Coronavirus Disease Vaccination In Patients With Pulmonary Hypertension: A National Prospective Cohort Study

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RATIONALE: COVID-19 has potential risks for both the clinical course and mortality among patients with pulmonary hypertension (PH), with vaccines play an important role in preventing this pandemic. The PH patients are mostly ruled out from vaccine trials, so data still lacking regarding the protective role of vaccination among this population. This study aimed to assess the safety of approved vaccination for patients with PH. METHODS: In this national prospective cohort study, patients diagnosed with PH (World Health Organization [WHO] groups 1 and 4) from 3 national referral centers in China were included between October 2021 and March 2022. Patients were asked vaccination status and stratified into vaccinated (VAC) and un-vaccinated (unVAC) groups. unVAC group was followed up for 4 months while VAC group were followed up for 3 months after vaccination completion. The primary outcome was the composite of PH-related major adverse events. Inverse probability weighting (IPW) approach was used to control for possible confounding factors in the baseline patient characteristics. Results: Totally 706 patients participated (mean age, 40.3 years; mean duration after diagnosis, 8.2 years). All patients underwent standardized treatment for PH in accordance with guidelines. 278 patients did not receive vaccination, whereas 428 patients completed the vaccination series. Overall, 398 patients received inactivated vaccines (CoronaVac), whereas 30 received protein subunit vaccines (ZF2001). None of the participants were infected with COVID-19 during our study. After adjusting for baseline covariates using IPW approach, the odds of having any adverse events due to PH in VAC group did not increase (6.3% versus 8.5%, odds ratio=0.72, p=0.3). Approximately half of the vaccinated patients reported at least one post-vaccination side effect, most of which were mild, including pain at the injection site (37·1%), fever (2·6%), and fatigue (6·1%). Conclusions: COVID-19 vaccination did not augment the PH-related major adverse events for patients with WHO groups 1 and 4 PH, although there were some tolerable side effects. A large-scale randomized controlled trial is warranted to confirm this finding. The final approval of the COVID-19 vaccination for patients with PH as a public health strategy is promising.

Table. Percentage of PH Patients with Adverse Events during the Follow-up Period: Unadjusted and Adjusted Analysis

				Unadjusted Data				Data Adjusted with the Use of Inverse Probability Weighting	
	Total (N=706)	Vaccinated (N=428)	Unvaccinated (N=278)	OR (95% CI)	p-value	Vaccinated (N=428)	Unvaccinated (N=278)	OR (95% CI)	p-value
Total deterioration	57 (8.1)	22 (5.1)	35 (12.6)	0.38 (0.22–0.66)	<0.001	27 (6.3)	24 (8.5)	0.72 (0.39–1.34)	0.30
Worsened WHO functional class (%)	7.2	4.4	11.5	0.36 (0.20–0.64)	0.001	5.3	7.8	0.67 (0.34–1.29)	0.23
Unplanned medication adjustments (%)	5.2	2.3	9.7	0.22 (0.11–0.47)	<0.001	2.4	6.2	0.37 (0.17–0.79)	0.01
Hospitalisations for heart failure (%)	3.8	1.9	6.8	0.26 (0.11–0.60)	0.002	2.1	4.7	0.44 (0.18–1.08)	0.07
All-cause mortality (%)	0.1	0.2	0.0	NE		0.2	0.0	NE	

Abbreviations: PH, pulmonary hypertension; COVID-19, coronavirus disease; OR, odds ratio; CI, confidence interval; WHO, World Health Organization.

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