Pain Physician. 2006;9:249-252, ISSN 1533-3159

A Case Report

Feasibility of Spinal Cord Stimulation in a Patient with a Cardiac Pacemaker

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Objective: To report about the safe use of a spinal cord stimulator (SCS) and a permanent cardiac pacemaker (PPM).

Design: Open-label case report.

Case Description: A 75-year-old male with a history of diabetic polyneuropathy and a permanent pacemaker was followed for 6 months after implantation of a SCS.

Conclusion: The simultaneous use of bipolar SCS in a patient with a PPM is not contraindicated. However, because false inhibition of a cardiac pacemaker may potentially lead to serious events, individual testing is mandatory to ascertain safety in each patient.

Key words: spinal cord stimulation, cardiac pacemaker, diabetic polyneuropathy, chronic pain, peripheral neuropathy

The use of spinal cord stimulation (SCS) has been established since the late 1970s as a treatment modality for several medical conditions. The most common indications are severe angina pectoris, peripheral vascular disease, complex regional pain syndrome and failed back syndrome. Earlier case reports have indicated that SCS can be combined with cardiac permanent pacemaker (PPM), provided that caution is used (1). Romano et al. (2), studied a series of ten patients with SCS and PPM where inhibition of the PPM was detected in one patient and the general safety of the combined devices could not be stated. The patient in their study in whom inhibition appeared had both devices in the unipolar mode, which can be expected to increase the risk of interference.

Lately, SCS is being used to treat diabetic polyneuropathy. Patients with diabetic polyneuropathy may also suffer from cardiac disorders that necessitate the use of a PPM. The combination of SCS and PPM has previously been considered hazardous because of possible false inhibition of the PPM. Most of the SCS companies have issued "black box" warnings. In this report we present a case of diabetic polyneuropathy in a patient with a permanent pacemaker, which was successfully treated with SCS.

At the 6-month follow-up the patient reported an improved quality of life, decreased use of pain medications and overall better pain control. The SCS did not interfere with PPM treatment. This case report indicates that bipolar SCS and PPM can be safely combined in patients with painful conditions requiring SCS implantation.

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Disclaimer: There was no external funding in preparation of this manuscript.
Conflict of interest: None
Manuscript received on 5/15/06
Revision submitted on 6/6/06
Accepted for publication on 6/8/06

Case Description

The patient is a 75-year-old man who had a history of atrial fibrillation for more than 20 years. He has been treated with a permanent bipolar pacemaker AAIR (sensing atrium, inhibiting atrium, response device) along with warfarin for anticoagulation (Table 1). He had been stable from a cardiac standpoint. Recent echogram and a stress test were negative. He was also diagnosed with a diabetic polyneuropathy. The patient reported severe burning pain in the left lower extremity in a stocking-like distribution below the knee. Before presenting to our office he had tried several treatment modalities, including IGG transfusion, narcotics and antiepileptic medications. None of these therapies had been successful. He continued to complain of pain, significantly impairing his daily activities and quality of life.

After the risks and benefits of the spinal cord stimulator were explained to the patient, he consented for the SCS trial.

The SCS system was implanted under monitored anesthesia care. Under x-ray guidance, an Octrode lead was inserted via the epidural approach with its tip at the level of T12. Correct electrode positioning produced paresthesiae in the lower extremities during intraoperative test stimulation corresponding to the location of the patient's pain.

The pacemaker sensitivity and possible interferences between the PPM and SCS were tested perioperatively. The tests were performed in cooperation with cardiologists in pacemaker-specialized units, where the pacemaker could be fully monitored. The main principle was to temporarily maximize the probability of interference. The PPM ventricular sensing was set in the unipolar mode and the ventricular sensing threshold was lowered to the lowest acceptable level. The SCS output was standardized to the bipolar mode at a pulse rate of 42 Hertz, while the pulse

Table 1. *Programmable Functions and Parameters of Cardiac Pacemakers.*

Standby rate (base rate, low rate limit): The rate at which the patient is paced unless the spontaneous rhythm is faster
Upper rate limit: The highest rate at which the ventricles are paced 1:1 in response to the atrial rate
AV interval: The interval between the paced or sensed P wave and the delivery of the ventricular pacing stimulus
Atrial refractory period: The time after a sensed P wave or delivery of an atrial output pulse during which the atrial channel is refractory to electrical signals; the refractory period that follows a paced QRS complex, referred to as the PVARP
Ventricular refractory period: The time after a sensed QRS or ventricular output pulse during which the ventricular channel is refractory to electrical signals
Sensitivity (atrial and ventricular channels): The amplitude of the intrinsic atrial and ventricular depolarizations that are to be sensed
Energy output (atrial and ventricular channels): Volts, current and pulse duration
Modes of function: AAI, VVI, AOO, VOO, VDD, DDI, DOO, DDD, OOO
Sensor on
Sensor off
Sensor-based parameters: Time to achieve peak pacing rate; time to decline to standby rate; criteria for sensor activation
Mode switch on: Upon sensing an atrial tachyarrhythmia, a DDD(R) device will automatically switch to DDI(R) or VVI(R) mode of function, and will automatically switch back to DDD(R) mode upon sensing normal atrial rhythm
Mode switch off

width and the amplitude were set individually, to reach the maximally tolerated stimulation energy output, which was approximately 120% of the stimulation level that was used clinically. A sitting position allowed for a higher stimulation output. The supine position, however is responsible for the highest chance of interference between the PPM and SCS. Both of these positions were tested perioperatively. Continuous ECG monitoring was used to detect any cardiac pacing inhibition. After the test, the PPM and the SCS were reset to the clinically chosen parameters. The SCS device amplitude limit was programmed to prevent the patient from exceeding the tested safe level of stimulation energy. The sensing level in the testing situation was compared with the clinical level.

The patient was then admitted to the telemetry floor for observation. After 2 days of continuous ECG monitoring no interferences between PPM and SCS were noted. He reported significant pain relief and opted for permanent implantation of the SCS system.

A week later he was brought to the operating room and two Octrode leads were implanted. After appropriate testing an extension wire was tunneled subcutaneously to the implantable pulse generator, which was placed in a subcutaneous pouch below the costal margin. The system was thus fully implanted, and was programmed telemetrically. The stimulation was switched on and off and the amplitude was increased and decreased (within preset limits) by the patient. Pacemaker sensitivity was tested and no interferences were noted.

At the 6-month follow-up, the patient reported about 50% pain relief, was able to significantly decrease his oral pain medications, including opiods and had an overall improved quality of life.

Discussion

Implantation of permanent pacemakers (PPMs) for various forms of arrhythmias is an evidence-based treatment that is safe and effective and routinely performed even in small hospitals (3). The combination of SCS and PPM has previously been considered hazardous because of possible interdevice interference with consequent severe bradycardia or possible cardiac arrest (2, 4). Other sources of interference, such as external electromagnetic fields (from cellular telephones, metal detectors, welders etc.), are also of concern in PPM treated patients (5, 6).

Patients with PPM probably have been denied SCS in the past because of such considerations. However, a lack of awareness of the safety problem may have led to patients with SCS later having received PPM without appropriate safety considerations.

The risk of inappropriate inhibition (i.e., that the SCS signals would be falsely interpreted by the PPM as normal R waves) is dependent on the sensing mode (bipolar or unipolar), the sensing level of the PPM (6), the output mode (bipolar or unipolar), the frequency, and the output energy (pulse amplitude and pulse duration) of the SCS (2). In the study by Romano et al. (2) inhibition of the PPM was detected in one patient, who had both devices in the unipolar mode, which can be expected to increase the risk of interference.

In this case the SCS was used in the bipolar mode, as adequate paresthesiae, a prerequisite for pain relief, were obtained using bipolar SCS. Specific and extended test protocols have to be defined to ascertain the safety in case SCS treatment should be combined with pacing systems.

This case report indicates that the simultaneous use of bipolar SCS for diabetic polyneuropathy and PPM treatment for cardiac arrhythmias is not

necessarily contraindicated. Since false inhibition of a cardiac pacemaker may potentially lead to serious events, individual testing is mandatory to ascertain safety in each patient.

The PPM has priority over the SCS system, and before the interference test is performed the SCS should be switched off. Also, the patient should be referred to a center having the facilities for adequate testing before activation of the SCS. After the testing there should be no major reprogramming of either device without a new test. Furthermore, the SCS should always be used in the bipolar mode. If a PPM is implanted in a patient with SCS, the PPM should use bipolar sensing. In addition, the patient should be urged to report any signs of possible interdevice disturbances, such as light headiness, rapid heart rate, etc.

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