mean age	47	43.8	
Male/female (%)	50/50	43.4/56.6	
Primary diseases	**n**	**n**	
Rheumatoid arthritis	5	11	
Ankylosing spondylitis	4	25	
Psoriasis	1	16	
Reactive arthritis	0	1	
Biological drug used	**n**	**n**	**n (%)**
Adalimumab	4	19	23 (36.5)
Infliximab	0	6	6 (9.5)
Etanercept	2	15	17 (27)
Golimumab	1	4	5 (7.9)
Tofacitinib	2	4	6 (9.5)
Abatasept	1	0	1 (1.6)
Ustekinumab	0	2	2 (3.2)
Tocilizumab	0	2	2 (3.2)
Certolizumab	0	1	1 (1.6)
Vaccination commenced prior to biological drug (%)	50	45.3	
Mean length of drug use among subjects using medication (months)	19.4 ±24.2	21.4 ±28.1	

Conclusion. In our study, anti-HBs positivity was achieved in 84.1% of patients receiving doses of 40 µg. Although the ideal situation is for patients to start receiving vaccination at least 2 weeks before starting ID, vaccination in the shortest time possible after commencement of treatment is recommended for previously unvaccinated patients. In conclusion, physicians need not be concerned that response to vaccination cannot be achieved in patients started on ID, and seronegative patients must be enrolled in the HBV vaccination program as quickly as possible.

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2487. Vaccination Rates in Post-Transplant Hematopoietic Stem Cell Transplant (HSCT) Patients: Where Do We Stand?

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Session: 254. Vaccines for the Elderly and Immune Compromised
Saturday, October 6, 2018: 12:30 PM

Background. HSCT patients are at an increased risk of developing infections after transplant due to the loss of immunogenicity from prior vaccinations. Current national and international guidelines recommend routine revaccinations at a fixed dosing schedule for HSCT patients post-transplant. Although immunization adherence is vital to prevent infections, compliance with post-transplant vaccinations is unknown. The primary endpoint of this study was the completion rate of the post-transplant vaccination series. Secondary endpoints included identifying reasons for noncompliance, rates of breakthrough vaccine-preventable infections, and assessing post-vaccination antibody responses based on titers.

Methods. A single-center, retrospective study of adult HSCT patients at Yale New Haven Hospital between January 2010 and September 2015 was performed. Patients were excluded if: <18 years of age, deceased prior to one year post-transplant, transferred care to an outside facility, or were lost to follow-up.

Results. A total of 512 HSCT patients were evaluated. 390 (76%) patients were initiated on the vaccination series. Of the 390 patients, 275 (71%) patients were started at one year follow-up per institutional guidelines. The most common reasons for non-initiation or delayed initiation of the vaccine series included disease relapse (14%), active graft vs. host disease (9%), and the need for immunosuppressive therapy (5%). Of the patients initiated on the vaccination series, only 187 (48%) patients completed the entire vaccination series; with the majority of whom were autologous HSCT patients (72%). The most common reasons for an incomplete vaccination series included maintenance chemotherapy (19%), disease relapse (16%), and lost to follow-up (10%). Of the patients who completed the vaccination series, 19% had the appropriate post-vaccination titers obtained. Of the patients who received at least one or more doses of pneumococcal vaccine post-transplant, 8 patients (2%) developed a breakthrough infection with *S. pneumoniae*.

Conclusion. This study adds important data to the limited body of literature on HSCT vaccine compliance rates. Future studies on the best interventions to improve compliance rates are warranted.

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2488. The Impact of Reactogenicity After Administration of the Recombinant Zoster Vaccine Upon the Physical Functioning and Quality of Life of Older Adults

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Session: 254. Vaccines for the Elderly and Immune Compromised
Saturday, October 6, 2018: 12:30 PM

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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Session: 254. Vaccines for the Elderly and Immune Compromised
Saturday, October 6, 2018: 12:30 PM

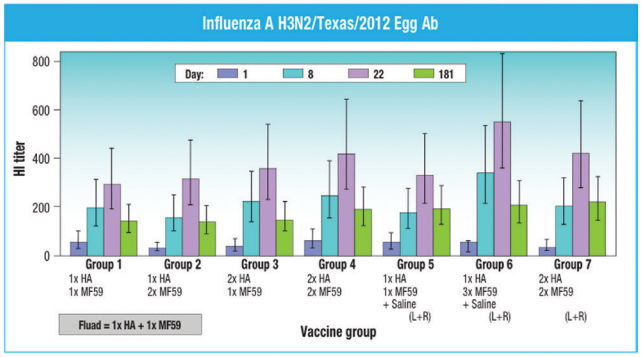
Background. Influenza virus infection in the elderly remains one of the ten leading causes of death. One successful strategy to enhance the magnitude of their influenza vaccine immune response has been the addition of the adjuvant MF59®.

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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Session: 255. Virology Potpourri
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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.