Comparative clinical outcome of dronedarone and sotalol in Asian patients with atrial fibrillation

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**Introduction:** There are limited data about the safety and effectiveness of dronedarone compared with alternative anti-arrhythmic agents which have a similar indication, i.e., sotalol. This study aimed to evaluate the comparative safety and effectiveness of dronedarone and sotalol in Asian patients with AF in real-world clinical practice.

**Methods:** Using the Korean Health Insurance Review and Assessment database from August 2013 to December 2016, we identified AF patients who newly received dronedarone or sotalol and analyzed the risk of all-cause hospitalization (cardiovascular [CV] or non-CV hospitalization) and all-cause death. Receiving advanced rhythm control (catheter ablation, chemical or electrical cardioversion) was defined as an exploratory secondary outcome. The clinical outcomes were evaluated until December 2017. The propensity score weighting method was used to balance covariates across dronedarone and sotalol users.

**Result:** A total of 3,119 patients treated with dronedarone and 1,575 patients treated with sotalol were included (median follow-up time of 177 days [IQR: 56-501]). After propensity score weighting, there were no significant differences between two treatment groups (mean age 62 years, 66% males, and mean CHA2DS2-VASc score 2.7±1.7). Dronedarone use was associated with a lower risk of all-cause hospitalization compared with sotalol use (hazard ratio [HR], 0.79; 95% confidence interval [CI], 0.70-0.88, p<0.001) (Figure). In detail, the dronedarone group showed a significantly lower risk of CV hospitalization than sotalol group (HR 0.62, 95% CI 0.53-0.72, p<0.001), but there was no significant difference in non-CV hospitalization between groups (HR 1.05, 95% CI 0.91-1.22, p=0.49). Especially, dronedarone use was associated with lower risks of CV hospitalization due to conduction disorders/arrhythmias (HR 0.59, 95% CI 0.49-0.70, p<0.001), ischemic stroke/transient ischemic attack (HR 0.56, 95% CI 0.37-0.87, p=0.003), and heart failure (HR 0.46, 95% CI 0.22-0.95, p=0.024) than sotalol use. However, we could not find any significant difference in the risk of all-cause death between groups (HR 0.88, 95% CI 0.41-1.91, p=0.75). The dronedarone group was significantly less likely to receive advanced rhythm control treatment during follow-up compared with sotalol group (HR 0.81, 95% CI 0.69-0.96, p=0.02), and the difference was mainly due to the lower risk of receiving non-pharmacological rhythm control composed of catheter ablation and electrical cardioversion (HR 0.63, 95% CI 0.51-0.77, p<0.001)

**Conclusion:** Treatment with dronedarone showed a significantly lower risk of CV hospitalization along with a lower need for non-pharmacological rhythm control than sotalol in a large-scale registry of
Asian patients with AF. Dronedarone might be an effective medical treatment option with a good safety profile for Asian AF patients.