

## Safety of Inactivated and mRNA COVID-19 Vaccination among Patients Treated for Hypothyroidism: A Population-based Cohort Study

David T.W. Lui. *The University of Hong Kong*

David Lui<sup>1</sup>, Xi Xiong<sup>1</sup>, Carlos Wong<sup>1</sup>, Ivan Au<sup>1</sup>, Francisco Lai<sup>1</sup>, Xue Li<sup>1</sup>, Eric Wan<sup>1</sup>, Celine Chui<sup>1</sup>, Esther Chan<sup>1</sup>, Franco Cheng<sup>1</sup>, Kristy Lau<sup>1</sup>, Chi Ho Lee<sup>1</sup>, Yu Cho Woo<sup>1</sup>, Ian Wong<sup>1</sup>

<sup>1</sup>The University of Hong Kong, Hong Kong, China

**Background:** Thyroiditis and Graves' disease have been reported after COVID-19 vaccination. Patients with hypothyroidism due to various etiologies may be at risk of thyroid-specific outcomes. We aimed to evaluate the risks of thyroid-specific outcomes and adverse events after COVID-19 vaccination among patients treated for hypothyroidism.

**Methods:** In this population-based cohort from Hong Kong Hospital Authority electronic health records with Department of Health vaccination records linkage, levothyroxine users were categorized into unvaccinated, vaccinated with BNT162b2 (mRNA vaccine) or CoronaVac (inactivated vaccine) between 23 February and 9 September 2021. Propensity score (PS) weighting with inverse probability of treatment weighting (IPTW) was applied to balance the baseline characteristics among the three groups, which included age, sex, history of COVID-19, health care utilization, comorbidities, baseline thyroid-stimulating hormone (TSH) level (within the 6 months before the index date), and recent use of medications including anti-hypertensive, anti-diabetic and lipid-lowering agents. Study outcomes were dosage reduction or escalation in levothyroxine, emergency department visit, unscheduled hospitalization, adverse events of special interest (AESI) according to World Health Organization's Global Advisory Committee on Vaccine Safety, and all-cause mortality.

**Results:** In total, 47,086 levothyroxine users were identified (BNT162b2: n=12,310; CoronaVac: n=11,353; unvaccinated: n=23,423). After PS weighting, all baseline characteristics had standardized differences of less than 0.2, implying a balance of covariates among the three groups. COVID-19 vaccination was not associated with increased risks of levothyroxine dosage reduction (BNT162b2: HR=0.971, 95% CI 0.892–1.058; CoronaVac: HR=0.968, 95% CI 0.904–1.037) or escalation (BNT162b2: HR=0.779, 95% CI 0.519–1.169; CoronaVac: HR=0.715, 95% CI 0.481–1.062). Besides, COVID-19 vaccination was not associated with a higher risk of emergency department visits (BNT162b2: HR=0.944, 95% CI 0.700–1.273; CoronaVac: HR=0.851, 95% CI 0.647–1.120) or unscheduled hospitalization (BNT162b2: HR=0.905, 95% CI 0.539–1.520; CoronaVac: HR=0.735, 95% CI 0.448–1.207). There were two (0.016%) deaths and six (0.062%) AESI recorded for BNT162b2 recipients, and one (0.009%) and three (0.035%) for CoronaVac recipients, respectively. Sensitivity analyses were performed by stratifying the groups according to age, sex and pre-vaccination thyroid status. The results were largely consistent with the main analysis.

**Conclusion:** BNT162b2 or CoronaVac vaccination is not associated with unstable thyroid status or an increased risk of adverse outcomes among patients treated for hypothyroidism. These reassuring data should encourage them to get vaccinated against COVID-19 for protection from potentially worse COVID-19-related outcomes.

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