Conclusions. The current standard of care for multiple myeloma (MM) patients is to administer the influenza vaccine (InfV) annually. While in immunocompetent patients, the influenza vaccine is associated with significant benefit in morbidity and mortality, the inherent immunodeficiency from MM and its treatments reduce the InfV efficacy but it is thought to have some benefit. The effect on morbidity and mortality in MM patients has not been evaluated. Our study aims to investigate whether InfV vaccination status affects outcomes of MM patients diagnosed with Influenza A or B (FluA, FluB).

Methods. This was a retrospective study, using Arkansas Clinical Data Repository, which identified all MM patients diagnosed with FluA or FluB during five consecutive flu seasons from September 1st to April 30th, 2015-2020. Those with hospital-acquired influenza were excluded. The outcome data were collected for 30 days following the initial diagnosis. Fisher Exact test was used to compare categorical variables, and Mann Whitney U test to compare continuous variables.

Results. We identified 194 MM patients diagnosed with FluA or FluB. Sixty-five (34%) were vaccinated and 129 (66%) were not vaccinated. A total of 87 (45%) were admitted to the hospital. Twenty-five (38%) of the vaccinated vs. 62 (48%) of the unvaccinated group were hospitalized (p=0.22), and 4/65 vaccinated vs. 12/129 unvaccinated required ICU treatment (p=0.59). Two patients in the vaccinated and 3 in the non-vaccinated group were intubated (p=1). The mean length of stay (LOS) for the vaccinated and unvaccinated was 10 days and 14 days, respectively, which was not significantly different (p=0.197). Two (3%) patients died within 30 days of diagnosis in the vaccinated group while four (3%) died in the unvaccinated group (p=1).

Conclusion. The InfV status of MM patients had no effect on outcomes including the need for hospital admission, ICU stay, mechanical ventilation, LOS, and death. Hospitalization was common, but severe illness requiring ICU care and intubation were less common. Six patients died within 30 days of influenza diagnosis. Vaccination strategy, including high-dose and repeat doses, should be examined in MM patients.

Disclosures. All Authors: No reported disclosures

18. An Easy-to-Implement Clinical-Trial Frailty Index Based on Accumulation of Deficits: Validation in Zoster Clinical Trials
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Background. The impact of frailty on the efficacy and safety of vaccines and therapeutic interventions is increasingly recognized, yet assessment of frailty in clinical trials is often considered logically challenging. We developed the retrospective Clinical Trial Frailty Index (CT-FI), using baseline medical history and patient reported outcomes collected via standard instruments (Short Form Survey 36 and Euro Quality of Life-5 Dimension) in two clinical trials of the adjuvanted recombinant zoster vaccine (RZV, ZOE-50 [NCT01165177] and ZOE-70 [NCT01165229]). This post-hoc analysis aimed to show that CT-FI is a robust measure that may be used in any analysis where sufficient patient data has been collected in a clinical trial.

Methods. Items included in the CT-FI were scored from 0 to 1, summed for each participant and divided by the total number of potential deficits. CT-FI was validated using descriptive methods verifying distribution and age- and sex-associations in relation to established FI characteristics, Cox regressions in relation to fatal outcomes hypothesically related to frailty, and re-sampling methods (jackknife and Bootstrap procedures) within the FI to demonstrate robustness to inclusion/exclusion of specific individual variables.

Results. The CT-FI distribution followed a gamma distribution with a range of 0 to 0.695; the distribution shifted to the right with age. The age-related slope of mean deficit accumulation per year increased with chronological age and was higher for women than men. The rate of mean deficit accumulation was 0.0025 for women vs. 0.0016 for men < 70 years of age, and this increased to 0.0058 for women vs. 0.0047 for men ≥ 70 years of age. In univariate and multivariate Cox regression survival analyses, FI, chronological age and sex were significant predictors for mortality. The Jackknife and Bootstrap re-sampling methods showed that the performance of CT-FI was not sensitive to inclusion/exclusion of specific individual or groups of variables, demonstrating the robustness of this methodology.

Conclusion. The current analysis validates that CT-FI, an easy-to-implement FI, is a robust method which allows retrospective/prospective evaluation of clinical outcomes by frailty status in clinical trials.

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