中文題目：生理性心臟節律器之臨床預後的研究：一個南部醫學中心的經驗

英文題目：Clinical and Pacing Outcomes of Conduction System Pacing at a Medical Center in Southern Taiwan

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Background: Permanent pacemaker is an effective therapy for patients with symptomatic bradyarrhythmia, including sinus nodal dysfunction and atrioventricular block. Right ventricular pacing (RVP) has been reported to increase the risks of atrial fibrillation, heart failure (HF) hospitalization, or mortality. Conduction system pacing (CSP) including His bundle pacing (HBP) and left bundle branch area pacing (LBBAP) is a physiologic pacing method in comparison to traditional RVP for bradyarrhythmia. Recently, conduction system pacing, such as His-bundle pacing (HBP) and left bundle branch pacing (LBBP), are emerging physiological pacing strategies. Pacing through the conduction system theoretically aims to avoid the deleterious effects of dyssynchronous electromechanical ventricular activation, which has been associated with increase in heart failure, atrial fibrillation, and cardiomyopathy as shown in the MOST (MOde Selection Trial) and DAVID (Dual Chamber and VVI Implantable Defibrillator) trials. While HBP is generally safe, placement of lead at the His bundle could be technically challenging due to its smaller size and surrounding fibrous tissue. This also leads to less stability and required increase in capture thresholds. An emerging modality in LBBAP can overcome these shortcomings of HBP due to its simpler to execute and lower, more stable capture thresholds. Despite the promises of improved outcome, the widespread use of CSP still needs further validation to establish its safety and efficacy. Accordingly, we conducted this prospective observational study to evaluate the clinical and pacing outcomes of CSP in a consecutive diverse group of patients with symptomatic bradycardia at our institution.

Methods: This study enrolled 193 consecutive patients with attempted CSP from February 2020 to July 2022. Clinical outcomes including HF hospitalization and all-cause mortality were recorded. Regarding to procedures of CSP, in HBP group, a 4.1-French lumenless lead (SelectSecure 3830, Medtronic Inc., Minneapolis, MN, USA) was delivered via a nondeflectable curve sheath (C315 His, Medtronic Inc., Minneapolis, MN, USA) and the lead tip was fixed into the His bundle area. Testing for pacing threshold was starting at 5.0 V @ 1 ms, and pacing threshold of either selective or nonselective HBP less than 2.0 V @ 1 ms was acceptable. For LBBP, the ventricular septal thickness was assessed by echocardiography before procedures. The delivery sheath (C315 His, Medtronic Inc., Minneapolis, MN, USA) was placed about 1 to 1.5 cm from His bundle site or septal leaflet of tricuspid vale toward RV apex (fluoroscopy right anterior oblique views 30°). A 4.1-French lumenless lead (SelectSure 3830, Medtronic Inc., Minneapolis, MN, USA) was advanced via the

C315 His sheath and the lead tip was abutting the septum. Pacing at 5.0 V @ 0.4 ms was applied to create electrocardiographic QRS morphology of "W" pattern with the notch closer to nadir in lead V1, and then, the pacing lead was screwed perpendicularly into LV septum, and the advance was stopped till confirmation of capture of the left bundle branch. Pacing parameters, procedural time, procedure-related complications, electrocardiographic and echocardiographic parameters were assessed.

Results: The mean age of the entire study subjects was 74.7 ± 9.9 years and 48.7% of the study subjects were male. The HBP group was older than the LBBP and control groups, although the difference did not reach statistical significance (77.1 ± 7.9 vs. 74.1 ± 10.3, P = 0.052). The LBBAP group had a higher prevalence of coronary artery disease compared with HBP group (15.8% vs. 2.4%, P = 0.032). The HBP group had a higher prevalence of atrial fibrillation (61.0% vs. 28.9%, P < 0.001). The prevalence of hypertension, diabetes mellitus, hyperlipidemia, heart failure, and chronic kidney disease did not differ between HBP and LBBAP groups. The procedural successful rates of the HBP and LBBAP group were in 89.1% and 98.0% patients, respectively. The LBBAP group had a higher prevalence of symptomatic atrioventricular block compared with the HBP group (53.3% vs. 14.6%, P < 0.001), and had a higher ventricular pacing percentage comparison to the HBP group (55 ± 44 vs. 23 ± 38%, P = 0.003). The QRS duration of intrinsic rhythm did not differ between the HBP and LBBAP groups (98 ± 22 vs. 106 ± 29 ms), and the QRS duration of pacing rhythm was narrowing in the HBP group, compared with LBBAP group (115 ± 12 [non-selective pacing] vs. 122 ± 15 ms, P = 0.004). The procedural and fluoroscopy time of the HBP and LBBAP groups were similar (134 ± 53 vs. 130 ± 43 mins, P = NS; 22 ± 16 vs. 24 ± 13 mins, P = NS). About pacing parameters, the LBBAP group had higher R wave amplitude at implant and follow-up, lower pacing threshold at 6-month follow-up and 12-month follow-up, and higher pacing impedance at implant and follow-up compared with the HBP group. Pre-implant left ventricular ejection fraction did not differ between the HBP and LBBAP groups (67 ± 9 vs. 66 ± 10%, P = NS), and post-implant left ventricular ejection fraction was preserved both in the HBP (67 ± 9% at implant vs. 66 ± 9% at 6-month follow-up) and LBBAP (66 ± 10% at implant vs. 65 ± 9% at 6-month follow-up) groups. Total complications rate of CSP was 11.4%, in which HBP group was 17.1% and LBBAP was 9.9%. No procedure-related complication such as hemo/pneumothorax or cardiac tamponade occurred. Two HBP patient (4.9%) and two LBBAP patient (1.3%) experienced lead dislodgement. One HBP patient received lead revision for high pacing threshold, and we implanted a new LBBAP lead after removal of old HBP lead. The incidence of major device-related infection was 1%. Clinical outcomes including all-cause mortality and HF hospitalization were 4.7% during a mean follow-up time of 11.9 ± 6.8 months, and the cumulative incidence of all-cause mortality or HF hospitalization did not differ between the HBP and LBBAP groups (7.3 vs. 4.0%, P = NS).

Conclusions: This prospective observational study suggests that CSP is safe with high success rates and good clinical outcomes during nearly 1-year follow-up. The number of LBBAP patients increased in our institution owing to more stable pacing parameters, compared with HPB group.