#572 - Real-world Effectiveness of COVID-19 mRNA Vaccines against Hospitalizations and Deaths in a Retrospective Cohort

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Introduction

The effectiveness of Severe Acute Respiratory Syndrome Coronavirus 2 vaccines after two doses needs to be demonstrated beyond clinical trials in the United States across different populations.

Methods

In a retrospective cohort assembled from a cross-institution comprehensive data repository[1], established patients of the health care system were categorized as having received no doses, one dose or two doses of SARS-CoV-2 mRNA vaccine through April 4, 2021. Outcomes were COVID-19 related hospitalization and death. Multivariable cox-proportional model was performed adjusted for age, sex, race, ethnicity, Area Deprivation Index and Charlson Comorbidity Index for hospitalization. Cumulative incidence for hospitalization over time also performed to account for cohort transition across vaccinated states. Odds ratio of COVID-19 mortality also calculated.

Results

- Of 94,018 patients 27.7% had completed two doses and 3.1% had completed one dose of a COVID-19 mRNA vaccine.
- The two dose group was older with more comorbidities.
- 1.0% of the two dose group had a COVID-19 hospitalization, vs. 4.0% and 2.7% in the one dose and no dose groups.

Table 1: Socio-demographics of two, one and no dose COVID-19 groups

	Two Doses (n = 26,064)	One Dose (n = 2,886)	No Dose (n = 65,068)		Two Doses (n = 26,064)	One Dose (n = 2,886)	No Dose (n = 65,068)
Demographics, Social, Behavioral Characteristics				Area Deprivation Index – median (IQR)	34 (18 – 56)	40 (23 – 62)	44 (24 – 67)
Age – mean (SD)	65.8 (14.9)	58.1 (16.0)	54.8 (20.1)	Tobacco Use (Current / Former)[4]	9,633 / 25,492 (37.8)	1,058 / 2,828 (37.4)	23,105 / 62,827 (36.8)
Female – n (%)	15,524 (59.6)	1,878 (65.1)	41,251 (63.4)	Alcohol Use[4]	8,157 / 14,135 (57.7)	873 / 1,558 (56.0)	16,806 / 32,245 (52.1)
Race – n (%)				Comorbidities and Co-existing Conditions			
White	19,282 (74.0)	2,026 (70.2)	44,959 (69.1)	Charlson Comorbidity Index (CCI) Score – median (IQR)	5 (3 – 9)	4 (2 – 8)	3 (1 – 7)
Black	4,343 (16.7)	628 (21.8)	14,615 (22.5)				
Asian	1,657 (6.4)	109 (3.8)	2,615 (4.0)				
Other	782 (3.0)	123 (4.3)	2,879 (4.4)	BMI – mean (SD)	29.5 (6.7)	31.0 (7.6)	29.8 (8.1)
Hispanic – n (%)	3,436 / 25,897 (13.3)	540 / 2,875 (18.8)	12,296 / 64,676 (19.0)				

Results cont.

**Figure 1: Cohort Enrollment and Distribution by Immunization Status and Vaccine effectiveness against mortality:**
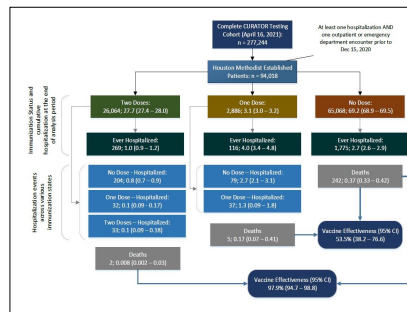
Cohort members are described by their immunization status and hospitalization at the end of the study period ending April 4th, 2021. Each group is divided into when hospitalized events occurred across immunization status. These percentages compare the number of events to the population in the immunization status at the end of the analysis period. Odds ratios for mortality were calculated and vaccine effectiveness calculated as 1 minus odds ratio times 100%.

Table 2: Hazard Ratios, odds ratios and vaccine effectiveness associated with COVID-19 hospitalizations and death after COVID-19 mRNA vaccine

	Hospitalization HR (95% CI)	Hospitalization VE (95% CI)
Unadjusted		
Two doses	0.05 (0.04 – 0.07)	95% (93 – 96)
One dose	0.23 (0.20 – 0.24)	77% (76 – 80)
Adjusted [a]		
Two doses	0.04 (0.03 – 0.05)	96% (95 – 97)
One dose	0.23 (0.21 – 0.24)	77% (76 – 79)

	Death	No Death	OR (95% CI)	VE (95% CI)
Two Doses	2	26,062	0.021 (0.012 – 0.053)	97.9 (94.7 – 98.8)
One Dose	5	2,881	0.465 (0.234 – 0.618)	53.5 (38.2 – 76.6)
Two or One Dose	7	28,943	0.065 (0.043 – 0.098)	93.5 (90.2 – 95.7)
No Dose	242	64,826		

[a] Age, Sex, Race, Ethnicity, Area Deprivation Index (ADI), Charlson Comorbidity Index (CCI) Burden

Figure 2: Cumulative incidence (1 - Kaplan Meier risk and 95% CI [shaded area]) of COVID-19 hospitalization among individuals with no dose, one dose, and two doses.
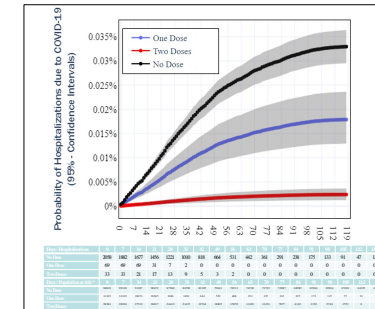
The number of patients at risk per week and the cumulative number of hospitalizations are also shown over number of days since entering vaccine group (two dose, one dose, no dose).

- Vaccine effectiveness at preventing hospitalization was conserved across age, race, ethnicity, Area Deprivation Index and Charlson Comorbidity Indices.

Conclusions

- After two doses, vaccine effectiveness for COVID-19 mortality was 97.9% (95%CI:91.7–99.5), and 53.5% (95%CI:0.28–80.8) after one dose in a pre-delta variant environment
- In the adjusted Cox proportional-hazards model, vaccine effectiveness after two doses (vs. no dose) was 96%(95% confidence interval(CI):95–97), compared to 78%(95%CI:76–82) after one dose.
- In a large, diverse US cohort, receipt of two doses of an mRNA vaccine was highly effective in the real-world at preventing COVID-19 related hospitalizations and deaths with a substantive difference in effectiveness between one and two doses

For references and online slide please scan QR code