

## Leadless or conventional transvenous ventricular permanent pacemakers: a nationwide matched control study

Bodin AB.; Clementy NC.; Bisson ABI; Pierre BP.; Herbert JH.; Babuty DB.; Fauchier LF.

University Hospital of Tours, Cardiology, Tours, France

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### Introduction / Background

Leadless ventricular permanent pacemakers (leadless VVI, LPM) were designed to reduce lead-related complications of conventional VVI pacemakers (CPM).

**Purpose:** The aim of our study was to assess and compare real-life clinical outcomes within the first 30 days and during a mid-term follow-up with the two techniques at a nationwide level.

**Methods:** This French longitudinal cohort study was based on the national hospitalization database covering hospital care from for the entire population. All adults (age  $\geq 18$  years) hospitalized in French hospitals From January 1, 2017 to September 1, 2020, who underwent a first LPM or CPM implantation were included.

**Results:** Of 42,315 patients included in the cohort, 40,828 patients (96%) had a CPM and 1,487 had a LPM. Using propensity score, 1,344 patients with CPM were adequately matched in a 1:1 fashion with LPM patients.

### Clinical outcomes at day 30

In the unmatched population, within the 30 days after implantation, patients with LPM had a lower rate of all-cause mortality (OR: 0.635, 95%CI: 0.527-0.765,  $p < 0.0001$ ) and from a cardiovascular cause (OR: 0.568, 95%CI: 0.405-0.797,  $p = 0.001$ ). They also had lower rates of major bleeding and need for transfusion. There was no significant difference between groups regarding tamponade, pneumothorax or hemothorax.

In the matched population, LPM implantation was still significantly associated with a lower rate of all-cause death (OR: 0.583, 95%CI: 0.456-0.744,  $p < 0.0001$ ), cardiovascular death (OR: 0.413, 95%CI: 0.271-0.629,  $p < 0.0001$ ) or transfusion (OR: 0.481, 95%CI: 0.296-0.780,  $p < 0.0001$ ). However, tamponade, pneumothorax or hemothorax and major bleeding were not significantly different between the two groups.

### Clinical outcomes during mid-term follow-up

In the unmatched patients, mean follow-up was  $8.6 \pm 10.5$  months. Annual incidence of all-cause death was high in both groups, and significantly higher in the LPM group than in CPM group (31%/year vs. 20%/year,  $p < 0.0001$ ) with a HR of 1.519 (95%CI: 1.296-1.780). Cardiovascular death was not significantly different between groups. Infective endocarditis was higher in the LPM group than in the CPM group with a HR of 2.108 (95%CI: 1.119-3.973). In the matched patients, mean follow-up was  $6.2 \pm 8.7$  months. All-cause death, cardiovascular death and infective endocarditis were not significantly different between groups.

**Conclusion:** Patients treated with leadless VVI pacemakers had better clinical outcomes in the first month compared to the patients treated with conventional VVI pacing. During a mid-term follow-up, risk of all-cause death, cardiovascular death and endocarditis in patients treated with leadless VVI pacemaker was not statistically different after propensity score matching.