Interim analysis of the 'DEVICE-DETECTED CARdiac TACHYARRHYTHMIC EVENTS AND SLEEP-disordered BREATHING (DEDiCATES)' study

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Introduction: In the Device-Detected CARdiac TACHYARRHYTHMIC events and SLEEP-disordered BREATHING (DEDiCATES) study, we aim to determine whether device-detected sleep-disordered breathing (SDB) events are associated with increased risk of cardiac arrhythmias or other cardiovascular (CV) outcomes. We performed interim analysis of the study to investigate the prevalence of baseline SDB in cardiac implantable electronic device (CIED) patients.

Methods: The study was designed as a prospective, multicenter, and observational study to include 600 patients: 300 each with low-voltage pacing or high-voltage defibrillating devices. Eligible patients have dual chamber CIEDs with AP Scan™ function (Boston Scientific Inc., Marlborough, MA, USA) which reports the average number of sleep disturbance events per hour per night in the form of a Respiratory Disturbance Index (RDI). The daily RDI values were collected to measure the severity and burden of SDB. The baseline severity of SDB was determined according to RDI data recorded during the first 1 week, 1 month, and 3±1 months after CIED implantation; patients with RDI≥ 30/h for at least one night are classified into the severe SDB group.

Result: A total of 313 patients who completed the first device interrogation at 3±1 months were included for analysis. The mean age and CHA2DS2VASc score were 69 and 3.1, respectively. Forty-nine percent of patients were men, and 35.5% were classified as high risk for SDB by Berlin questionnaire. The rate of severe SDB increased as the monitoring time got longer (83.8% at 1 week, 91.6% at 1 month, and 96.4% at 3±1 months). There was no baseline demographic difference between the severe and non-severe SDB groups, except that baseline body mass index (BMI) was higher in the severe group (24.5% vs. 21.5%, p = 0.01). The mean RDI was 36.3, 34.2, and 33.0 per night during the first 1 week, 1 month, and 3±1 months, respectively. The BMI was significantly higher in patients with supra-median mean RDI than those with infra-median value as well. In multivariate analysis, male gender and higher BMI were significantly associated with supra-median mean RDI.

Conclusion: The prevalence of severe SDB at baseline was very high (>90%) according to conventional method using a single RDI value, which seems to be inadequate for CV risk stratification considering that most patients were classified into the severe group. In future outcome analysis, we expect to establish a discriminative SDB criteria to detect high-risk patients better than the conventional one.