Spinal Cord Stimulation Patients with Permanent Pacemakers and Defibrillators

Jaymin Patel, MD; Fred DeFrancesch, MD; and Clark C. Smith, MD, MPH on behalf of the Spine Intervention Society’s Patient Safety Committee

Spinal cord stimulation (SCS), a treatment growing in popularity, is FDA approved for use in “failed back surgery syndrome” (FBSS), painful peripheral neuropathy, multiple sclerosis, and complex regional pain syndrome, among other disorders [1]. Off-label uses include peripheral artery disease and refractory angina. Candidates for SCS may have concomitant arrhythmias, coronary artery disease, heart failure, or other conditions that necessitate permanent pacemaker (PPM) or implantable cardioverter defibrillator (ICD) placement. In the past, concern has been expressed regarding potential interference of SCS with these potentially life-preserving technologies.

A basic understanding of PPM and ICD function are paramount in order to grasp the safety considerations of SCS use in patients with these devices. The primary functions of a pacemaker are to sense the heart rhythm and rate and to pace the heart. A pacemaker is able to deliver an electrical current to signal cardiac muscle contraction. An ICD also senses the rhythm and rate of the heart, but instead of pacing the rate, it delivers a shock to restore a normal heart rhythm. Both of these devices rely on the detection of electrical cardiac activity, rhythm, and rate to function properly. Concern about interference between cardiac devices and SCS is based on reports of pacemaker inhibition noted in prior studies [2]. Inhibition of PPM function by SCS has been reported in patients for whom the PPM is set in a unipolar mode. A unipolar pacing lead only has one electrode in the heart chamber and the current flows through the heart and back to the pulse generator through the body and soft tissues [3]. These systems are more commonly used in temporary pacing situations where nodal function is expected to return. In contrast, a bipolar pacing lead has both the cathode and anode along the same lead, which results in a much shorter path for the current to travel.

Alternatively, mounting evidence has demonstrated safe simultaneous use of SCS and PPM/ICD technologies. There have been multiple reports of uncomplicated placement of spinal cord stimulators in patients with prior PPM/ICD with bipolar leads without interaction when properly monitored during placement [4-7]. Engaard reported successful placement in 5 cases without specification of bipolar or unipolar leads of the ICD [8]. A recent prospective double-blind randomized controlled trial (RCT) pilot study demonstrated no interference between patients with an ICD followed by SCS implantation for the treatment of systolic heart failure in nine patients [9]. Lead polarity of the cardiac devices was not specified. In-depth testing was performed intraoperatively including arrhythmia induction attempts to test detection and termination by the ICD under the supervision of cardiac electrophysiology specialists. There were no reported instances of SCS directly impacting ICD/PPM function, including detection of arrhythmias and delivering therapies.

A recent prospective, multicenter pilot trial was performed to evaluate the safety and effectiveness of an SCS system for the treatment of systolic heart failure. No deaths or device-device interactions were noted during the 6-month period in the 17 SCS-treated patients. The leads were placed at T1-3 with a frequency of 50 Hz and 200 ms pulse width, which are similar to the parameters used in chronic pain conditions. The results of this trial suggest that high thoracic SCS is safe and feasible in patients with an implanted defibrillator [10].

Another study looked at a potential change in left ventricular end-systolic volume index from baseline to 6 months of SCS therapy in the treatment arm compared to the control arm as measured by echocardiography. Seventy-six percent (50 of 66) had an ICD at the baseline visit. No statistically significant differences were observed.
between the control and treatment arms in ventricular tachycardia/ventricular fibrillation episodes or rate of non-sustained ventricular tachycardia and premature ventricular complexes among 19 control and 33 treated patients that had concomitant ICDs and had reported device data available for analysis. At no point in the trial were any artifact interactions noted between the implanted SCS and an implanted Medtronic cardiac device (implantable pulse generator or ICD), indicating that patients can safely have dual Medtronic devices implanted and operational [11].

Successful implantation of a high-frequency SCS device in a patient with a prior ICD has been reported with close cardiac monitoring during the trial period and at time of implantation [12]. Use of high-frequency SCS should be discussed with the individual device manufacturer prior to use in a patient with ICD/PPM placement.

Conclusions & Recommendations

SCS is a safe treatment option for various chronic pain disorders in patients who have bipolar cardiac pacemakers and defibrillators. If a decision is made to proceed with neuromodulation in these patients, the following are recommendations to maximize safety and minimize complications:

1. Educate the patient on the theoretical hazards and risks of SCS in the setting of a pre-existing PPM or ICD, particularly with a unipolar lead.
2. Ensure that the patient is followed by a cardiologist/electrophysiologist and obtain prior approval from that provider.
3. Identify the PPM/ICD device manufacturer and indication for cardiac device implantation.
4. Coordinate trial/SCS implantation with the cardiac device manufacturer to have on-site support for interrogation of the cardiac device during and after the procedure, to assure functionality of the PPM or ICD after the SCS implantation.
5. Changes in the SCS settings should be made in the stimulation and frequency parameters tested for safety at time of implantation. If changes outside of these settings are made, it is recommended to have the cardiac device evaluated for compatibility.

References