ABSTRAK

Latar Belakang: COVID-19 telah menjadi pandemi dan menyebar hampir di seluruh dunia termasuk Indonesia. Virus ini merupakan ancaman pada kelompok komorbid dengan penurunan daya tahan tubuh, termasuk pasien gagal ginjal. Pasien penyakit ginjal tahap akhir (PGTA) yang menjalani hemodialisis menunjukkan respon imun yang lebih rendah pasca pemberian vaksin non COVID-19, seperti vaksin influenza dan vaksin hepatitis. Imunogensitas dan keamanan pasca vaksin COVID-19 pada pasien PGTA yang menjalani hemodialis masih belum banyak diketahui.

Tujuan: Peneliti ingin mengetahui imunogensitas dan keamanan pasca vaksinasi COVID-19 pada kondisi PGTA yang menjalani hemodialisis dibanding populasi non-PGK.

Metode Penelitian: Penelitian ini merupakan studi kohort prospektif yang melibatkan 146 subjek, terdiri atas 75 pasien hemodialisis dan 71 kontrol sehat yang menerima 2 dosis vaksin CoronaVac. Imunogenisitas diukur dengan pengukuran *geometric mean titer* IgG-sRBD dan persentase inhibisi NAbs 21 hari pasca dosis kedua. Efek samping vaksin diamati hingga 1 bulan pasca vaksinasi dosis kedua.

Hasil: Tidak ditemukan perbedaan bermakna pada GMT IgG-sRBD, persentase serokonversi IgG-sRBD, dan persentase inhibisi NAbs antara kelompok HD dan kontrol. Angka serokonversi pasca dosis kedua lebih rendah pada kelompok HD dibandingkan kontrol namun tidak berbeda bermakna (45,3% vs 60,6%, p=0,065). Efek samping *solicited* pasca vaksin dosis pertama tidak berbeda bermakna, sedangkan efek samping *solicited* pasca dosis kedua lebih tinggi pada pada kelompok HD dibanding kontrol (29,45% vs 21,92%, p = 0,006). Efek samping *unsolicited,* angka kejadian thrombosis, dan pendarahan pasca vaksin dosis pertama maupun dosis kedua tidak berbeda secara bermakna antara kedua kelompok serta efek samping serius sangat jarang terjadi.

Kesimpulan: Pasien PGTA yang menjalani hemodialisis mengembangkan respon imun humoral yang cukup kuat setelah dua dosis vaksinasi CoronaVac. Vaksinasi CoronaVac secara umum aman diberikan pada pasien PGTA yang menjalani hemodialisis dan efek samping serius sangat jarang terjadi.

Kata kunci: vaksinasi, hemodialisis, COVID-19, imunogenisitas, efek samping.

ABSTRACT

Background: COVID-19 has become a pandemic and spread worldwide, including in Indonesia. This virus poses a threat to population with comorbid diseases and immunosuppression, including chronic kidney disease (CKD) patients. End-stage renal disease (ESRD) patients undergoing haemodialysis (HD) demonstrate lower immune response after vaccination, such as influenza and hepatitis. The immunogenicity and safety of COVID-19 vaccination in ESRD patients undergoing haemodialysis has not been clearly elucidated.

Objective: To evaluate the immunogenicity and safety of COVID-19 vaccination among end-stage renal disease patients undergoing haemodialysis in comparison with controls without CKD.

Methods: This study was an observational cohort prospective study involving a total of 146 participants consisting of 75 haemodialysis patients and 71 healthy controls, who received two doses of CoronaVac. The immunogenicity was measured with IgG sRBD geometric mean titer (GMT) and neutralizing antibodies (NAbs) percentage of inhibition 21 days after the second dose. The adverse events (AEs) were observed until one month after the second dose.

Results: We observed no significant difference in IgG sRBD GMT, seroconversion rate of IgG sRBD, and NAbs percentage of inhibition between HD and control groups. The seroconversion rate after the second dose was lower among HD patients compared to controls, but not statistically significant (45.3% vs 60.6%, $p = 0.065$). The numbers of solicited adverse events after the first dose were not significantly different. Meanwhile, the solicited AEs rate after the second dose was significantly higher in HD group compared to controls (29.45% vs 21.92%, $p = 0.006$). The unsolicited AEs, thrombotic events, and hemorrhagic events after vaccination were not significantly different among both groups. No serious AEs were reported in either group.

Conclusions: ESRD patients undergoing HD mount adequate humoral immune response after two doses of CoronaVac vaccination. Generally, CoronaVac vaccine can be safely administered to ESRD patients undergoing HD without serious or life-threatening AEs.

Keywords: vaccination, haemodialysis, COVID-19, immunogenicity, adverse events