

中文題目：交叉隨機分派試驗比較心血管植入式電子儀器有無心率加速功能之生活品質差異

英文題目：A Cross-over Randomized Controlled Trial of Quality of Life between Cardiovascular Implantable Electronic Device with and without Rate Adaptive Pacing [NCT04383392]

作者：劉曉盈<sup>1</sup>，鄭莉縈<sup>1</sup>，張曉琪<sup>1</sup>，陳俊凱<sup>1</sup>，廖敏村<sup>1</sup>，賴超倫<sup>1</sup>

服務單位：<sup>1</sup>新竹臺大分院新竹醫院內科部

**Background:** Clinical implantable electronic devices, such as permanent pacemaker, implantable cardioverter defibrillator and cardiac resynchronization therapy are used in current daily practice for patients with bradycardia, ventricular arrhythmia, or heart failure. The rapid progress of permanent pacemaker function is growing to replace human's degenerating electrophysiology of heart. The ability of physical work is an important cornerstone of quality of life. In daily activities, rate response to higher rate is importance for patients with bradycardia who could not accelerate their heart rate. And rate-adapting pacing of permanent pacemaker is a design to increase heart rate pacing according to physical activity or emotional activity.

Patients with rate-adaptive pacing will get more cardiac output and overcome the physical activity such as stair climbing. But there are few studies to evaluate whether the rate-adaptive pacing of permanent pacemaker will improve the quality of life in people with bradycardia. The aim of this study is to compare turn-on with turn-off this function (DDDR vs DDD) whether rate-adaptive pacing will improve quality of life in patients with permanent pacemakers.

**Method:** The study was conducted as a prospective randomized 3-month-crossover, single blind, single-center study comparing quality of life in patients with sick sinus syndrome during dual-chamber pacemaker rate adaptive versus no rate adaptive pacing. The primary objective outcome was to determine the difference in quality of life with and without rate adaptive DDD pacing. Short-form 36 was used as comparison of quality of life which was assessed at 0, 3, 6 months.

**Results:** From January 2016 to October 2019, seventy-four patients were enrolled in this study. Eight patients did not complete the 6-month questionnaires. The mean age was  $76.5 \pm 8.6$  years old and male gender was 35.1%. The data showed that there were no differences in physical

functioning, social functioning, role functioning (emotional), mental health, vitality, pain or change in health between patients with or without rate-adaptive pacing.

**Conclusion:** There were several limitations in this study. First, there is possibility of withdrawal of patients due to non-medical reasons due to a little longer follow-up period (6 months). Secondary, there is no wash-out period in this study which maybe have carry-over effect. Third, the improvement in quality of life is small due to better Short-form 36 score of patients at baseline. This study revealed the rate adaptive pacing did not improve the quality of life in patients with pacemaker. [NCT04383392]

Keywords : rate-adaptive pacing; pacemaker; quality of life