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Case Report

Implanted Spinal Cord Stimulator Dysfunction After Electrical Shock

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Spinal cord stimulation (SCS) has played a significant role in chronic pain since its inception during the late 1960s. There are several proposed mechanisms for SCS, one of which works via electrical pulses that target the dorsal horn of the spinal cord to inhibit afferent pain signals to achieve analgesia (Gate Control Theory). This can lead to an overall improvement in pain control when pharmacologic therapy is inadequate or ineffective. SCS also reduces pharmacologic needs, and hence alleviates side effects associated with opioids and other medications.

We present the case of a 44-year-old male with chronic pain and an implanted SCS in place who presented to our university institution pain clinic for lumbar back pain with bilateral radiculopathy. He had suffered from back pain since 1996 and an implanted SCS was placed in June 2013. Three years after the SCS placement, the patient suffered an alternating (60 Hz) current 120-volt electrical shock while working on kitchen appliances resulting in SCS dysfunction. Prior to the electrocution event, the SCS was operating normally with a battery life registering three-fourths full. The stimulator was turned on one day prior to the incident. At the time of the electrical shock, the SCS was not actively stimulating. Following the incident, the patient tried to turn on the stimulator without success.

Implantable devices, including pacemakers and neuromodulators, have a circuit protective mode which should prevent this type of occurrence. Using the physician programmer, we were unable to detect, connect, or interrogate his stimulator. With the help of a device representative, we attempted a physician mode recharge (PMR) for 10 minutes while in office. We were then able to pair the patient's charger with the stimulator, and enter into the normal feedback-enabled charge mode. His charger display screen indicated a drained battery. After approximately 25 minutes of recharging, a second attempt to interrogate the device was successful.

We hope this encourages all current and future SCS manufacturers to perform further device testing, quality control development, and research and development to make subsequent SCS even more reliable and resistant to damage or premature failure.

Key words: Spinal cord stimulator (SCS), spinal cord generator, power-on reset (POR), SCS malfunction, electrical shock, dysfunction

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Spinal cord stimulation (SCS) has played a significant role in chronic pain since its inception during the late 1960s. There are several proposed mechanisms for SCS, one of which (Gate Control Theory) works via electrical pulses that target the dorsal horn of the spinal cord to inhibit afferent pain signals to achieve analgesia (1). This can lead to an overall improvement in pain control when pharmacologic therapy is inadequate or ineffective. It also reduces phar-

macologic needs, and hence alleviates side effects associated with opioids and other medications. Up to 40% of patients who have undergone lumbosacral spinal surgery in the US report persistent or recurrent pain, referred to as failed back surgery syndrome (FBSS). Retrospective studies have shown that SCS placement for FBSS resulted in a much higher success and patient satisfaction rating in managing this persistent radicular pain compared to repeated operation, radiofrequency ablation (RFA), and dorsal root ganglionectomy (2).

A multi-database comprehensive literature review using MEDLINE, Clinical Key, Wiley Online Library, and PubMed databases was performed. Keywords included 'spinal cord stimulator,' 'SCS', 'spinal cord generator,' paired with 'failed,' 'damaged,' 'malfunction,' 'generator,' or 'battery.' Also "power-on reset" was searched using these databases. In addition, the device-makers Office of Medical Affairs performed an independent literature search, as well as reviewing internally reported cases. Their correspondence stated that there are no detailed clinical studies or internal reports of this phenomenon [SCS dysfunction after electrocution] currently (3). The device-makers searched EMBASE, PubMed, Google Scholar Medical, and scientific databases.

Literary review did find a few documented case reports of SCS malfunction due to other causes including RFA and epidural steroid injection (4,5).

Levy (6) reported in his review paper that while there are many causes of SCS failure in alleviating pain, malfunction of the implantable pulse generator (IPG) itself comprised only 1.2% of these cases). According to Roth and Keiser's literature review (7), lead fracture, migration, and disconnection comprised the remainder. However, device related failures may be the smallest part of the overall quality control problem. In the United States, the procedural failure rates are significantly greater than those of device failures and occur at all phases of SCS treatment (6).

CASE DESCRIPTION

A 44-year-old male chronic pain patient with an implanted SCS in place presented to our university institution pain clinic for lumbar back pain with bilateral radiculopathy. He has suffered from back pain since 1996. In 1997, he underwent a L4-5 microdiscectomy. Subsequently he underwent transforaminal lumbar interbody fusion (TLIF) of L4-L5 in 2001. In June 2013, his IPG was replaced due to battery end of life (EOL). A 37714 RestoreSensor (Medtronic, Inc., Minneapolis, MN) pulse generator was installed along with a 39565-30 paddle (surgical) lead. The 2 60 mm extenders (3708160) were reused from the previous implant. He reported significant pain improvement with continued use of his SCS from 2013, up until this electrocution event 3 years later.

The patient reported that his SCS had not turned on since suffering an electrical shock while working on the stove/oven exhaust fan in his kitchen 3 weeks prior to his appointment. While manipulating the old exhaust fan, his left second and third digits came into contact with 2 wires when they arched leading to a shock. The shock radiated proximally up his left arm. After the initial jolt of the electric shock, he reported a burning dysesthesia in the 2 digits which lasted for a few hours afterwards. He never lost consciousness, although he did report that following the episode, his chronic back pain was aggravated by the incident. The electrical short was enough to cause that particular circuit breaker to trip into an open state. Prior to the kitchen work, his stimulator battery was three-fourths charged. The stimulator was last turned on the day prior to the incident. At the time of incident it was not actively stimulating. Following the incident, the patient tried to turn on the stimulator without success.

A few days later, the patient returned so that we could attempt to interrogate the device using a physician programmer. We were unable to detect, connect, or interrogate his stimulator. With the help of a device representative, we attempted a physician mode recharge (PMR) for 10 minutes while in office. We were able to pair the patient's charger with the stimulator and enter into the normal feedback-enabled charge mode. His charger display screen indicated a drained battery. After approximately 25 minutes of recharging, a second attempt to interrogate the device was successful. The data file showed normal impedance checks which indicate that the leads remain intact without shortage or lead malfunction (8). Following up with the patient a week later he reported good function and pain control, similar to before the shock occurred.

DISCUSSION

This Medtronic RestoreSensor™ IPG (Medtronic Inc., Minneapolis, MN) was designed and tested

to withstand electromagnetic interference (EMI). Integrated components that include Zener diodes and filtered feed-through that protect the SCS hybrid circuitry from external/induced voltages onto the lead wires (9). There are 2 primary ways to charge the stimulator battery. Normal charging mode is used the majority of the time, as long as the stimulator has adequate charge to communicate with the charger. Communication between the charger and stimulator is bidirectional and the feedback requires both devices to have adequate voltage reserve. The other option is the PMR. This mode is unidirectional and doesn't need feedback from the stimulator. In the event the stimulator goes into circuit protect mode, or power on recharge (POR), or it enters an over-discharged (OD) state (a state equivalent to having a depleted battery for > 30 days), the only way to charge the device is using the PMR. Normally it charges the stimulator in this mode for 60 minutes. If successful, the patient can use the regular charge mode to completely restore the battery charge to capacity.

The devices were designed and tested to comply with the regulatory electromagnetic compatibility (EMC) standards (TUV, FCC, IEC 60601-1). This standard governs medical device design, including general requirements for basic safety and essential performance (9). Compliance has become a requirement to bring new medical devices into the market in most countries (10). The IPGs have been tested and deemed safe in magnetic resonance imaging (MRI) with up to 1.5 T strength magnetic fields. This has been further validated by independent studies (11-13). No major lasting device abnormalities were noted after reprogramming.

There are 2 explanations of this event, first is the errant state-machine state theory: it is possible that the current generated by the electrocution event placed either the telemetry transmission logic or microprocessor logic into an errant "lockup" state. When the physician programmer was used to perform a PRM, it automatically sent a system reset command to the SCS, which could have corrected this errant state by rebooting the system. The complementary metal-oxide-semiconductor (CMOS) Latch-up theory: the generated electric current triggered a CMOS latch-up condition which can rapidly drain the battery. It is only when the charge is sufficiently depleted that the latch-up condition can no longer take place.

In regards to battery longevity, if the SCS was truly in OD mode, then an OD strike likely occurred. If the errant state-machine theory was the case, then an OD strike probably didn't occur. Repeated OD events are known to directly reduce battery lifespan. Regardless of mechanism, it is unlikely any noticeable harm occurred to the battery as it would not have been in an over-discharged state long enough for any appreciable capacity loss (9). According to the device manual, patients can expect to recharge their SCS about every 10 days when new (14).

Literary review found some cases of police tasers, also known as neuromuscular inhibitory devices (NMID), causing disruption of other types of IPGs (such as pacemakers or automated cardio defibrillators), without any lasting effects on battery voltage or longevity. A Taser X26 produces high voltage, low current pulsations with enough energy to generate involuntary neuromuscular activation incapacitating the recipient. These pulses correspond to an average power output of < 1.5 W. In at least 1 paper, none of the IPGs tested experienced a POR or elective replacement indicator after the shock (15). In the U.S., the standard household voltage is 110 volts. Most circuits are designed to draw up to 15 amperes, giving a maximum discharge of 1650 W. Household alternating current (AC) electricity traveling through the body can potentially generate several amps of current, which is enough to overwhelm the protection circuitry and either directly affect its operation or damage its electronics (9). Circuit breakers are designed to trip in about 100 mS, significantly limiting the watts realized (16,17).

CONCLUSION

IPGs undergo rigorous testing that subjects them to "worst-case" scenarios exposing them to voltages up to 700 V and inducing current up to several amps. Placing one end of the AC cord in contact with the casing, and the other directly to the lead tip is one of these scenarios. A few cases of the device going into POR mode have occurred, but no device failures were reported.

Based on the location of where the electricity came into contact with the patient, the location of the IPG, it is unlikely that any permanent damage was done to the SCS. In addition, it does not seem that the patient suffered any undo injury or pain, besides the inability

to benefit from the IPG mediated pain relief. Prior to incident, the IPG battery charge would last approximately 2 - 3 weeks. After following up with patient, he reported no noticeable changes in stimulator efficacy, or length of time between battery recharges.

In our modern healthcare economy, cost per quality adjusted life year (QALY) is the basis for which patients are considered for a particular therapy (cost effectiveness). In order to keep QALY low, the expertise of the implanter, superior patient selection/screening, and a zero-defect goal for devices. Levy's research (6) showed a combined manufacture device failure rate of up to 25%, which not only increases cost due to the device itself, but also of removal and/or replacement. Intentional device obsolescence is also a burden to QALY . Other studies show that an SCS system pays for itself within 2 - 3 years due to decreased medical visits, oral analgesic use, and patients are more likely to return to work (18). So as one can easily see, identifying potential hazards that can cause device failure post hoc is of paramount importance to help minimize the increased costs. We hope this encourages all current and future SCS manufacturers to perform further device testing, quality control development, and research and development to make subsequent INS even more reliable and resistant to damage or premature failure.

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