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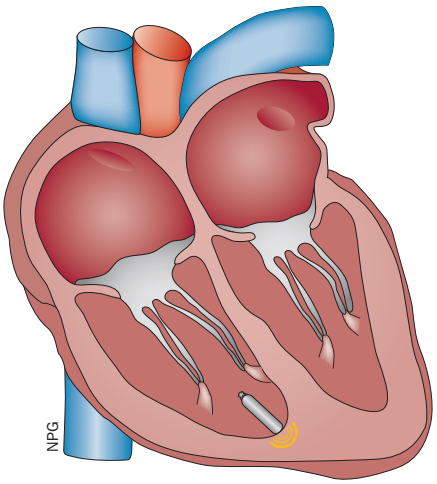
DEVICE THERAPY

Leadless pacemaker demonstrates safety, efficacy, and retrievability

A self-contained, leadless, nonsurgically implanted right-ventricle pacemaker has been shown to meet prespecified safety and efficacy end points, and is safely retrievable, according to results presented at the ESC Congress 2015 and published in *The New England Journal of Medicine*.

Despite decades of use and technological improvements, conventional cardiac pacemakers for bradycardia and heart block are still subject to problems related to both the surgically implanted pulse generators and the pulse-carrying transvenous leads. The leads, for example, can dislodge, suffer material failure, and cause infection, cardiac perforation, venous occlusion, and tricuspid regurgitation. To overcome these problems, the Nanostim™ (St. Jude Medical, USA) leadless pacemaker contains battery, pulse generator, and electrodes in a 1 ml device that is delivered by femoral vein catheter and nonsurgically implanted at the apex of the right ventricle.

In an ongoing, prospective, nonrandomized, multicentre trial, the Nanostim™ pacemaker was successfully implanted in 504 of 526 patients (mean age 75.8 ± 12.1 years) who required permanent single-chamber ventricular pacing.



Primary end-point analysis was performed on the first 300 patients to complete 6 months of follow-up.

The intention-to-treat primary efficacy end point of acceptable pacing threshold (≤2.0 V at 0.4 ms) and sensing amplitude (R wave ≥5.0 mV, or equal to or greater than the value at implantation) through 6 months was met in 270 of 300 patients (90.0%), which was significantly better than the 85% performance goal (95% CI 86.0–93.2%, $P = 0.007$). Similarly, the safety end point of freedom from device-related serious adverse events through 6 months was met in 280 patients (93.3%), significantly more than the 86% performance goal (95% CI 89.9–95.9%, $P < 0.001$). Adverse events included device dislodgement with percutaneous retrieval, cardiac perforation, and pacing-threshold elevation requiring device replacement.

Although the Nanostim™ does not provide electrographic data, pacemaker function was verified in a subgroup of 30 patients with 24-h ambulatory electrocardiography. The percentage of ventricular pacing was 50.3, mean minimum heart rate 58.2 bpm, and mean maximum heart rate 111.1 bpm. On the basis of such measurements, battery longevity was estimated at 15.0 ± 6.7 years. In seven patients, undislodged pacemakers were retrieved without complications.

Long-term follow-up is now required for this device. In addition, to develop its use beyond the minority application of the single-chamber ventricular pacemaker, "refinements in device-to-device communication, atrial affixation, and device diagnostics would be necessary," acknowledge the researchers.

Robert Phillips

Original article Reddy, V. Y. *et al*. Percutaneous implantation of an entirely intracardiac leadless pacemaker. *N. Engl. J. Med*. doi:10.1056/NEJMoa1507192